DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, Maryland 21244-1850

January 7, 2026

Innovaccer Inc.
201 Mission Street, Suite 2900
San Francisco, CA 94105

Delivered via email to all active contacts for Innovaccer Inc. in the WISeR Participant Portal

Re: WISeR-0043 Innovaccer Inc. – Request for Corrective Action Plan – Noncompliance with WISeR Model Participation Agreement Requirements

Dear Innovaccer Inc.,

The Centers for Medicare & Medicaid Services (CMS) requires Innovaccer Inc. to submit a Corrective Action Plan (CAP) for failure to comply with the following requirements of the Wasteful and Inappropriate Service Reduction (WISeR) Model Participation Agreement (Agreement):

- *Article III Section 3.7(C), Customer Service*
- *Article V Functional Requirements, Section 5.2(B) Telecommunications*
- *Article VI Prior Authorization Process, Section 6.2(A) Prior Authorization Process and Exemption Status*
- *Article VI Section 6.5(C) and 6.5(D) Pre-Payment Review*

NONCOMPLIANCE

Innovaccer Inc.'s December 2, 2025, email disclosed a number of concerns to CMS related to Innovaccer Inc.'s readiness for WISeR Model implementation, specifically the following text:

- "As mentioned in our disclosures when signing the Participation Agreement we will not have a portal live by the January 5th Go Live Date."
- "We are also still establishing the phone line for provider inquiries…"
- "…it is highly unlikely that Innovaccer will be able to reliably process pre-pay claims by that date." (in reference to the model start date)
- "…Innovaccer respectfully requests CMS's consideration to postpone Innovaccer's operational go-live date for WISeR J15 Ohio to February 1, 2026."

Accordingly, Innovaccer Inc. is noncompliant with the following sections of the Participant Agreement expected to be in place by January 1, 2026, the Start Date:

- Section 3.7(C): The WISeR Participant shall respond to WISeR Provider and

WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.

- Section 5.2(B): The WISeR Participant shall, at a minimum, use or have the ability to interface with the Electronic Submission of Medical Documentation ("**esMD**"), and any other CMS approved electronic portals to exchange data with CMS, the WISeR Providers, WISeR Suppliers, and applicable MACs.

- Section 6.2(A): The WISeR Participant shall accept Prior Authorization for the Select Items and Services by fax, mail, Electronic Submission of Medical Documentation ("**esMD**"), and any other CMS approved electronic portals from WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).

- Section 6.5(C)(D): : The WISeR Participant must use its WISeR Clinicians or WISeR Clinical Reviewers, as applicable, to perform Pre-Payment Review as detailed in the WISeR Participant Guide.

REQUIREMENT TO SUBMIT A CORRECTIVE ACTION PLAN TO CMS

As a result of this noncompliance and pursuant to Section 13.2(A)(9) of the Agreement, CMS requires Innovaccer Inc. to submit a detailed CAP for CMS approval in the form and manner, and by the date specified below.

Please include the following information as part of your proposed CAP:

1. An acknowledgement of the noncompliance described above;
2. The steps Innovaccer Inc. will take, including timeframe, for establishing a phone line for provider inquiries;
3. The steps Innovaccer Inc. will take to establish the capabilities to respond to WISeR Provider and WISeR Supplier electronic, telephone, and written inquiries promptly, clearly and accurately;
4. A detailed plan for developing and implementing a secure portal for the electronic submission of prior authorization requests from WISeR Providers and WISeR Suppliers;
5. The steps Innovaccer Inc. will take to establish the capabilities to receive Prior Authorization for the Select Items and Services by fax, mail, Electronic Submission of Medical Documentation ("**esMD**"), and any other CMS approved electronic portals from WISeR Providers, WISeR Suppliers, and their corresponding MAC(s); and
6. A plan that identifies the actions Innovaccer Inc. has taken or will take, the identity of the official(s) responsible for those actions, and associated milestones/timeline, to correct the deficiencies listed above, by February 5, 2026.

Please provide clear and concise explanations and supplemental documentation, where necessary to fully address this CAP request. CMS will require documentation confirming that the approved CAP has been implemented and periodic reports on progress may be requested during the CAP period.

Please acknowledge receipt of this letter by **5 p.m. ET on January 9, 2026.**

Please submit your proposed CAP to CMS **by 5 p.m. ET on Friday, January 16, 2026**, through the WISeR Model mailbox at WISeR@cms.hhs.gov. Title your submission: "WISeR-00043 Innovaccer Inc. Proposed CAP - Readiness."

CMS's approval of the proposed CAP is contingent on the CAP satisfactorily addressing all the required information identified above. CMS reserves the right to request additional information and may request that Innovaccer Inc. make modifications to the proposed CAP as a condition of CMS approval of the CAP and Innovaccer Inc.'s continued participation in the WISeR Model. If Innovaccer Inc. fails to submit or implement the CAP, the CAP is rejected, or Innovaccer Inc. otherwise fails to meet CMS and WISeR Model standards, CMS may take further remedial actions as specified in Article XIII of the Agreement, up to or including terminating Innovaccer Inc.'s participation in the WISeR Model under Section 13.3 of the Agreement..

We appreciate your prompt attention to this matter. If you have any questions concerning the information and request above, please email WISeR@cms.hhs.gov.

Sincerely,

The WISeR Model Team

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January 16, 2026

The WISeR Model Team
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, MD 21244-1850

Via email: WISeR@cms.hhs.gov

Re: WISeR-0043 Innovaccer Inc. – Proposed Corrective Action Plan – Readiness

Dear WISeR Model Team:

Innovaccer Inc. acknowledges receipt of CMS's January 7, 2026 letter titled "WISeR-0043 Innovaccer Inc. – Request for Corrective Action Plan – Noncompliance with WISeR Model Participation Agreement Requirements."

I. Acknowledgement and context

Innovaccer takes its obligations under the WISeR Model Participation Agreement and Amendment 2025-1 very seriously and remains fully committed to supporting a successful implementation of the WISeR Model. As disclosed to CMS in October 2025, Innovaccer accepted WISeR participation with the explicit understanding that it would go live on January 5, 2026 with a minimally viable product and phased capability rollout, rather than full functionality at launch.

In its January 7, 2026 letter, CMS identifies potential noncompliance with Article III Section 3.7(C), Article V Section 5.2(B), Article VI Section 6.2(A), and Article VI Sections 6.5(C)–(D), and requests a Corrective Action Plan addressing six specific items. Innovaccer appreciates the opportunity to clarify current status, correct factual inaccuracies, and outline the short-term actions being taken to ensure that all required capabilities are fully documented and demonstrably in place by February 5, 2026.

Table 1 below outlines the alleged areas of noncompliance and Innovaccer's current status as of the date of this letter.

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Table 1: Alleged Area of Noncompliance and Innovaccer Status

Participant Agreement Section	Participant Agreement Title	Alleged Area on Noncompliance	Innovaccer Compliance Status	Corrective Action Plan
Section 3.7(C)	Customer service (provider/supplier inquiries)	Section 3.7(C): The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.	Compliant	Not applicable. • Dedicated WISeR email established 11/26/2025 • Dedicated WISeR phone line active 1/1/2026
Section 5.2(B)	Telecommunications / electronic interfaces	Section 5.2(B): The WISeR Participant shall, at a minimum, use or have the ability to interface with the Electronic Submission of Medical Documentation ("esMD"), and any other CMS approved electronic portals to exchange data with CMS, the WISeR Providers, WISeR Suppliers, and applicable MACs.	Compliant	Not applicable. • Fully integrated with esMD by 1/1/2026 • Fully integrated with HETS by 1/1/2026 • Fully integrated with PECOS by 1/1/2026
Section 6.2(A)	Prior authorization submission channels	Section 6.2(A): The WISeR Participant shall accept Prior Authorization for the Select Items and Services by fax, mail, Electronic Submission of Medical Documentation ("esMD"), and any other CMS approved electronic portals from WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).	Substantially Compliant	Not applicable: • Technical capabilities established by 1/1/2026 • Prior authorization requests accepted via CGS-provided fax, mail and the CGS portal as of 1/5/2026 consistent with CMS go live date (based on CMS action) • Prior authorization requests accepted via esMD as of 1/5/2026 consistent with CMS go live date (based on CMS action) Corrective Action Plan: • Innovaccer Provider Portal is not active (as disclosed on

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				10/2025 and 12/12/2025). Innovaccer plan enclosed.
Sections 6.5(C)–(D)	Use of WISeR Clinicians / Clinical Reviewers	Section 6.5(C)(D): The WISeR Participant must use its WISeR Clinicians or WISeR Clinical Reviewers, as applicable, to perform Pre-Payment Review as detailed in the WISeR Participant Guide.	Compliant	Not applicable: • Clinicians and reviewers are in place and available to perform pre-payment reviews

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II. Response on identified areas of noncompliance

1. Section 3.7(C) – Customer service (provider/supplier inquiries)

Area of Alleged Noncompliance: Section 3.7(C): The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.

Innovaccer Response: Innovaccer established, and is actively operating, both an email inbox and a dedicated telephone line for WISeR provider and supplier inquiries.

- Innovaccer established a dedicated WISeR provider inquiry email address (ohcmswiser-inquiry@innovaccer.com) on November 26, 2025. This inbox has been actively monitored since that time with all inquiries being responded promptly, clearly, and accurately. The established email was communicated to CMS in Innovaccer's December 2, 2025 email correspondence regarding readiness and implementation risk. Innovaccer communicated the dedicated email to the provider community through webinars on December 12, 2025 and December 17, 2025. CGS posted this information on their CMS WISeR webpage (https://www.cgsmedicare.com/partb/pa/wiser.html) and announced this via email to their provider listserv. Additionally, we have received more than 100 emails from providers or external stakeholders to this email box since its inception. We are also accepting inquiries and responding to them, through our webpage "Contact Us" feature.
- Innovaccer established a dedicated WISeR Provider inquiry telephone line (202-796-1619) that went live on January 1, 2026. The phone line is fully staffed to respond to WISeR Provider and WISeR Supplier inquiries promptly, clearly, and accurately. Our normal business hours are from 8 am to 6 pm EST, Monday through Friday, excluding federal holidays. As of go live, more than 150 inbound and outbound calls have been made, with 80.95% of calls being answered within 60 seconds. If there is a need for follow-up, the follow-up is being performed, in most cases, within 1-2 business days depending on the complexity of the issue.

Accordingly, Innovaccer is currently meeting the functional requirement in Section 3.7(C) to respond to electronic, telephone, and written inquiries.

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2. Section 5.2(B) – Telecommunications / electronic interfaces

Area of Alleged Noncompliance: Section 5.2(B): The WISeR Participant shall, at a minimum, use or have the ability to interface with the Electronic Submission of Medical Documentation ("esMD"), and any other CMS approved electronic portals to exchange data with CMS, the WISeR Providers, WISeR Suppliers, and applicable MACS.

Innovaccer Response: Innovaccer is using and has the ability to interface with CMS-approved electronic systems for WISeR data exchange, including:

- esMD for the electronic submission of medical documentation, both for direct submissions from providers and for submissions transmitted via CGS as the applicable MAC.
- HETS for beneficiary eligibility verification and PECOS for provider enrollment status, which were added as new core integrations **during implementation** and were built, credentialed, and tested and functioning as expected as part of the WISeR solution before the January 5, 2026 go live.

These integrations were acknowledged by CMS during implementation discussions as new or evolving requirements that expanded beyond the original project plan and contributed to the need for a phased rollout. Innovaccer is therefore currently complying with the core functional requirement of Section 5.2(B).

3. Section 6.2(A) – Prior authorization submission channels

Area of Alleged Noncompliance: Section 6.2(A): The WISeR Participant shall accept Prior Authorization for the Select Items and Services by fax, mail, Electronic Submission of Medical Documentation ("esMD"), and any other CMS approved electronic portals from WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).

Innovaccer Response: Innovaccer began accepting prior authorization (PA) requests for WISeR Select Items and Services on go live January 5, 2026 via:

- Fax, mail, and the CGS portal, for submissions routed through CGS as the WISeR MAC.
- esMD, for prior authorization requests submitted directly by WISeR Providers and WISeR Suppliers.

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The only WISeR submission pathway not yet in production is Innovaccer's own secure provider portal. Innovaccer explicitly disclosed the Innovaccer WISeR Portal would not be available at the January 5, 2026 go-live date in Innovaccer's October 2025 disclosure letter and again in the December 12, 2025 "Approach to Implementation and Go-Live" letter to CMS. CMS indicated at that time that it would work with Innovaccer on a phased rollout, including portal functionality. Innovaccer therefore is substantially complying with Section 6.2(A) and is taking steps under this CAP to finalize and implement its own portal by February 5, 2026.

4. Sections 6.5(C)–(D) – Use of WISeR Clinicians / Clinical Reviewers

Area of Alleged Noncompliance: Section 6.5(C)(D): The WISeR Participant must use its WISeR Clinicians or WISeR Clinical Reviewers, as applicable, to perform Pre-Payment Review as detailed in the WISeR Participant Guide.

Innovaccer Response: Innovaccer's WISeR Clinicians and WISeR Clinical Reviewers are in place and are available to be used to perform pre-payment review for cases that require clinical review, in accordance with the WISeR Participant Guide.

Since the WISeR Model is only applicable for dates of service that occur from January 15, 2026 and after, Innovaccer has not yet received pre-payment review claims.

All cases requiring non-affirmation determinations will be handled by WISeR Clinicians or WISeR Clinical Reviewers as required by Sections 6.5(C)–(D). Accordingly, Innovaccer is currently meeting the functional requirement in Section 6.5(C)–(D).

III. Corrective Action Plan – Response to six CMS items

CMS requested that Innovaccer address six specific elements in its proposed CAP. Innovaccer's responses and planned actions are as follows.

Item 1 – Acknowledgement of noncompliance

Innovaccer acknowledges that:

- Innovaccer does not yet have its own WISeR provider portal in production for the electronic submission of prior authorization requests. Innovaccer previously disclosed that the provider portal would not be available by the January 5, 2026 go live date. As

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part of Innovaccer's October 2025 transmittal disclosures, and again in our December 12, 2025 go-live approach letter we reiterated the portal was not considered in scope as a minimum viable product (MVP) and would be available following the January go live.

Innovaccer respectfully notes, however, that as of January 1, 2026, the required customer service email and telephone capabilities are operational, that Innovaccer is interfacing with esMD, PECOS, and HETS, and that prior authorization requests are being accepted via fax, mail, CGS portal, and esMD. The primary remaining gap is Innovaccer's own secure provider portal, which is being addressed through an accelerated, time-bound plan described below.

Item 2 – Steps and timeframe for provider inquiry phone line

Innovaccer Status: Compliant

The dedicated WISeR provider inquiry phone line (202-796-1619) was established January 1, 2026 and is fully staffed.

Item 3 – Steps to respond to electronic/telephone/written inquiries

Innovaccer Status: Compliant

Innovaccer is already responding to WISeR Provider and WISeR Supplier inquiries through:

- Email: ohcmswiser-inquiry@innovaccer.com (live since November 26, 2025).
- Telephone: 202-796-1619 (live since January 1, 2026).
- Written correspondence received through the Innovaccer website and corporate address, if applicable.

Item 4 – Plan for secure electronic PA submission portal

Innovaccer Status: Partially compliant

Innovaccer's secure provider portal is in active development and was originally scheduled as part of a later phase in the phased capability rollout, following CMS's decision not to delay the model start date and Innovaccer's commitment to go live with a minimally viable solution and auto-affirmation.

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A high level action plan to meet the target date of February 5, 2026 for the Provider Portal can be found in Table 2 below:

Table 2: Action Plan to Establish Provider Portal

Task	Action Step	Status	Target Date	Person/Team Responsible
Development	Complete functionality to securely authenticate providers / suppliers	In Progress	01-30-26	Innovaccer Product and Engineering
Development	Complete functionality to allow submission of prior authorization requests electronically	In Progress	01-30-26	Innovaccer Product and Engineering
Development	Enable providers / suppliers to securely upload supporting clinical documentation	In Progress	01-30-26	Innovaccer Product and Engineering
Development	Complete functionality to allow providers / suppliers to provide near real-time authorization status	In Progress	01-30-26	Innovaccer Product and Engineering
Testing	Perform end-to-end testing between the portal, esMD, internal adjudication workflows and CGS interfaces	Not started	01-31-26	Innovaccer Product and Engineering, CS, and core integration partners
Deployment	Portal availability to providers and suppliers	Not started	02-05-26	Innovaccer Product and Engineering and CS

Responsible party:

- Responsible official: (b)(6)

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Item 5 – Steps to establish PA receipt via all required channels

Innovaccer Status: Partially Compliant

As of January 5, 2026, Innovaccer is able to receive PAs via CGS fax, mail, and portal, as well as directly from the esMD. The remaining step is to bring Innovaccer's own portal, as described in Section III, Item 4.

Innovaccer will also establish inbound fax and mail for prior authorization request submission and additional documentation request submission for the prepay claim process by February 5th, 2026.

Responsible party:

- Responsible official (b)(6)

Item 6 – Consolidated plan, owners, and milestones through February 5, 2026

Innovaccer proposes the following consolidated action plan to fully document and, where necessary, enhance the capabilities at issue by February 5, 2026:

CAP Area	Key Actions	Responsible Official	Target Completion
Portal development	Complete development; conduct testing; launch	(b)(6)	February 5, 2026
Inbound Fax and Mail	Secure fax number and integrate with ingestion pipeline		February 5, 2026

Innovaccer will provide CMS with:

- A written confirmation by February 5, 2026 that all CAP milestones have been completed or, if any are delayed, an updated remediation schedule and explanation.
- Supporting documentation on request, including sample workflow diagrams, training materials, and evidence of portal testing and launch.

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IV. Reservation of rights and request for continued collaboration

Innovaccer respectfully reiterates that the key implementation risks, including the absence of a provider portal and the need for an interim auto-affirmation strategy, were disclosed prior to execution of the Participation Agreement and were re-affirmed in the October 10, 2025 transmittal disclosures and the December 12, 2025 go-live approach letter. Innovaccer understands that CMS elected not to delay the model start date, and Innovaccer proceeded in good faith to meet the January 5, 2026 go-live with a minimally viable product while continuing to build the full production solution.

Innovaccer remains committed to full compliance with all WISeR Model requirements, to minimizing provider abrasion, and to protecting Medicare beneficiaries, and welcomes continued collaboration with CMS and CGS throughout this initial rollout period.

Please let Innovaccer know if CMS requires additional information or adjustments to this Corrective Action Plan. Innovaccer looks forward to CMS's review and approval.

Sincerely,

(b)(6)

Innovaccer Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, Maryland 21244-1850

February 6, 2026

Genzeon Corporation
559 W Uwchlan Ave.
Exton, PA 19341

Delivered via email to all active contacts for Genzeon Corporation in the WISeR Participant Portal

Re: WISeR-00145 Genzeon Corporation – Request for Information – Outstanding WISeR Prior Authorization Cases

Dear Genzeon Corporation,

The Centers for Medicare & Medicaid Services (CMS) requires Genzeon Corporation to respond to this Request for Information (RFI) regarding outstanding reviews for the Wasteful and Inappropriate Service Reduction (WISeR) Model applicable to the below sections of the WISeR Participation Agreement:

- *Section 3.4 (C) and (D) Required Prior Authorization Activities*
- *Section 3.7 (C) Customer Service*
- *Section 6.3 (B) Prior Authorization Determinations*

OBSERVATION #1

An email received by a Medicare Administrative Contractor (MAC) disclosed several cases to CMS that were outstanding as of January 27, 2026, and are detailed below:

- 459 cases are awaiting a decision letter from Genzeon. Case age 5-23 days.
- 459 cases that have a UTN failure needing to be reconciled. Case age 5-23 days.
- 342 cases awaiting a decision response or a dismissal letter from Genzeon. Cases age 4-23 days.

Accordingly, CMS is concerned with Genzeon Corporation's alignment with the following sections of the Participant Agreement that began January 1, 2026, the WISeR Model "Start Date":

- Section 3.4(C): The WISeR Participant shall review Prior Authorizations in its WISeR Jurisdiction submitted by all WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).
- Section 3.4(D): Consistent with Section 3.4(C), the WISeR Participant shall perform its Prior Authorization Process on Prior Authorizations received.
- Section 3.7(C): The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.

- Section 6.3(B): Initial Prior Authorization.
    1. The WISeR Participant shall issue an Initial Prior Authorization Determination to the WISeR Provider or WISeR Supplier within 3 Days of the WISeR Participant's receipt of the initial Prior Authorization.
    2. The WISeR Participant shall ensure the Initial Prior Authorization Determination is delivered to the WISeR Provider or WISeR Supplier in the same manner in which it was submitted via postmark, fax, or electronic delivery.

OBSERVATION #2

CMS has been notified that Genzeon is erroneously creating duplicates of UTNs, resulting in multiple instances of the same UTNs in both Genzeon's and your MAC's systems

REQUIREMENT TO RESPOND TO A REQUEST FOR INFORMATION BY CMS

As a result of the above observations, and pursuant to Section 13.2(A.2) of the Agreement, CMS requires Genzeon Corporation to provide additional information to CMS in the form and manner, and by the date specified below.

Please include the following information as part of your RFI:

1. An acknowledgement of the above observations described above;
2. Detailed causes of the delays in observation #1 and;
3. Detailed causes of the issue in observation #2

Please provide clear and concise explanations and supplemental documentation, where necessary to fully address this RFI request. Note that CMS may require additional documentation once your RFI is reviewed.

Please acknowledge receipt of this letter by **5 p.m. ET on February 9, 2026.**

Please submit your RFI to CMS **by 5 p.m. ET on Friday, February 13, 2026**, through the WISeR Model mailbox at WISeR@cms.hhs.gov. Title your submission: "WISeR-00145 Genzeon Corporation – RFI"

CMS's approval of the proposed RFI is contingent on the RFI satisfactorily addressing all the required information identified above. CMS reserves the right to request additional information and may request that Genzeon Corporation submit additional documentation as a condition of CMS approval of the RFI and Genzeon Corporation's continued participation in the WISeR Model.

We appreciate your prompt attention to this matter. If you have any questions concerning the information and request above, please email WISeR@cms.hhs.gov.

Sincerely,

The WISeR Model Team

WISeR-00145 Genzeon Corporation – Response to RFI

Outstanding WISeR Prior Authorization Cases

Date: February 13, 2026
To: WISeR Model Team, CMS
From: Genzeon Corporation
Re: Response to Request for Information dated February 6, 2026

Genzeon Corporation acknowledges receipt of CMS's Request for Information dated February 6, 2026, regarding outstanding prior authorization cases and UTN duplicate issues. We take these observations seriously and understand the critical importance of timely case processing and accurate UTN management to the successful operation of the WISeR Model.

We formally acknowledge the following observations:

Observation #1 - As of January 27, 2026:

- 459 cases awaiting decision letters (case age 5-23 days)
- 459 cases with UTN reconciliation failures (case age 5-23 days)
- 342 cases awaiting decision response or dismissal letters (case age 4-23 days)

Observation #2 - Erroneous creation of duplicate UTNs resulting in multiple instances of the same UTNs in both Genzeon's and the MAC's systems.

CURRENT OPERATIONAL STATUS

Most root cause issues contributing to the January 27 backlog have been resolved:

- **System bugs fixed:** Duplicate UTN creation race condition eliminated; no new duplicates being generated
- **Processing errors corrected:** Field formatting issues (Part A CCN mapping, MBI format, state identifiers) resolved
- **New submissions on track:** Cases received after corrections are processing within required 3-day timeframes
- **Backlog clearing:** Historical cases from January backlog being systematically resolved
- **Steady state approaching:** PECOS CR implementation on February 17 will enable pre-submission validation, eliminating the primary cause of UTN failures
- **Performance improving:** Daily metrics show consistent improvement in case processing velocity and UTN generation success rates
- **Provider communication enhanced:** Increased staffing to respond to provider inquiries and resolve issues via email and phone, reducing provider friction
- **Proactive provider outreach:** Educational initiatives with provider groups experiencing the most PA submission challenges, resulting in more streamlined submissions and faster decisions

Genzeon is transitioning from early implementation challenges to stable, compliant operations. The detailed root cause analysis and corrective actions for each observation are provided below.

ROOT CAUSE ANALYSIS & CORRECTIVE ACTIONS

OBSERVATION #1: Outstanding Cases

Issue 1: Decision Letters Not Sent to MAC

Root Cause: Unavailability of the esMD system, particularly during the week of January 19, caused significant delays in our ability to submit and generate UTNs, resulting in an increased backlog. We prioritized UTN generation over sending decision letters to the MAC to maximize utilization of limited esMD availability windows. Additional challenges in generating UTNs, discussed later in this document, further contributed to delays.

Impact: Cases with successfully generated UTNs remained open in MAC systems due to unreceived decision letters from Genzeon, causing confusion and processing delays.

Corrective Actions Completed:

- Transmitted all backlog decision letters to the MAC
- Created automated batch process that transmits decision letters to the MAC three times daily

Corrective Actions In Progress:

- Modifying processes to ensure decision letters are sent to the MAC simultaneously with provider notification

Issue 2: Multiple esMD IDs from Direct PA Submissions

Root Cause: The Direct PA pathway generates a unique esMD ID for each UTN generation attempt, unlike standard PA submissions that maintain a consistent esMD ID across multiple transmissions.

Impact: Multiple transmission attempts created separate records in both Genzeon and MAC systems, requiring manual reconciliation to prevent duplicate case counting.

Corrective Actions Completed:

- Leveraging a systematic process with MAC to clean up historical records with multiple esMD IDs
- Implemented tracking system to identify and flag related transmission attempts

Corrective Actions In Progress:

- Working to establish a coordination process with MAC to reconcile multiple esMD IDs to single esMD ID for Direct PA (like Standard PA)
- Developing automated reconciliation logic to streamline future processing and working with MAC to create standard formats to build automation around the same.

Issue 3: Field Formatting and Data Transmission Errors

Root Cause: Initial system configuration mismatches between Genzeon submission format and MAC expectations, including:

- Part A CCN submitted in incorrect field (Facility CCN vs. Facility PTAN)
- MBI formatting (hyphens removed incorrectly)

- State identifiers (full name vs. abbreviation)

Impact: UTN generation failures for affected cases, requiring resubmission and creating processing delays.

Corrective Actions Completed:

- Corrected Part A CCN field mapping issue
- Updated MBI and state field formatting rules
- Began processing backlog of previously failed Part A cases

Current Status: UTNs now generating successfully for corrected Part A cases; backlog clearing is in progress.

OBSERVATION #2: Duplicate UTN Creation

Issue 1: System-Generated Duplicate UTNs

Root Cause: Two primary factors contributed to duplicate UTN creation:

1. **System Bug:** A race condition in Genzeon's code caused Direct PA requests to be submitted multiple times (up to 5 instances) within seconds before the issue was detected
2. **Multi-Channel Submissions:** Providers occasionally submitted the same request through multiple channels (MAC fax, direct fax, Novitas portal, Genzeon portal)

Impact: Created duplicate UTNs in both Genzeon and MAC systems, requiring manual reconciliation and cleanup.

Corrective Actions Completed:

- Identified and resolved race condition bug in Direct PA submission code
- Implemented code review and testing protocols to prevent similar issues

Corrective Actions In Progress:

- Enhancing duplicate detection logic to automatically identify and prevent duplicate submissions across all channels
- Implementing auto-dismissal workflow for detected duplicates
- Coordinating with MAC to reconcile and remove existing duplicate UTNs from both systems

Issue 2: NPI/PTAN/CCN Validation Challenges

Root Cause: Inability to verify NPI-PTAN/CCN combinations from PECOS prior to UTN generation. Providers often submitted incorrect combinations for different service locations, causing UTN request failures discovered only after submission.

Impact: Failed UTN generation requests created a backlog of pending cases requiring manual review and dismissal.

Corrective Actions Completed:

- Implemented MAC-provided guidance (two weeks ago) to verify provider NPI type (hospital, ASC, specialty)
- Established process to identify and dismiss cases with invalid combinations upon UTN failure

Corrective Actions In Progress:

- PECOS Change Request (CR) implementation scheduled for Monday, February 17, 2026, enabling full NPI-PTAN/CCN validation pre-submission
- Expected to eliminate this category of failures going forward

MONITORING & PREVENTION

To ensure sustained compliance with WISeR Model requirements, Genzeon has implemented the following ongoing measures:

- **Daily Monitoring:** Case aging reports reviewed daily to identify delays before they exceed required timeframes
- **Automated Alerts:** System notifications for UTN failures requiring immediate attention
- **Weekly MAC Coordination:** Standing calls to address reconciliation issues proactively
- **Enhanced Testing:** Expanded pre-production validation for all system changes affecting UTN generation

We are committed to meeting the 3-day Initial Prior Authorization Determination requirement and maintaining seamless coordination with our MAC partners.

COMPLIANCE COMMITMENT

Genzeon Corporation remains committed to full compliance with all WISeR Model requirements. The issues identified stemmed from early implementation challenges that we have systematically addressed through technical fixes, process improvements, and enhanced MAC coordination.

We reaffirm our commitment to full compliance with the WISeR Participation Agreement, specifically:

- **Section 3.4(C) & (D):** We will review and process all Prior Authorizations in accordance with established procedures
- **Section 3.7(C):** We will respond to all inquiries promptly, clearly, and accurately
- **Section 6.3(B):** We will issue Initial Prior Authorization Determinations within 3 days of receipt

Genzeon Corporation takes full responsibility for the issues identified in this RFI. We have mobilized significant resources to address root causes and prevent recurrence. Our corrective actions are designed not only to resolve the immediate backlog but to establish sustainable processes and systems that ensure long-term compliance with all WISeR Model requirements.

We are committed to transparent communication with CMS and will provide weekly progress reports until all corrective actions are completed and performance targets are consistently achieved.

We request CMS's review and approval of this RFI response and welcome any additional questions or requests for clarification.

Submitted by:

(b)(6)

Genzeon Corporation

Date: February 13, 2026

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, Maryland 21244-1850

March 17, 2026

Virtix Health LLC
13835 N Tatum Blvd, Suite 9277
Phoenix, AZ 85032

Delivered via email to all active contacts for Virtix Health LLC in the WISeR Participant Portal

Re: WISeR-00040 Virtix Health LLC – Request for Information – Required Prior Authorization Activities, Determinations and Customer Service

Dear Virtix Health LLC,

The Centers for Medicare & Medicaid Services (CMS) requires Virtix Health LLC (Virtix) to respond to this Request for Information (RFI) for the Wasteful and Inappropriate Service Reduction (WISeR) Model regarding determination turnaround times that exceed established guidelines; denials that appear inaccurate or inconsistent with applicable criteria; delays between approval and issuance of required Unique Tracking Numbers (UTNs); portal functionality gaps, including limited visibility into authorization status; inadequate customer service, including lack of response and unresolved escalations; and issues related to diagnosis code reconciliation.

The aforementioned items are applicable to the below sections of the WISeR Participation Agreement:

- *Section 3.4(A) Required Prior Authorization Activities*
- *Section 3.5 (E) Determination Letters*
- *Section 3.7 (A, C) Customer Service*
- *Section 5.2 (B) Telecommunications*
- *Section 6.2 (A) Prior Authorization Process and Exemption Status*
- *Section 6.3 (B) Prior Authorization Determinations*

OBSERVATION
CMS has received multiple provider complaints regarding operational concerns associated with Virtix's implementation of the WISeR program. Providers have reported issues including turnaround times that exceed published WISeR timeliness standards; denial patterns that raise questions regarding alignment with published program guidance (for example, MSP denials), determination letters that are blank, or incomplete without the required Unique Tracking Number (UTN); limited visibility into authorization status; gaps in portal functionality; and customer service escalation pathways that do not consistently resolve time-sensitive issues. Additionally, CMS understands the Participant has questions regarding inconsistencies with diagnosis codes on claims versus medical record face sheets.

Accordingly, CMS is concerned with Virtix's alignment with the following sections of the Participant Agreement that began January 1, 2026, the WISeR Model "Start Date":

- Section 3.4 (A): The WISeR Participant shall receive and control Prior Authorizations for Select Items and Services, as detailed in Table 1 of Appendix A of this Agreement, from WISeR Providers and WISeR Suppliers or from their corresponding MAC(s) in accordance with the provisions set forth in this Agreement and in the WISeR Participant Guide.

- Section 3.5(E): The WISeR Participant's Prior Authorization determination letters to WISeR Providers and WISeR Suppliers must meet the requirements set forth in Section 6.3.A of this Agreement.

- Section 3.7 (A): The WISeR Participant shall provide ***quality*** prior authorization and Pre-Payment Review services effectively and to increase the overall level of customer service and satisfaction, in a form and manner determined by CMS, including as set forth in the WISeR Participant Guide.

- Section 3.7 (C): The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly, and accurately.

- Section 6.2 (A): The WISeR Participant shall accept Prior Authorization for the Select Items and Services by fax, mail, Electronic Submission of Medical Documentation ("**esMD**"), and any other CMS approved electronic portals from WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).

- Section 6.3(B): The WISeR Participant shall issue an Initial Prior Authorization Determination to the WISeR Provider or WISeR Supplier within 3 Days of the WISeR Participant's receipt of the initial Prior Authorization The WISeR Participant shall ensure the Initial Prior Authorization Determination is delivered to the WISeR Provider or WISeR Supplier in the same manner in which it was submitted via postmark, fax, or electronic delivery.

REQUIREMENT TO RESPOND TO A REQUEST FOR INFORMATION BY CMS

As a result of the above observations, and pursuant to Section 13.2(A.2) of the Agreement, CMS requires Virtix to provide additional information to CMS in the form and manner, and by the date specified below.

Please include the following information as part of your RFI response:

1. An acknowledgement of the observation and potential noncompliance described above;
2. Detailed information that explains determinations that may have been issued in error or required clarification;
3. Detailed causes of delays between approval and issuance of UTNs;
4. Detailed causes and steps you will take to complete prior authorizations received from your assigned MAC on a timely basis;
5. Detailed causes and steps you will take to address incomplete determination letters;
6. Detailed causes of customer service issues and detailed steps you will take to improve the escalation process and;
7. Detailed examples (if available) of inconsistencies with diagnosis codes on claims versus medical records face sheets, including information on how often this occurs

Please provide clear and concise explanations and supplemental documentation where necessary to fully address this RFI request. Note that CMS may require additional documentation once your RFI is reviewed.

Please acknowledge receipt of this letter by **5 p.m. ET on March 19, 2026.**

Please submit your RFI to CMS **by 5 p.m. ET on Thursday, March 24, 2026**, through the WISeR Model mailbox at WISeR@cms.hhs.gov. Title your submission: WISeR-00040 Virtix Health LLC. – RFI.

CMS reserves the right to request additional information and may request that Virtix submit additional documentation as a condition of CMS review of the RFI.

We appreciate your prompt attention to this matter. If you have any questions concerning the information and request above, please email WISeR@cms.hhs.gov.

Sincerely,

The WISeR Model Team

March 24, 2026

WISeR Model Team
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Via email to: WISeR@cms.hhs.gov

Re: WISeR-00040 Virtix Health LLC – Response to Request for Information – Required Prior Authorization Activities, Determinations and Customer Service

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Dear WISeR Model Team,

Please find enclosed Virtix Health LLC's formal response to the Request for Information issued by CMS on March 17, 2026. We have endeavored to address each of the seven items identified in the RFI with specificity, supporting data, and transparency regarding both the challenges we have encountered and the steps we have taken, and continue to take, to resolve them.

Virtix Health entered the WISeR program committed to effective program implementation and high-quality service to providers and beneficiaries in Washington state. The early weeks of the program presented operational challenges common to the launch of a novel federal prior authorization model, and Virtix Health has worked diligently to address them. We are equally committed to ensuring CMS has full visibility into the meaningful progress we have made. Average turnaround times have declined from a peak of (b)(4) days in week 5 to (b)(4) days in week 10, and we are currently meeting the 3-day average expectation consistently. Provider portal adoption has grown from approximately (b)(4) at program launch to (b)(4) today, and our customer service team has resolved over (b)(4) provider inquiries since program inception.

Beyond our operational work, Virtix Health has engaged proactively with various stakeholders to provide education on the WISeR program. We are making calls to providers to clarify the scope and process of the program going beyond the individual case outcome. We have responded to the Seattle Times prior to their publication to provide the context, goals, and the complexities of the program. We

have met with the federal legislative community in Washington state to ensure that members of Congress and their staffs have an accurate understanding of the WISeR program and Virtix Health's role within it. To date, we have met with staff from the offices of Senators Cantwell and Murray and Representatives Strickland, Schrier, and DelBene, and have plans for follow-up meetings in April and May. We view this engagement as part of our broader responsibility to support informed policy dialogue around WISeR, recognizing that as a new program there remains many questions and misunderstandings that can be resolved with proactive outreach and engagement.

We welcome the opportunity to discuss our response in further detail and are available at CMS's convenience.

Respectfully,

Virtix Health LLC

Virtix Health

Response to CMS Request for Information

WISeR Model | *March 24, 2026*

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1. *An acknowledgment of the observation and potential noncompliance described above.*

Virtix Health acknowledges the observations described in CMS' correspondence, including concerns raised regarding prior authorization turnaround times, delays in UTN issuance, incomplete determination letters, portal functionality, customer service escalation pathways, and diagnosis code reconciliation. We take these matters seriously and are committed to full transparency, continued operational improvement, and alignment with all applicable WISeR program requirements. The responses below address each area of concern in detail. and continued alignment with CMS program requirements.

2. *Detailed information explaining determinations that may have been issued in error or required clarification.*

The majority of requests requiring clarification involved provider misunderstanding of the WISeR program's scope and/or submission requirements, rather than errors in the underlying determination letters. The most common areas of confusion include, but are not limited to:

- A dismissal is not the same as a non-affirmation;
- Procedures not listed on Table A are outside the scope of WISeR;
- Trial procedures are outside the scope of WISeR;
- Revisions or replacement procedures are outside the scope of WISeR.

This misunderstanding has improved meaningfully over time. During the first four weeks of the program, over (b)(4) of all referrals were dismissed for these various reasons. In the most recent four-week period, the dismissal rate has declined to (b)(4) of all submissions. Virtix Health views continued reduction of the dismissal rate as a priority and is actively engaged in ongoing provider education efforts, including inbound and outbound outreach, dismissal-specific education calls, and updated FAQ and user guide materials, to further reduce avoidable submissions.

With respect to non-affirmations, peer-to-peer discussions have consistently helped clarify the applicable coverage criteria and the documentation standards required for a successful resubmission. It is important to note that these

situations did not result from determination letters issued in error or requiring reissuance. Non-affirmation decisions are made exclusively by Virtix Health's board-certified physicians following a thorough medical record review and the application of clinical judgment.

Virtix Health maintains a structured internal Quality Assurance approach to monitor the accuracy of its determinations. This process employs a standardized sampling methodology and provides the clinical team with targeted feedback and education informed by audit findings.

MSP Denials

CMS' RFI observation specifically cited MPS (Medicare Secondary Payer) denials as an example of denial patterns that raise questions regarding alignment with published program guidance. Our deployment of the HETS validation of beneficiary's enrollment in Medicare has been our source for validation. In the first several weeks of the program, the configuration (b)(4)

(b)(4)

3. *Detailed causes of delays between approval and issuance of UTNs.*

The delays experienced in UTN issuance during the early weeks of the program are attributable to several distinct operational and system factors. Virtix Health has worked diligently to resolve each of these issues and has made significant progress. However, some challenges related to MAC coordination remain unresolved, and Virtix Health respectfully requests CMS's assistance in addressing those items, as described below.

Initial MAC Package Requirements and Feedback Delays

In an effort to operate in full compliance with program requirements and following the completion of User Acceptance Testing (UAT) with our Medicare Administrative Contractor (MAC), Virtix Health submitted a series of sample cases requesting guidance on whether our submission packages met the MAC's standards. The MAC provided no feedback for over ten days. Once feedback was provided, Virtix Health learned that its packages were missing key required elements. Virtix Health worked collaboratively with the MAC to correct those issues and reformat its packages accordingly.

Unfortunately, this delay affected more than 500 submissions requiring UTNs during the first two weeks of the program, and created cascading delays that extended into subsequent weeks as the backlog was addressed. Virtix Health believes earlier feedback from the MAC during the UAT process would have materially reduced the scope of these delays. Notwithstanding, Virtix Health has cleared the backlog and our packages continue to be accepted by the MAC.

PECOS Validation Tool Limitations

At program launch, the PECOS validation tool initially available to Virtix Health did not support validation of provider PTANs and NPIs. As a result, determinations were issued based on validation of all other available data elements. Cases with provider PTAN and NPI discrepancies were unable to be processed by the MAC and later required reprocessing of the previously affirmed and non-affirmed determinations as dismissals, which created provider confusion and frustration.

Virtix Health has taken responsibility for communicating this workflow challenge directly to affected providers. However, given that the PECOS tool limitation was a program-level infrastructure issue rather than an operational failure by Virtix Health, we are continuing to engage the MAC on a standardized approach to handling these cases.

Additional MAC-Related Operational Issues

Virtix Health has encountered several recurring operational inconsistencies in its work with the MAC that have contributed to UTN delays and provider-facing confusion. We documented these here not as grievances but to provide CMS with full visibility into program-level friction points that may benefit from further CMS guidance or intervention:

- Error messaging from the MAC regarding reasons a UTN issuance fails is often vague, making timely resolution difficult without additional follow-up;
- UTN issuance has been inconsistent, the MAC has issued UTNs for a given provider PTAN/NPI combination and subsequently rejected the same combination on future submissions, creating uncertainty for the Virtix Health team in identifying which pairings are valid;
- Several cases were returned from the MAC with a blank UTN field; upon review, the MAC identified the error and provided the correct numbers via Excel;
- Some providers have disputed their inactive PTAN/NPI status as identified by the MAC;
- In select cases, the MAC has indicated that the provider falls under the jurisdiction of a different MAC;

- Some claims were submitted as Part A prior authorizations that should have been Part B, or vice versa.

Virtix Health has worked to resolve each of these issues on a case-by-case basis and has continued to absorb the provider-facing communication burden associated with MAC processing errors. We will continue to engage the MAC on MAC-related issues and more consistent UTN issuance standards so as to reduce the downstream disruption for both Virtix Health and the providers we serve. We welcome any input from CMS on the best path forward, specifically related to providers contracted with a different MAC and standardizing UTN error messaging.

Additional Contributing Factors

Beyond MAC-related challenges, two additional factors contributed to early TAT delays:

- High dismissal rates driven by provider misunderstanding of WISeR scope increased operational volume and rework during the first several weeks. During the first two months of the program, the average was (b)(4) (b)(4)
- Virtix Health received significantly higher-than-projected referral volume from the MAC during weeks 2 through 4, including backlog cases and some referrals sent in error. During that period, Virtix Health received approximately (b)(4) cases per day from the MAC, compared with approximatel (b)(4) er day currently, which the MAC confirmed was attributable to their backlog.

Despite these early challenges, Virtix Health's performance has improved materially. Current average TAT is well within the 3-day expectation, with week 9 at (b)(4) days and week 10 at (b)(4) days.

CMMI Guidance on Issuing Determination Letters Without a UTN

Section 1.7.6 of the WISeR Participation Guide states that CMS expects Virtix Health to "typically issue a determination to the WISeR Provider or WISeR Supplier within 3 days of receiving the initial or resubmitted request, including requests without a UTN present." In accordance with this guidance, and following discussions with CMMI during multiple all-participant calls, Virtix Health has been issuing determination letters to providers without the UTN when necessary to prevent further delays to providers awaiting an outcome. Once a UTN is received, the determination letter is reissued with the UTN included.

Virtix Health acknowledges that this practice of issuing letters in two stages has created some provider confusion and, in some cases, prompted duplicate submissions. More recently, the UTN issuance challenge has subsided, and we believe that this issue has been resolved and does not necessitate Virtix Health issuing multiple determination letters.

4. Detailed causes and steps taken to complete prior authorizations received from the assigned MAC on a timely basis.

Virtix Health is currently meeting the expected average turnaround time of 3 days, as specified in Section 1.7.6 of the WISeR Participation Guide (most recent version dated February 27, 2026). The table below reflects average turnaround times by week since program launch, inclusive of both initial submissions and resubmissions:

Week of Program	Avg. TAT (Days)	Volume
Wk 1 (Jan 5 – Jan 11)	(b)(4)	
Wk 2 (Jan 12 – Jan 18)		
Wk 3 (Jan 19 – Jan 25)		
Wk 4 (Jan 26 – Feb 1)		
Wk 5 (Feb 2 – Feb 8)		
Wk 6 (Feb 9 – Feb 15)		
Wk 7 (Feb 16 – Feb 22)		
Wk 8 (Feb 23 – Mar 1)		
Wk 9 (Mar 2 – Mar 8)		
Wk 10 (Mar 9 – Mar 15)		

As the data reflects, average TAT peaked in weeks 5 and 6 before declining consistently through weeks 7 through 10. Notably, TAT improvement has continued even as submission volumes increased in weeks 9 and 10, which Virtix

Health views as evidence that operational improvements are sustainable and not merely a function of lower volume.

Causes of Early TAT Delays

The elevated turnaround times observed in weeks 4 through 8 were attributable to a combination of factors, several of which are described in detail in response to Question 3. In summary:

- **MAC backlog and referral errors:** Virtix Health received approximately (b)(4) cases per day from the MAC during weeks 2 through 4, significantly higher than projected, including backlog cases and referrals sent in error. The MAC confirmed this volume spike was attributable to their backlog. Current MAC referral volume has declined to approximatel (b)(4) cases per day, consistent with the estimated volume provided to Virtix Health.
- **High dismissal rates:** During the first four weeks of the program, over (b)(4) of all referrals were dismissed due to provider misunderstanding of WISeR scope and submission requirements. This generated significant rework and consumed physician reviewer capacity. The dismissal rate has declined to (b)(4) over the most recent four-week period.
- **Resubmission volume:** During the first two months of the program, the average was (b)(4) submissions per case, with (b)(4) of unique submissions involving (b)(4) resubmissions. Repeated resubmissions for the same case consumed disproportionate clinical and operational resources.
- **UTN issuance delays:** As described in the response to Question 3, delays in UTN issuance from the MAC created downstream operational complexity that affected TAT during the early weeks of the program.

Steps Taken and Ongoing Commitments

Virtix Health has taken the following steps to improve turnaround performance and sustain current results:

- **Provider education and portal adoption:** Virtix Health has conducted proactive inbound and outbound outreach to providers to reduce out-of-scope submissions, avoidable dismissals, and repeated resubmissions. These efforts have contributed to a significant shift in submission channel. At program launch, ove (b)(4) of referrals were submitted via fax to the MAC then routed to Virtix Health via esMD, introducing delays of up to 10 days.

Portal submissions now account for approximately (b)(4) of referrals, enabling faster intake and more predictable turnaround times.

- **Support ticket resolutions:** Since program inception, Virtix Health has resolved over (b)(4) support tickets. Our team continues to respond to inbound requests and proactively engages with providers to address questions surrounding non-affirmation and dismissal education, UTN issues, and helping providers better understand how to leverage our portal. Additionally, Virtix Health has FAQ's and user guides that are available to providers to assist with more common questions.
- **Weekly performance monitoring:** Virtix Health monitors turnaround times on a weekly basis and uses that data to assess workflow performance, staff capacity, and case routing. This allows Virtix Health to identify and respond to volume or TAT trends before they become ongoing issues.
- **Internal QA:** Virtix Health maintains a structured internal quality assurance process for determinations, including targeted reviewer feedback and education, to support consistency and timeliness in clinical decision-making.
- **Ongoing MAC coordination:** Virtix Health continues to engage with the MAC to resolve package requirements, provider validation issues, and UTN issuance inconsistencies.

Virtix Health has identified inconsistent expectations of the definition of "timely" prior authorization reviews as we have interacted with providers. While 3 days is the expectation, there are some nuances in the communication and workflow of this expectation to various stakeholders. For example, in CMS' external-facing FAQ, providers are instructed "3. When will the *72-hour turnaround time* for a prior authorization request sent to a provider portal apply? The 72-hour turnaround time for requests sent to a WISeR participant electronic portal applies starting January 5, 2026." However, in the most recent version of the WISeR Participation Guide, dated February 27, 2026, section 6.3 states that "CMS expects that the WISeR Participant will typically issue a determination to the WISeR Provider or WISeR Supplier *within 3 days* of receiving the initial or resubmitted request, including requests without a UTN present." Providers have interpreted the FAQ to mean that no case will exceed 72 hours while the insertion of the word "typically" suggests more of an average turnaround time. Additionally, MACs are given 24-36 hours to issue a UTN, potentially limiting even further the amount of time Virtix Health has to issue a determination. Respectfully, we request CMS to provide additional guidance on the

expected turnaround time of the MAC and the WISeR Participants and the correlation between each expectation on the other as providers have voiced the concern that they expect that a determination with a UTN is available to them within 72 hours.

5. *Detailed causes and steps taken to address incomplete determination letters.*

Incomplete determination letters fall into two distinct categories, each with a separate cause and resolution.

Technical System Error – January 28-29, 2026

On January 28 and 29, 2026, a total of 64 determination letters were generated without clinical rationale due to a technical system error. Each affected case was reissued with the complete clinical rationale, and each impacted provider was notified within four calendar days of the original error. The underlying technical issue was identified, and corrective action was taken to prevent recurrence.

Determination Letters Issued Without a UTN

The remaining instances of incomplete determination letters involved letters issued without a UTN present. As described in the response to Question 3, issuing determinations without the UTN was discussed with CMMI during multiple all-participant calls and was approved by CMMI as an appropriate approach given the ongoing MAC delays in UTN issuance. This approach enabled providers to receive a timely outcome and, where applicable, submit additional documentation in the case of non-affirmation, without being forced to wait for extended periods of time for a UTN. Upon receipt of the UTN, each applicable determination letter was reissued with the UTN included.

Virtix Health acknowledges that the two-stage letter issuance process has created some provider confusion and, in some cases, prompted duplicate submissions. As noted in the response to Question 3, Virtix Health believes the general delay in UTN issuance has been resolved but continues to work with the MAC for case by case UTN challenges as they arise.

6. *Detailed causes of customer service issues and steps taken to improve the escalation process.*

Virtix Health maintains a dedicated customer service team currently comprising (b)(4) full-time employees responsible for managing inbound and outbound

provider inquiries. Since the program start date, this team has resolved over (b)(4) inquiries. Standard service levels include email responses within 24 hours, and inbound call monitoring aligned to the Pacific Time Zone. Providers may contact our WISeR support team at:

Email: wiser.support@virtixhealth.com | Phone: 833-943-2209

Causes of Provider Escalations

It is important to acknowledge that a significant portion of provider frustration is frequently attributable to factors that are independent of customer service performance. Escalated inquiries most commonly arise from one of three sources: provider misunderstandings of WISeR program requirements or scope, when documentation did not satisfy applicable LCD criteria, or UTN-related delays. In each of these categories, the underlying issues are clinical or operational in nature rather than a service delivery failure, though the customer service team absorbs the volume and burden of managing provider communication throughout.

As an illustrative example, a Seattle Times article recently featured a provider's account of a beneficiary scheduled for a Minimally Invasive Lumbar Decompression (MILD) procedure, characterizing the situation as a Virtix Health responsiveness issue. A review of the case record, however, reveals a more complex history:

- The provider's initial submission requesting the MILD procedure was dismissed as outside the scope of WISeR;
- A resubmission was filed with the same documentation, however the procedure was updated to an Epidural Steroid Injection (ESI); but, the documentation did not satisfy the applicable LCD requirements;
- A third submission was rejected by the system due to the provider entering an incorrect member ID for the same beneficiary; and
- A fourth attempt included an LCD checklist template but did not adequately address key LCD criteria.

Following multiple unsuccessful attempts to reach the provider by phone, Virtix Health ultimately was successful in scheduling a peer-to-peer discussion to resolve the outstanding documentation concerns. This case is representative of a broader pattern in which provider engagement challenges rooted in clinical or documentation complexity are perceived and reported as customer service failures.

Steps Taken and Ongoing Commitments to Improve the Escalation Process

Virtix Health has taken the following concrete steps to strengthen its escalation process and reduce provider friction:

- Dedicated escalation pathway: (b)(4)
  (b)(4)
- Proactive outbound outreach: (b)(4)
  (b)(4)
- Peer-to-peer availability: (b)(4)
  (b)(4)
- Provider education to reduce avoidable escalations: (b)(4)
  (b)(4)
- Ongoing monitoring: (b)(4)
  (b)(4)

Virtix Health welcomes the opportunity to directly address any specific provider complaints that CMS has received and is committed to resolving outstanding concerns promptly. Providers may contact our WISeR support team at wiser.support@virtixhealth.com or 833-943-2209.

7. Detailed examples of inconsistencies with diagnosis codes on claims versus records face sheets, including information on how often this occurs.

Virtix Health has reviewed its prepayment claim denials to identify the incidence and nature of diagnosis code discrepancies between claims and provider face

sheets. Of (b)(4) denied prepayment claims reviewed, (b)(4) were denied due to inconsistencies between the diagnosis codes reflected on the claim and those reflected on the provider's face sheet, representing (b)(4) incidence rate within the reviewed sample.

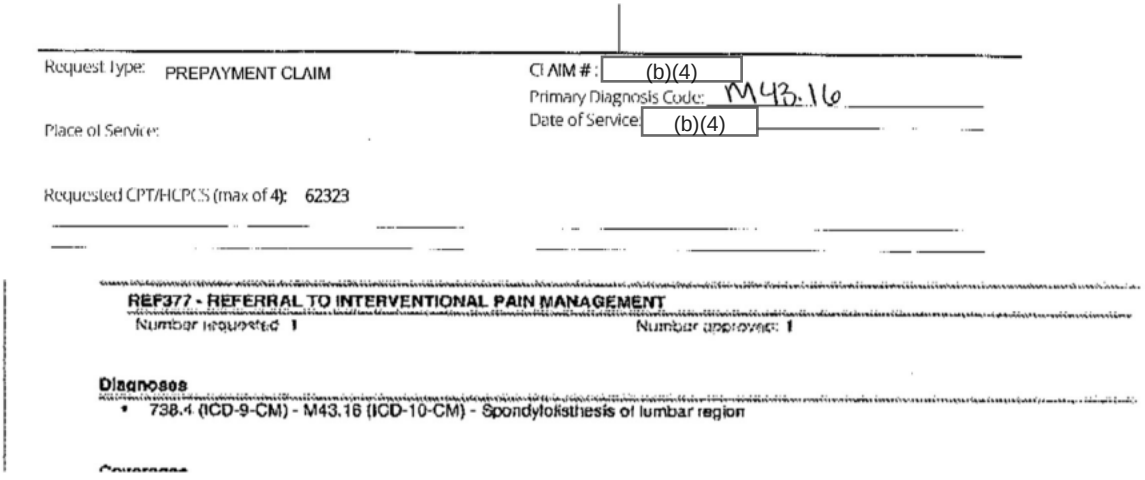
Virtix Health's review indicates that these discrepancies appear to originate at the provider level, arising from differences between the diagnosis codes submitted on the claim and those documented in the corresponding medical record face sheet. This is consistent with the nature of the ADR process, in which providers are asked to produce supporting documentation after the fact.

Five representative examples are summarized below based on the information contained in the claim package received from the MAC and the information reflected on the face sheet provided in response to the ADR:

Claim CPT	Claim Dx	Facesheet CPT	Facesheet Dx
62323	M48.061	62323	M43.16
64483	M54.16	64483	M51.26
62323	M54.16	62323	M41.124
62321	M54.14	62321	N/A
76600	M48.061	62323	M54.061

Supporting documentation for select cases is included below.

Case 1



Request Type: PREPAYMENT CLAIM

CLAIM # : (b)(4)

Primary Diagnosis Code: M43.16

Place of Service:

Date of Service: (b)(4)

Requested CPT/HCPCS (max of 4): 62323

REF377 - REFERRAL TO INTERVENTIONAL PAIN MANAGEMENT

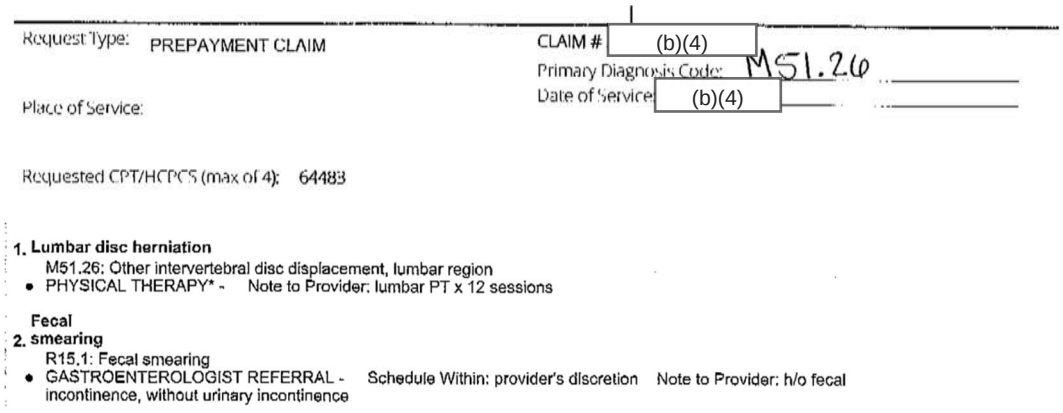
Number requested: 1 Number approved: 1

Diagnoses

- 738.4 (ICD-9-CM) - M43.16 (ICD-10-CM) - Spondylolisthesis of lumbar region

Coverage

Case 2


Request Type: PREPAYMENT CLAIM

CLAIM # (b)(4)

Primary Diagnosis Code: M51.26

Date of Service: (b)(4)

Place of Service:

Requested CPT/HCPCS (max of 4): 64483

1. **Lumbar disc herniation**
   M51.26: Other intervertebral disc displacement, lumbar region
   - PHYSICAL THERAPY* - Note to Provider: lumbar PT x 12 sessions

2. **Fecal smearing**
   R15.1: Fecal smearing
   - GASTROENTEROLOGIST REFERRAL - Schedule Within: provider's discretion Note to Provider: h/o fecal incontinence, without urinary incontinence

Steps Being Taken to Address This Pattern

Virtix Health is actively working to reduce the incidence of diagnosis code discrepancies through the following measures:

- Provider-level outreach: (b)(4)

  (b)(4)

- Earlier identification in the review workflow: (b)(4)

  (b)(4)

- MAC engagement: (b)(4)

  (b)(4)

Virtix Health will continue to monitor the incidence rate of this issue across the full claims population and is prepared to provide additional case-level data or documentation as requested by CMS.

Conclusion

In summation, Virtix Health acknowledges the observations described in CMS' correspondence and we remain committed to successfully fulfilling all applicable WISeR program requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, Maryland 21244-1850

February 20, 2026

Innovaccer Inc.
201 Mission Street, Suite 2900
San Francisco, CA 94105

Delivered via email to all active contacts for Innovaccer Inc., in the WISeR Participant Portal

WISeR-00043 Innovaccer Inc. – Performance Notice of Non-Compliance with WISeR Model Participation Agreement Requirements

Dear Innovaccer Inc.,

The Centers for Medicare & Medicaid Services (CMS) is providing Innovaccer Inc. with a Performance Notice for failure to adhere to Innovaccer's proposed corrective action plan (CAP) submitted to CMS on January 16, 2026. CMS sent Innovaccer a request for a CAP on January 7, 2026, outlining several areas of non-compliance regarding the availability of a public-facing Participant Portal. Innovaccer responded to the CAP on January 16, 2026, advising the portal would be available to WISeR Providers/Suppliers by February 5, 2026. CMS then sent Innovaccer a status check-in on January 30, 2026, to confirm whether Innovaccer remained on track to meet the target dates reflected in Table 2 of the CAP response dated January 16, 2026. On January 30, 2026, Innovaccer confirmed that they were on track with all items in Table 2. However, as of this writing the portal is not fully functional and does not meet WISeR Model requirements.

OBSERVATION

As of the date of assessment (February 20, 2026), Innovaccer has not yet adequately implemented or activated the CMS-required Participant Portal for WISeR Model Providers and Suppliers. The following link was provided by Innovaccer in an email indicating the portal is live (https://wiser.innovaccer.us/login); however, there appears only to be a login page, with no ability to create or register a new provider/supplier account. Additionally, there does not appear to be a link to a WISeR Provider/Supplier portal from Innovaccer's website. This differs from expectations CMS had when Innovaccer described their delay and proposed the February 5, 2026 implementation date.

Performance Notice of Non-Compliance

This Performance Notice of Non-Compliance is issued to formally document that:

1) Innovaccer is not currently meeting one or more requirements under the WISeR Model Participation Agreement. Under the Agreement, WISeR Participants are required to comply with all applicable terms, operational standards, and program requirements throughout the Agreement term. Despite the reminder on January 7, 2026, and the status check-in on January 30, 2026,

Innovaccer has failed to implement the WISeR Provider/Supplier portal by the deadline of February 5, 2026, and did not communicate a fully functioning portal would not be launched. Instead, Innovaccer proceeded with a limited launch on February 6, 2026, with a selected group of providers. The launch was limited in scope, and the system was not fully operational or functioning as required. This non-compliance affected the ability of Providers/Suppliers to engage with the WISeR Model as expected beginning January 5, 2026.

2) Innovaccer did not meet the CAP deadline of February 5, 2026, as agreed to by both parties and has therefore violated Section 13.1(A)(3) of the Participation Agreement.

Description of Compliance Deficiency
Requirement/Standard Not Met: Live Portal
Reference: Section 5.1 Functional and Infrastructure Requirements
Date(s) Observed: February 13, 2026
Summary of Deficiency: The WISeR Model Portal was required to be active and available for use by January 5, 2026. CMS provided an extension to February 5, 2026; however, the Portal was still not operational by that date. Missing both the original and extended deadlines constitutes a significant compliance concern. CMS views these missed deadlines as a serious matter given the importance of ensuring operational readiness and uninterrupted model implementation.

Impact and Risk
Innovaccer's failure to comply with WISeR requirements may pose risks to:
- Model integrity and performance
- Beneficiary protections
- Medicare program oversight
- Timeliness or accuracy of determinations

Potential Consequences of Continued Non-Compliance
If Innovaccer fails to correct the deficiencies within the required timeframe, CMS may take further remedial action pursuant to Section 13.2 of the Agreement, including but not limited to:
- Additional monitoring or audits
- Withholding, denial, or recoupment of WISeR Payments
- Suspension of ability to perform prior authorization activities
- Termination from the model

We require you to acknowledge this performance notice by February 24, 2026. Failure to acknowledge this notice may result in CMS taking further remedial actions as specified in Article XIII of the Agreement, up to or including terminating Innovaccer Inc.'s participation in the WISeR Model under Section 13.3 of the Agreement. Additionally, CMS will issue a new CAP request and expects Innovaccer to fully comply with all upcoming and future deadlines. We appreciate your prompt attention to this matter. If you have any questions concerning the information and request above, please email WISeR@cms.hhs.gov.

Sincerely,

The WISeR Model Team

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, Maryland 21244-1850

February 20, 2026

Innovaccer Inc.
201 Mission Street, Suite 2900
San Francisco, CA 94105

Delivered via email to all active contacts for Innovaccer Inc. in the WISeR Participant Portal

Re: WISeR-00043 Innovaccer Inc. – Reissued Request for Corrective Action Plan – Noncompliance with WISeR Model Participation Agreement Requirements

Dear Innovaccer Inc.,

The Centers for Medicare & Medicaid Services (CMS) requires Innovaccer Inc. to submit a Corrective Action Plan (CAP) for failure to adhere to the proposed corrective action plan (CAP) submitted to CMS on January 16, 2026, and to assure compliance with the following requirements of the Wasteful and Inappropriate Service Reduction (WISeR) Model Participation Agreement (Agreement):

- *Article III Section 3.7(C), Customer Service*
- *Article V Functional Requirements, Section 5.2(B) Telecommunications*
- *Article VI Prior Authorization Process, Section 6.2(A) Prior Authorization Process and Exemption Status*
- *Article VI Section 6.5(C) and 6.5(D) Pre-Payment Review*

NONCOMPLIANCE

Innovaccer Inc.'s December 2, 2025, email disclosed several concerns to CMS related to Innovaccer Inc.'s readiness for WISeR Model implementation as referenced in the CAP issued on January 7, 2026. The CAP outlined several areas of non-compliance regarding the availability of a public-facing Participant Portal. Innovaccer Inc., responded to the CAP on January 16, 2026, advising that the portal would be available to WISeR Providers/Suppliers by February 5, 2026. During a status check-in on Janaury 30, 2026, Innovaccer Inc. further confirmed that they were on track to meet the Februrary, 5, 2026 deadline. At the time of this writing the portal is not fully functional and does not meet WISeR Model requirements.

Accordingly, Innovaccer Inc. is noncompliant with the following sections of the Participant Agreement expected to be in place by February 5, 2026, the CAP Remediation Date:

- Section 3.7(C): The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.

- Section 5.2(B): The WISeR Participant shall, at a minimum, use or have the ability to interface with the Electronic Submission of Medical Documentation ("**esMD**"), and any other CMS approved electronic portals to exchange data with CMS, the WISeR Providers, WISeR Suppliers, and applicable MACs.

- Section 6.2(A): The WISeR Participant shall accept Prior Authorization for the Select Items and Services by fax, mail, Electronic Submission of Medical Documentation ("**esMD**"), and any other CMS approved electronic portals from WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).

- Section 6.5(C)(D): The WISeR Participant must use its WISeR Clinicians or WISeR Clinical Reviewers, as applicable, to perform Pre-Payment Review as detailed in the WISeR Participant Guide.

REQUIREMENT TO SUBMIT A CORRECTIVE ACTION PLAN TO CMS

As a result of this noncompliance and pursuant to Section 13.2(A)(9) of the Agreement, CMS requires Innovaccer Inc. to submit a detailed CAP for CMS approval in the form and manner, and by the date specified below.

Please include the following information as part of your proposed CAP:

1. An acknowledgement of the noncompliance described above;
2. The steps Innovaccer Inc. will take to establish the capabilities to respond to WISeR Provider and WISeR Supplier electronic, telephone, and written inquiries promptly, clearly and accurately;
3. A detailed plan for fully implementing and operationalizing a public-facing, secure portal for the electronic submission of prior authorization requests from all WISeR Providers and WISeR Suppliers in Ohio no later than **Thursday, March 5, 2026**;
4. A plan that identifies the actions Innovaccer Inc. has taken or will take, the identity of the official(s) responsible for those actions, and associated milestones/timeline, to correct the deficiencies listed above, by **Thursday, March 5, 2026.**

Please provide clear and concise explanations and supplemental documentation, where necessary to fully address this CAP request. CMS will require documentation confirming that the approved CAP has been implemented and periodic reports on progress may be requested during the CAP period.

Not adhering to both the original (January 1, 2026) and extended (February 5, 2026) deadlines constitutes a significant compliance concern. CMS views these missed deadlines as a serious matter given the importance of ensuring operational readiness and uninterrupted model implementation.

Please acknowledge receipt of this letter by **5 p.m. ET on February 24, 2026.**

Please submit your proposed CAP to CMS **by 5 p.m. ET on February 27, 2026.** through the WISeR Model mailbox at WISeR@cms.hhs.gov. Title your submission: "WISeR-00043 Innovaccer Inc. Proposed Reissued CAP - Readiness."

CMS' approval of the proposed CAP is contingent on the CAP satisfactorily addressing all the required information identified above. CMS reserves the right to request additional information and may request that Innovaccer Inc. make modifications to the proposed CAP as a condition of CMS approval of the CAP and Innovaccer Inc.'s continued participation in the WISeR Model.

If Innovaccer Inc. fails to submit or implement the CAP, the CAP is rejected, or Innovaccer Inc. otherwise fails to meet CMS and WISeR Model standards, this failure will result in **payments being withheld** under Section 13.2(A)(6) of the Participation Agreement. CMS may also take further remedial actions as specified in Article XIII of the Agreement, up to or including terminating Innovaccer Inc.'s participation in the WISeR Model under Section 13.3 of the Agreement.

We appreciate your prompt attention to this matter. If you have any questions concerning the information and request above, please email WISeR@cms.hhs.gov.

Sincerely,

The WISeR Model Team

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201 Mission St, Suite 2900
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February 27, 2026

The WISeR Model Team
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, MD 21244-1850

Via email: WISeR@cms.hhs.gov

Re: WISeR-00043 Innovaccer Inc. – Reissued Request for Corrective Action Plan – Noncompliance with WISeR Model Participation Agreement Requirements

Dear WISeR Model Team:

Innovaccer Inc. ("**Participant**") acknowledges receipt of CMS's January 7, 2026 letter titled "WISeR-00[0]43[1] Innovaccer Inc. – Request for Corrective Action Plan – Noncompliance with WISeR Model Participation Agreement Requirements" (hereinafter referred to as "**Initial CAP**") and CMS's February 20, 2026 letter titled "WISeR-00043 Innovaccer Inc. - Reissued Request for Corrective Action Plan - Noncompliance with WISeR Model Participation Agreement Requirements." (hereinafter referred to as "**Reissued CAP**").

1. **Acknowledgement & Commitment to Compliance**

Participant takes its obligations under the WISeR Model Participation Agreement and Amendment 2025-1 very seriously and remains fully committed to supporting a successful implementation of the WISeR Model.

2. **Response to Initial CAP**

Participant responded promptly to the CAP and indicated that 3 out of 4 items were fully compliant as of the time of commencement of the program.[2] There was one open item, the WISeR Participant portal. According to the WISeR Model Participation Agreement executed between CMS and Innovaccer on October 16, 2025 and the WISeR Participant Guide dated December 23, 2025 there are no details about the minimum viable criteria for a WISeR Participant Portal to be deemed "fully functional." The CMS WISeR team requested a status check on January 30, 2026 implicitly acknowledging receipt and acceptance of the Initial CAP response which included the following items:

- Complete functionality to securely authenticate providers / suppliers;
- Complete functionality to allow submission of prior authorization requests electronically;

[1] Third zero in Innovaccer Inc.'s WISeR Participant ID was previously unintentionally omitted.
[2] The full response supplied to the CMS WISeR team with its response to the request for a Corrective Action Plan (CAP) sent on January 16, 2026 is attached in Exhibit A.

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- Enable providers / suppliers to securely upload supporting clinical documentation;
- Complete functionality to allow providers / suppliers to provide near real-time authorization status;
- Perform end-to-end testing between the portal, esMD, internal adjudication workflows and CGS interfaces; and
- Portal availability to providers and suppliers.

3. WISeR Participant Portal

The Reissued CAP raises three issues with the WISeR Participant portal, each described below.

a. Live date: Participant acknowledges that the WISeR Participant portal was complete as of February 6, 2026, a day later than originally communicated. (b)(6) (Innovaccer) confirmed with the CMS WISeR team via email that the Innovaccer WISeR Provider Portal was live and included a link to the portal.[3] On February 10, 2026, the CMS WISeR team resolved CS4800487, acknowledging that Innovaccer supplied the WISeR Participant portal link.

b. Phased Rollout: The portal rollout was phased with a select group of providers. This was done to quickly address any issues and gather direct feedback from providers. We understood that the phased roll out plan was acceptable to CMS. Twice on February 9, 2026 the CMS WISeR team confirmed receipt of the email notice that the WISeR Participant portal was live and held a meeting with Innovaccer on the afternoon of February 9, 2026. CMS did not share any concerns related to Innovaccer's approach during that call. We understand from the Reissued CAP letter that this was deemed a compliance issue and we reiterate that at this time it is fully implemented.

c. New requirements: The Reissued CAP letter indicated that the portal is non-compliant because it does not:
   i. Permit the ability to create or register a new provider/supplier account; and
   ii. Link the WISeR Provider/Supplier portal from Innovaccer's website (both of these elements referred to hereafter as the "**New Requirements**")

The Reissued CAP letter notes that Participant is "required to comply with all applicable terms, operational standards, and program requirements throughout the Agreement term." However, the Reissued CAP letter does not provide any citation to any term, operational standard or program requirement that includes the New Requirements. Instead, CMS merely indicates that since the portal did not meet the New Requirements, it did not meet the "expectations CMS had when Innovaccer described their delay and proposed the February 5, 2026 implementation date."

[3] *See*, email sent by (b)(6) on February 6, 2026 to Claire Kihn, Laura Missett, CMS CMMI WISeR Model listserv with a carbon copy to (b)(6)

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We reiterate that in the multiple conversations and exchanges with CMS about the portal, CMS has not informed the Participant of the New Requirements in any written form, whether a manual or other operational documents. Finally, CMS has not verbally described the New Requirements during the various meetings and discussions that were held about the portal. Innovaccer respectfully requests clarification of the requirements and WISeR team expectations for the WISeR Participant portal.

4. Response on alleged areas of noncompliance

Table 1 below outlines the alleged areas of noncompliance and Innovaccer's status as of February 27, 2026.

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Table 1: Alleged Area of Noncompliance and Innovaccer Status as of February 27, 2026

Participant Agreement Section	Participant Agreement Title	Alleged Area on Noncompliance	Innovaccer Compliance Status	Corrective Action Plan
Section 3.7(C)	Customer service (provider/supplier inquiries)	Section 3.7(C): The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.	Compliant	Not applicable. • Dedicated WISeR email established 11/26/2025 • Dedicated WISeR phone line active 1/1/2026
Section 5.2(B)	Telecommunications / electronic interfaces	Section 5.2(B): The WISeR Participant shall, at a minimum, use or have the ability to interface with the Electronic Submission of Medical Documentation ("esMD"), and any other CMS approved electronic portals to exchange data with CMS, the WISeR Providers, WISeR Suppliers, and applicable MACs.	Compliant	Not applicable. • Fully integrated with esMD by 1/1/2026 • Fully integrated with HETS by 1/1/2026 • Fully integrated with PECOS by 1/1/2026
Section 6.2(A)	Prior authorization submission channels	Section 6.2(A): The WISeR Participant shall accept Prior Authorization for the Select Items and Services by fax, mail, Electronic Submission of Medical Documentation ("esMD"), and any other CMS approved electronic portals from WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).	Compliant	Not applicable. • Technical capabilities established by 1/1/2026 • Prior authorization requests accepted via CGS-provided fax, mail and the CGS portal as of 1/5/2026 consistent with CMS go live date (based on CMS action) • Prior authorization requests accepted via esMD as of 1/5/2026 consistent with CMS go live date (based on CMS action) • Innovaccer Provider Portal active as of 2/6/2026

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Participant Agreement Section	Participant Agreement Title	Alleged Area on Noncompliance	Innovaccer Compliance Status	Corrective Action Plan
				• Innovaccer Provider Portal available for all providers and suppliers as of the date of this letter.
Sections 6.5(C)–(D)	Use of WISeR Clinicians / Clinical Reviewers	Section 6.5(C)(D): The WISeR Participant must use its WISeR Clinicians or WISeR Clinical Reviewers, as applicable, to perform Pre-Payment Review as detailed in the WISeR Participant Guide.	Compliant	Not applicable. • Clinicians and reviewers are in place and available to perform pre-payment reviews

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5. Detailed Plan to Implement and Operationalize Participant Portal

A public-facing, secure WISeR Participant portal for the electronic submission of prior authorization requests from all WISeR Providers and WISeR Suppliers in Ohio is available via Innovaccer's CMS WISeR website under "Prior Authorization" webpage and again under the "Resources and Links" webpage. A Portal User Guide and a form for WISeR Providers and Suppliers to register for portal access are available.

6. Plan and Responsible Party to Correct Alleged Deficiencies

As previously stated in the January 16, 2026 Initial CAP response and reiterated in this Reissued CAP response in Table 1 (above), Innovaccer has implemented solutions that address all alleged deficiencies. Innovaccer Inc. respectfully requests written acknowledgement from the CMS WISeR team of the satisfactory resolution of both the Initial CAP and Reissued CAP.

7. Reservation of rights and request for continued collaboration

Innovaccer respectfully reiterates its commitment to compliance, transparency and operating in good faith. These commitments are the reasons Innovaccer has *proactively* disclosed past implementation risks and the need for an interim strategy or phased rollout. Innovaccer understands that CMS elected not to delay the WISeR Model start date, and Innovaccer proceeded in good faith to meet subsequent deadlines with a minimally viable product while continuing to build the full production solution.

Innovaccer remains committed to full compliance with all WISeR Model requirements, to minimizing provider abrasion, and to protecting Medicare beneficiaries, and welcomes continued collaboration with CMS.

To support Innovaccer's compliance with the CMS WISeR Participation Agreement and ability to correct the previously alleged compliance deficiencies, Innovaccer, Inc. respectfully requests:

- A meeting with CMS to discuss the compliance challenges to date and seek to understand the expectations CMS has of the WISeR Participants; and
- Continued transparency of the minimum criteria WISeR Participants will be evaluated against in relation to compliance with the Participation Agreement.

Please let Innovaccer know if CMS requires additional information or adjustments to this Revised Corrective Action Plan. Innovaccer looks forward to CMS's review and approval.

Sincerely,

(b)(6)

Innovaccer Inc.

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Exhibit A. Initial CAP Response

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January 16, 2026

The WISeR Model Team
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, MD 21244-1850

Via email: WISeR@cms.hhs.gov

Re: WISeR-0043 Innovaccer Inc. – Proposed Corrective Action Plan – Readiness

Dear WISeR Model Team:

Innovaccer Inc. acknowledges receipt of CMS's January 7, 2026 letter titled "WISeR-0043 Innovaccer Inc. – Request for Corrective Action Plan – Noncompliance with WISeR Model Participation Agreement Requirements."

I. Acknowledgement and context

Innovaccer takes its obligations under the WISeR Model Participation Agreement and Amendment 2025-1 very seriously and remains fully committed to supporting a successful implementation of the WISeR Model. As disclosed to CMS in October 2025, Innovaccer accepted WISeR participation with the explicit understanding that it would go live on January 5, 2026 with a minimally viable product and phased capability rollout, rather than full functionality at launch.

In its January 7, 2026 letter, CMS identifies potential noncompliance with Article III Section 3.7(C), Article V Section 5.2(B), Article VI Section 6.2(A), and Article VI Sections 6.5(C)–(D), and requests a Corrective Action Plan addressing six specific items. Innovaccer appreciates the opportunity to clarify current status, correct factual inaccuracies, and outline the short-term actions being taken to ensure that all required capabilities are fully documented and demonstrably in place by February 5, 2026.

Table 1 below outlines the alleged areas of noncompliance and Innovaccer's current status as of the date of this letter.

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Table 1: Alleged Area of Noncompliance and Innovaccer Status

Participant Agreement Section	Participant Agreement Title	Alleged Area on Noncompliance	Innovaccer Compliance Status	Corrective Action Plan
Section 3.7(C)	Customer service (provider/supplier inquiries)	Section 3.7(C): The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.	Compliant	Not applicable. • Dedicated WISeR email established 11/26/2025 • Dedicated WISeR phone line active 1/1/2026
Section 5.2(B)	Telecommunications / electronic interfaces	Section 5.2(B): The WISeR Participant shall, at a minimum, use or have the ability to interface with the Electronic Submission of Medical Documentation ("esMD"), and any other CMS approved electronic portals to exchange data with CMS, the WISeR Providers, WISeR Suppliers, and applicable MACs.	Compliant	Not applicable. • Fully integrated with esMD by 1/1/2026 • Fully integrated with HETS by 1/1/2026 • Fully integrated with PECOS by 1/1/2026
Section 6.2(A)	Prior authorization submission channels	Section 6.2(A): The WISeR Participant shall accept Prior Authorization for the Select Items and Services by fax, mail, Electronic Submission of Medical Documentation ("esMD"), and any other CMS approved electronic portals from WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).	Substantially Compliant	Not applicable: • Technical capabilities established by 1/1/2026 • Prior authorization requests accepted via CGS-provided fax, mail and the CGS portal as of 1/5/2026 consistent with CMS go live date (based on CMS action) • Prior authorization requests accepted via esMD as of 1/5/2026 consistent with CMS go live date (based on CMS action) Corrective Action Plan: • Innovaccer Provider Portal is not active (as disclosed on

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				10/2025 and 12/12/2025). Innovaccer plan enclosed.
Sections 6.5(C)–(D)	Use of WISeR Clinicians / Clinical Reviewers	Section 6.5(C)(D): The WISeR Participant must use its WISeR Clinicians or WISeR Clinical Reviewers, as applicable, to perform Pre-Payment Review as detailed in the WISeR Participant Guide.	Compliant	Not applicable: • Clinicians and reviewers are in place and available to perform pre-payment reviews

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II. Response on identified areas of noncompliance

1. Section 3.7(C) – Customer service (provider/supplier inquiries)

Area of Alleged Noncompliance: Section 3.7(C): The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.

Innovaccer Response: Innovaccer established, and is actively operating, both an email inbox and a dedicated telephone line for WISeR provider and supplier inquiries.

- Innovaccer established a dedicated WISeR provider inquiry email address (ohcmswiser-inquiry@innovaccer.com) on November 26, 2025. This inbox has been actively monitored since that time with all inquiries being responded promptly, clearly, and accurately. The established email was communicated to CMS in Innovaccer's December 2, 2025 email correspondence regarding readiness and implementation risk. Innovaccer communicated the dedicated email to the provider community through webinars on December 12, 2025 and December 17, 2025. CGS posted this information on their CMS WISeR webpage (https://www.cgsmedicare.com/partb/pa/wiser.html) and announced this via email to their provider listserv. Additionally, we have received more than 100 emails from providers or external stakeholders to this email box since its inception. We are also accepting inquiries and responding to them, through our webpage "Contact Us" feature.
- Innovaccer established a dedicated WISeR Provider inquiry telephone line (202-796-1619) that went live on January 1, 2026. The phone line is fully staffed to respond to WISeR Provider and WISeR Supplier inquiries promptly, clearly, and accurately. Our normal business hours are from 8 am to 6 pm EST, Monday through Friday, excluding federal holidays. As of go live, more than 150 inbound and outbound calls have been made, with 80.95% of calls being answered within 60 seconds. If there is a need for follow-up, the follow-up is being performed, in most cases, within 1-2 business days depending on the complexity of the issue.

Accordingly, Innovaccer is currently meeting the functional requirement in Section 3.7(C) to respond to electronic, telephone, and written inquiries.

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2. Section 5.2(B) – Telecommunications / electronic interfaces

Area of Alleged Noncompliance: Section 5.2(B): The WISeR Participant shall, at a minimum, use or have the ability to interface with the Electronic Submission of Medical Documentation ("esMD"), and any other CMS approved electronic portals to exchange data with CMS, the WISeR Providers, WISeR Suppliers, and applicable MACS.

Innovaccer Response: Innovaccer is using and has the ability to interface with CMS-approved electronic systems for WISeR data exchange, including:

- esMD for the electronic submission of medical documentation, both for direct submissions from providers and for submissions transmitted via CGS as the applicable MAC.
- HETS for beneficiary eligibility verification and PECOS for provider enrollment status, which were added as new core integrations **during implementation** and were built, credentialed, and tested and functioning as expected as part of the WISeR solution before the January 5, 2026 go live.

These integrations were acknowledged by CMS during implementation discussions as new or evolving requirements that expanded beyond the original project plan and contributed to the need for a phased rollout. Innovaccer is therefore currently complying with the core functional requirement of Section 5.2(B).

3. Section 6.2(A) – Prior authorization submission channels

Area of Alleged Noncompliance: Section 6.2(A): The WISeR Participant shall accept Prior Authorization for the Select Items and Services by fax, mail, Electronic Submission of Medical Documentation ("esMD"), and any other CMS approved electronic portals from WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).

Innovaccer Response: Innovaccer began accepting prior authorization (PA) requests for WISeR Select Items and Services on go live January 5, 2026 via:

- Fax, mail, and the CGS portal, for submissions routed through CGS as the WISeR MAC.
- esMD, for prior authorization requests submitted directly by WISeR Providers and WISeR Suppliers.

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The only WISeR submission pathway not yet in production is Innovaccer's own secure provider portal. Innovaccer explicitly disclosed the Innovaccer WISeR Portal would not be available at the January 5, 2026 go-live date in Innovaccer's October 2025 disclosure letter and again in the December 12, 2025 "Approach to Implementation and Go-Live" letter to CMS. CMS indicated at that time that it would work with Innovaccer on a phased rollout, including portal functionality. Innovaccer therefore is substantially complying with Section 6.2(A) and is taking steps under this CAP to finalize and implement its own portal by February 5, 2026.

4. Sections 6.5(C)–(D) – Use of WISeR Clinicians / Clinical Reviewers

Area of Alleged Noncompliance: Section 6.5(C)(D): The WISeR Participant must use its WISeR Clinicians or WISeR Clinical Reviewers, as applicable, to perform Pre-Payment Review as detailed in the WISeR Participant Guide.

Innovaccer Response: Innovaccer's WISeR Clinicians and WISeR Clinical Reviewers are in place and are available to be used to perform pre-payment review for cases that require clinical review, in accordance with the WISeR Participant Guide.

Since the WISeR Model is only applicable for dates of service that occur from January 15, 2026 and after, Innovaccer has not yet received pre-payment review claims.

All cases requiring non-affirmation determinations will be handled by WISeR Clinicians or WISeR Clinical Reviewers as required by Sections 6.5(C)–(D). Accordingly, Innovaccer is currently meeting the functional requirement in Section 6.5(C)–(D).

III. Corrective Action Plan – Response to six CMS items

CMS requested that Innovaccer address six specific elements in its proposed CAP. Innovaccer's responses and planned actions are as follows.

Item 1 – Acknowledgement of noncompliance

Innovaccer acknowledges that:

- Innovaccer does not yet have its own WISeR provider portal in production for the electronic submission of prior authorization requests. Innovaccer previously disclosed that the provider portal would not be available by the January 5, 2026 go live date. As

innovaccer

The AI Cloud for Healthcare Performance

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San Francisco, CA 94105
United States

part of Innovaccer's October 2025 transmittal disclosures, and again in our December 12, 2025 go-live approach letter we reiterated the portal was not considered in scope as a minimum viable product (MVP) and would be available following the January go live.

Innovaccer respectfully notes, however, that as of January 1, 2026, the required customer service email and telephone capabilities are operational, that Innovaccer is interfacing with esMD, PECOS, and HETS, and that prior authorization requests are being accepted via fax, mail, CGS portal, and esMD. The primary remaining gap is Innovaccer's own secure provider portal, which is being addressed through an accelerated, time-bound plan described below.

Item 2 – Steps and timeframe for provider inquiry phone line

Innovaccer Status: Compliant

The dedicated WISeR provider inquiry phone line (202-796-1619) was established January 1, 2026 and is fully staffed.

Item 3 – Steps to respond to electronic/telephone/written inquiries

Innovaccer Status: Compliant

Innovaccer is already responding to WISeR Provider and WISeR Supplier inquiries through:

- Email: ohcmswiser-inquiry@innovaccer.com (live since November 26, 2025).
- Telephone: 202-796-1619 (live since January 1, 2026).
- Written correspondence received through the Innovaccer website and corporate address, if applicable.

Item 4 – Plan for secure electronic PA submission portal

Innovaccer Status: Partially compliant

Innovaccer's secure provider portal is in active development and was originally scheduled as part of a later phase in the phased capability rollout, following CMS's decision not to delay the model start date and Innovaccer's commitment to go live with a minimally viable solution and auto-affirmation.

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United States

A high level action plan to meet the target date of February 5, 2026 for the Provider Portal can be found in Table 2 below:

Table 2: Action Plan to Establish Provider Portal

Task	Action Step	Status	Target Date	Person/Team Responsible
Development	Complete functionality to securely authenticate providers / suppliers	In Progress	01-30-26	Innovaccer Product and Engineering
Development	Complete functionality to allow submission of prior authorization requests electronically	In Progress	01-30-26	Innovaccer Product and Engineering
Development	Enable providers / suppliers to securely upload supporting clinical documentation	In Progress	01-30-26	Innovaccer Product and Engineering
Development	Complete functionality to allow providers / suppliers to provide near real-time authorization status	In Progress	01-30-26	Innovaccer Product and Engineering
Testing	Perform end-to-end testing between the portal, esMD, internal adjudication workflows and CGS interfaces	Not started	01-31-26	Innovaccer Product and Engineering, CS, and core integration partners
Deployment	Portal availability to providers and suppliers	Not started	02-05-26	Innovaccer Product and Engineering and CS

Responsible party:

- Responsible official: (b)(6)

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Item 5 – Steps to establish PA receipt via all required channels

Innovaccer Status: Partially Compliant

As of January 5, 2026, Innovaccer is able to receive PAs via CGS fax, mail, and portal, as well as directly from the esMD. The remaining step is to bring Innovaccer's own portal, as described in Section III, Item 4.

Innovaccer will also establish inbound fax and mail for prior authorization request submission and additional documentation request submission for the prepay claim process by February 5th, 2026.

Responsible party:

- Responsible official: (b)(6)

Item 6 – Consolidated plan, owners, and milestones through February 5, 2026

Innovaccer proposes the following consolidated action plan to fully document and, where necessary, enhance the capabilities at issue by February 5, 2026:

CAP Area	Key Actions	Responsible Official	Target Completion
Portal development	Complete development; conduct testing; launch	(b)(6)	February 5, 2026
Inbound Fax and Mail	Secure fax number and integrate with ingestion pipeline		February 5, 2026

Innovaccer will provide CMS with:

- A written confirmation by February 5, 2026 that all CAP milestones have been completed or, if any are delayed, an updated remediation schedule and explanation.
- Supporting documentation on request, including sample workflow diagrams, training materials, and evidence of portal testing and launch.

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United States

IV. Reservation of rights and request for continued collaboration

Innovaccer respectfully reiterates that the key implementation risks, including the absence of a provider portal and the need for an interim auto-affirmation strategy, were disclosed prior to execution of the Participation Agreement and were re-affirmed in the October 10, 2025 transmittal disclosures and the December 12, 2025 go-live approach letter. Innovaccer understands that CMS elected not to delay the model start date, and Innovaccer proceeded in good faith to meet the January 5, 2026 go-live with a minimally viable product while continuing to build the full production solution.

Innovaccer remains committed to full compliance with all WISeR Model requirements, to minimizing provider abrasion, and to protecting Medicare beneficiaries, and welcomes continued collaboration with CMS and CGS throughout this initial rollout period.

Please let Innovaccer know if CMS requires additional information or adjustments to this Corrective Action Plan. Innovaccer looks forward to CMS's review and approval.

Sincerely,

(b)(6)

Innovaccer Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, Maryland 21244-1850

February 27, 2026

Zyter Inc.
2600 Tower Oaks Blvd, Suite 700
Rockville, MD 20852

Delivered via email to all active contacts for Zyter Inc. in the WISeR Participant Portal

Re: WISeR-00081 Zyter Inc. – Request for Information – Required Prior Authorization Activities and Determinations

Dear Zyter Inc.,

The Centers for Medicare & Medicaid Services (CMS) requires Zyter Inc. to respond to this Request for Information (RFI) for the Wasteful and Inappropriate Service Reduction (WISeR) Model regarding invalid submissions to the Electronic Submission of Medical Documentation (esMD) system, prior authorization determination communications missing a valid Unique Tracking Number (UTN), untimely determination letters and inconsistent timing in addressing prior authorizations. The aforementioned items are applicable to the below sections of the WISeR Participation Agreement:

- *Section 3.4(A, B) Required Prior Authorization Activities*
- *Section 3.6 (A, 3) WISeR Clinicians and WISeR Clinical Reviewers*
- *Section 3.7 (A, C) Customer Service*
- *Section 6.2 (A) Prior Authorization Process and Exemption Status*
- *Section 6.3 (B) Prior Authorization Determinations*

OBSERVATION

A series of emails received by a Medicare Administrative Contractor (MAC) and the esMD contractor disclosed that Zyter was submitting duplicate and invalid submissions in the esMD application, that submissions were missing a valid UTN, that Zyter is not issuing determination letters in a timely manner, and is addressing prior authorizations received through the Zyter portal on a more regular cadence than ones received from your assigned MAC. Issues submitting information through esMD were reported as recently as February 20, 2026, and Zyter disclosed that no prior authorization determination letters had been sent to provider/supplier or beneficiaries as of February 18, 2026. In addition, CMS received communications that indicate that Zyter may lack adequate processes for responding to and escalating provider/supplier concerns about prior authorization including peer-to-peer reviews in a timely manner.

Accordingly, CMS is concerned with Zyter's alignment with the following sections of the Participant Agreement that began January 1, 2026, the WISeR Model "Start Date":

- Section 3.4 (A): The WISeR Participant shall receive and control Prior Authorizations for Select Items and Services, as detailed in Table 1 of Appendix A of this Agreement, from WISeR Providers and WISeR Suppliers or from their corresponding MAC(s) in accordance with the provisions set forth in this Agreement and in the WISeR Participant Guide.

- Section 3.4 (B): The WISeR Participant shall use its Enhanced Technology to perform prior authorization functions for the Medicare program to support accurate and timely coverage determinations consistent with established Medicare Coverage Criteria for Beneficiaries.

- Section 3.6 (A)(3): The WISeR Participant must perform compliance and oversight activities to ensure its WISeR Clinicians and WISeR Clinical Reviewers are engaging in Medical Review activities that are accurate and appropriate and do not risk the health of any Beneficiary. Such compliance and oversight activities by the WISeR Participant may include without limitation, review and audits of data related to each WISeR Clinician's or WISeR Clinical Reviewer's:

  i. Timing and accuracy of determinations;
  ii. Denial rates;
  iii. Affirmation rates;
  iv. Resubmission rates; and
  v. Other necessary and appropriate data related to its Medical Review activities to ensure the accuracy and appropriateness of determinations.

- Section 3.7(C): The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.

- Section 6.3(B): Initial Prior Authorization.
  1. The WISeR Participant shall issue an Initial Prior Authorization Determination to the WISeR Provider or WISeR Supplier within 3 Days of the WISeR Participant's receipt of the initial Prior Authorization.
  2. The WISeR Participant shall ensure the Initial Prior Authorization Determination is delivered to the WISeR Provider or WISeR Supplier in the same manner in which it was submitted via postmark, fax, or electronic delivery.

REQUIREMENT TO RESPOND TO A REQUEST FOR INFORMATION BY CMS

As a result of the above observations, and pursuant to Section 13.2(A)(2) of the Agreement, CMS requires Zyter to provide additional information to CMS in the form and manner, and by the date specified below.

Please include the following information as part of your RFI response:

1. An acknowledgement of the observation and potential noncompliance described above;
2. The types of cases involved in the above potential noncompliance by affirmed/non-affirmed determination status and HCPCS/CPT code;
3. Detailed causes of the duplicate, invalid or missing UTNs;
4. Items Zyter needs or steps you will take to issue timely determinations
5. Detailed causes and steps you will take to complete prior authorizations received from your assigned MAC on a timely basis.
6. Information on the status of prior authorizations with determinations that have not been communicated to providers or beneficiaries.
7. Detailed steps you will take to improve the peer-to-peer review process.

Please provide clear and concise explanations and supplemental documentation, where necessary to fully address this RFI request. Note that CMS may require additional documentation once your RFI is reviewed.

Please acknowledge receipt of this letter by **5 p.m. ET on March 2, 2026.**

Please submit your RFI to CMS **by 5 p.m. ET on Friday, March 6, 2026**, through the WISeR Model mailbox at WISeR@cms.hhs.gov. Title your submission: WISeR-00081 Zyter – RFI.

CMS reserves the right to request additional information and may request that Zyter submit additional documentation as a condition of CMS' review of the RFI.

We appreciate your prompt attention to this matter. If you have any questions concerning the information and request above, please email WISeR@cms.hhs.gov.

Sincerely,

The WISeR Model Team

March 5, 2026

via Email

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, Maryland 21244-1850
WISeR@cms.hhs.gov

Re: ***WISeR-00081 Zyter – RFI***

Dear WISeR Model Team,

Zyter, Inc. (hereinafter "Zyter") respectfully submits the enclosed substantive responses to the Centers for Medicare & Medicaid Services (CMS) Request for Information (RFI) dated February 27, 2026, issued under the Wasteful and Inappropriate Service Reduction (WISeR) Model. This response addresses the specific areas of concern identified by CMS.

Zyter takes these matters seriously and has undertaken a thorough review of its internal processes, systems, and documentation practices to provide CMS with accurate and complete information. The attached substantive responses detail Zyter's findings, actions already implemented, and any additional improvement steps planned to ensure ongoing compliance with the WISeR Model requirements.

For ease of reference, the enclosed responses are organized to correspond directly to each area of concern raised in the RFI. Zyter remains committed to full transparency and cooperation with CMS throughout this process.

Should CMS require any additional information or clarification regarding the enclosed responses, please do not hesitate to contact me at 1(718)419-3082 or Sundar@zyter.com. We are prepared to discuss these matters further at CMS's convenience.

Sincerely,

Sundar Subramanian
Chief Executive Officer
Zyter, Inc.

Enclosure:

Substantive Responses to CMS RFI – WISeR Model

I. Acknowledgement of Observation

"Please include the following information as part of your RFI response: 1. An acknowledgement of the observation and potential noncompliance described above;"

Acknowledgment of observation:

Zyter acknowledges CMS's observations regarding prior authorizations, UTN processing and creation, as well as determination communication timeliness following pilot launch. These observations relate to technical and workflow issues identified during the early stabilization period following pilot launch. Zyter promptly investigated the underlying causes and implemented corrective measures, which are described below.

As of February 28, 2026, operational workflows are functioning in alignment with WISeR timing requirements. All determinations include valid UTN following the UTN generation process, and required communications are being issued in a timely manner. Ongoing operational monitoring and transaction-level validation controls are in place to ensure continued compliance and stability.

Immediately following go-live, Zyter experienced some technical and workflow challenges associated with the accelerated implementation timeframe and the compressed onboarding timeline under which Zyter entered the WISeR Model pilot, having joined the WISeR Model pilot approximately one month after the initial cohort. File transmission and UTN workflow handling items were identified through real-time operational monitoring during the initial hypercare period and addressed through targeted system configuration updates and workflow refinements, and system controls were strengthened.

Additionally, during stabilization, certain UTNs required downstream validation and reconciliation within the Noridian esMD processing workflow following successful transmission from Zyter. Zyter and Noridian coordinated daily to reconcile and finalize those transactions. Throughout this period, Zyter completed authorization determinations timely, and decision status remained visible to providers in real time through the Provider Portal.

Response to identified issues:

Zyter recognizes the importance of full compliance with all WISeR Participation Agreement requirements and takes the observations raised by CMS seriously. Zyter proactively brought these matters to the attention of CMMI WISeR Program leadership on February 4, 2026, as part of our commitment to transparency and collaborative program operations with CMS.

Zyter notes that the circumstances referenced occurred during the early pilot stabilization period when technical and workflow stabilization challenges were encountered due to the compressed implementation timeframe. These issues were identified through operational monitoring and addressed through targeted system and workflow refinements as described

above. Zyter appreciates the ongoing collaboration with CMS during the initial implementation phase and remains committed to supporting the successful execution of the WISeR Model.

II. Types of Cases Involved

"The types of cases involved in the above potential noncompliance by affirmed/non affirmed determination status and HCPCS/CPT code;"

The types of cases involved included both affirmed and non-affirmed determinations. However, the challenges Zyter experienced were technical in nature and did not affect the clinical review process or determination outcomes. They were also not tied to any specific HCPCS/CPT code but impacted the routine mix of WISeR prior authorization requests being processed during that period. These technical and workflow items were addressed during the stabilization period and resolved as of February 28, 2026.

III. Detailed Cause of Duplicate/Invalid/or Missing UTN's

"Detailed causes of the duplicate, invalid or missing UTNs;"

As of the date of this response, all prior authorization submissions requiring UTNs have been transmitted by Zyter, and corresponding submission packets have been provided to Noridian. Determination timeliness and provider visibility of disposition status were maintained throughout the pilot period.

The UTN-related issues observed during the early pilot stabilization period were attributable to the following technical factors:

1. During early integration with the esMD workflow, certain submissions required additional validation of provider address and PTAN information, which required elements for successful esMD processing. CMS released the updated PECOS API including PTAN data on February 16, 2026. Zyter implemented enhancements on February 18, 2026, to retrieve PTAN and provider address information using the PECOS API and NPI Registry lookup, closing this validation gap.
2. Submission data elements required alignment with esMD specifications, including handling of certain review code values and ZIP code data types. These items were addressed, and (b)(4) (b)(4) Enhancements were completed by February 20, 2026.
3. Identifier misalignment during downstream processing of metadata and decision files, resulting from the use of an inconsistent unique identifier within Noridian's processing workflow. Zyter and Noridian aligned standardized identifier mapping to ensure consistent use of a single unique ID across files. This alignment was completed by February 27, 2026.

All three technical and workflow items were resolved by February 28, 2026. Submission success rates increased following implementation of these enhancements, and standardized transaction monitoring has been implemented to monitor transaction performance and prevent similar issues going forward.

IV. Steps to Ensure Timely Determinations
"Items Zyter needs or steps you will take to issue timely determinations."

Authorizations are current within the established turnaround times for both standard and expedited requests. There are procedures in place to monitor and escalate the mitigation of aging requests at certain intervals based on the level of urgency, as well as ensuring that determinations are communicated accordingly. These procedures include the following:

- (b)(4)
- (b)(4) Real-time electronic visibility of determinations and supporting rationale within the Provider Portal to facilitate resubmissions and approval pathways. In addition to these procedures, we have maintained executive oversight review of determinations and timeliness to ensure identification of roadblocks and resolutions accordingly. Identified issues are prioritized, workflow changes are communicated if applicable, and resolution tracking is performed multiple times a day.

V. MAC-Received Prior Authorization Remediation
"Detailed causes and steps you will take to complete prior authorizations received from your assigned MAC on a timely basis."

As of March 1, 2026, Zyter is processing prior authorizations on the same day of receipt in most cases, including requests received through the assigned MAC, and within established WISeR turnaround time requirements regardless of intake channel.

During early pilot stabilization, turnaround time variability was driven by initial request volume normalization associated with Zyter's late addition to the pilot as operational workflows were being brought fully online. Authorization request volumes fluctuated temporarily as pilot activity stabilized. These conditions have since been stabilized. Zyter expanded clinical review capacity with its clinical delegate to establish a consistent processing baseline. Operational dashboards now monitor processing cadence across all intake pathways, and standing coordination meetings with the MAC remain in place to proactively manage operational items. Current

performance reflects steady-state operations, and quarterly reporting will capture pilot trends as workflows mature.

VI. Status of Uncommunicated Determinations
"Information on the status of prior authorizations with determinations that have not been communicated to providers or beneficiaries"

As of February 28, 2026, all prior authorization determinations with issued UTNs have been communicated to providers and, where applicable, beneficiaries through the appropriate submission channels. Communication workflows are automated, and determination letters are available in the Provider Portal.

Historically, certain letters were not released because a UTN had not yet been generated. A UTN must be issued before a formal determination letter can be sent. Once the technical issues affecting UTN generation were resolved, all impacted letters were issued.

VII. Peer-to-Peer Process Enhancements
"Detailed steps you will take to improve the peer-to-peer review process."

The following measures have already been implemented to ensure and maintain compliance while attempting to reduce provider abrasion within this pilot program.

-
- (b)(4)
- Escalation path is available when needed and can be requested via the call center agents. Following any request for escalated turnaround of a Peer to Peer, the call center team engages a Senior Program Leader at Zyter who will directly coordinate with the Clinical Director as needed for urgent requests.
- A tracking dashboard is used with quarterly audit reviews for timeliness.
- Zyter has made invitations to certain specific large providers to provide feedback on the P2P process to assist in identifying roadblocks and improvement opportunities.

With ongoing monitoring and provider engagement, we are not only meeting the standards of the program but exceeding them by having these mechanisms in place to identify concerns early and address them through the prioritization and resolution framework outlined above.

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00006

Requested by (b)(6) on 07/28/2025 12:29

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	CompliantRx, Inc
b. Doing Business As (DBA) Name(s)	CompliantRx, Inc
c. Street Address	10850 Wiles Road
d. City	Coral Springs
e. State	FL
f. Zip Code	33076
g. Tax Identification Number	920875056
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	CompliantRx Overview CompliantRx is a healthcare technology company purpose-built to help Medicare providers and suppliers navigate complex medical documentation and coverage rules. Our mission is simple: reduce administrative burden, prevent billing errors, and ensure that every claim meets Medicare's coverage criteria before it's submitted. Founded by veterans of the durable medical equipment industry, CompliantRx was built out of firsthand experience scaling supplier operations in a highly regulated and audit-prone environment. As we grew, we saw the increasing compliance burden on ethical suppliers and the persistent problem of fraudulent actors slipping through. We built CompliantRx to solve both challenges: empower compliant providers to stay audit-ready and successful, and make it harder for fraud, waste, and abuse to persist in Medicare. We serve DME companies, physician practices, and other Part B suppliers who deliver high-risk or heavily regulated products and services. Our technology enables these providers to understand and apply National and Local Coverage Determinations (NCDs and LCDs) in real time. What sets CompliantRx apart is our combination of AI-powered automation and human clinical oversight enabling scalable, high-accuracy compliance without replacing staff or sacrificing patient care. We operate on a "Compliance-as-a-Service" model that delivers three core functions: 1. Real-Time Policy Review:Our (b)(4) named after (b)(4) allows staff to ask plain-language questions about coverage criteria and receive instant, policy-backed answers grounded in real CMS guidelines. 2. Automated Medical Record Review: Our system compares uploaded clinical documentation against applicable coverage policies (e.g., LCD L33822 for CGMs) and generates easy-to-understand reports showing what's missing using visual flags and plain-English summaries. 3. (b)(4) (b)(4)

	(b)(4) (b)(4) We have no involvement in product sales or fulfillment and no financial stake in any claim outcome. Our sole focus is helping providers meet Medicare standards keeping good actors in good standing and supporting CMS's mission to protect the program from waste, abuse, and inappropriate care.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	7351 Wiles Road
Street Address	Suite 104
City	Coral Springs
State	Florida
Zip Code	33067

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00006_Ownership_CompliantRx_WISER_Ownership_Disclosure
Uploaded On	6/29/2025, 1:06 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address Name Title/Position Address Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address Name Title/Position	(b)(6)
Address	7351 Wiles Road Suite 104, Coral Springs, FL 33067
Business Phone Number	(b)(6)

Contact Type	Tertiary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00006_Licensure_Compliant RX Inc. - Certificate of Incorporation (Certified) (1)
Uploaded On	6/29/2025, 1:13 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.	
N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	CompliantRx maintains HIPAA-compliant Business Associate Agreements (BAAs) with all of its covered entity partners, including durable medical equipment (DME) suppliers, healthcare providers, and health systems that utilize our platform for medical record review, documentation analysis, and coverage determination support. We currently have active BAAs in place with more than a dozen national and regional DME companies that serve Medicare and Medicare Advantage beneficiaries. These organizations rely on CompliantRx to analyze protected health information (PHI) to validate compliance with CMS LCD/NCD requirements and payer-specific coverage criteria prior to claim submission or prior authorization. Representative covered entity partners include: (b)(4) (b)(4) (b)(4) This list is not exhaustive. CompliantRx requires a fully executed BAA prior to onboarding any HIPAA-covered entity, and all BAAs are reviewed, tracked, and maintained in accordance with our internal HIPAA compliance and data governance policies.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	CompliantRx was founded by the executive team behind Quest Health Solutions, a nationally accredited DME supplier that serves tens of thousands of Medicare beneficiaries across all 50 states. Our firsthand experience navigating the operational and compliance complexities of medical record review, prior authorization, and documentation retrieval across hundreds of payors—particularly Medicare Advantage (MA) plans—led us to build CompliantRx as a purpose-built AI platform to solve those problems at scale. We didn't start this company as a tech solution looking for a use case. We built it to stop the real-world administrative waste and clinical friction we encountered while processing tens of thousands of claims across diverse plan types and jurisdictions. We've seen the human and financial cost of inappropriate utilization—and the cost of documentation errors that could have been prevented. That's the root of CompliantRx. Experience Working with Medicare Advantage Plans Through Quest, our team has directly worked with over 150 Medicare Advantage plans, including but not limited to: (b)(4) (b)(4) Our payer operations team manages these contracts and processes claims daily. On average, (b)(4) encompassing eligibility checks, benefit coverage validation, and documentation compliance for product categories like CGMs, insulin pumps, CPAPs, and urological supplies. Our work spans the full prior authorization lifecycle: Eligibility and benefit determination via clearinghouse integrations (b)(4) Automated documentation collection and review for adherence to both CMS LCD/NCD policy and MA plan-specific requirements Real-time alerts to clinical and billing staff when documentation is incomplete or fails to support medical necessity Electronic prior auth submission through payer portals and integrations Appeals preparation and coordination with providers in the event of claim denial Audit response support for both internal QA and external CMS/MAC-level audits Platform Capabilities and Technical Infrastructure We've translated this real-world experience into a platform that blends healthcare-specific AI with practical workflow tools. (b)(4) (b)(4) (b)(4) Impact on Fraud, Waste, and Abuse CompliantRx was explicitly designed to reduce inappropriate utilization—not just by automating documentation checks, but by surfacing behavioral patterns that often go unnoticed. (b)(4) (b)(4) (b)(4) Readiness to Support WISeR We believe our experience and platform uniquely position us to support the WISeR model. We've already operationalized many of the systems CMS hopes to test: intelligent, policy-based review of documentation before claims are submitted; AI-enhanced decision support with human-in-the-loop oversight; and reporting that enables systemic risk reduction. We understand the delicate balance between reducing unnecessary utilization and protecting timely access to medically necessary services. Our platform is designed to support that balance: empowering clinicians and billing teams, not replacing them, while ensuring that care meets both policy and patient standards. In short, CompliantRx is already doing the work WISeR aims to evaluate—at scale, across the country, in the trenches. We would be honored to partner with CMS to take that impact even further.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National	2a) CompliantRx was developed by the team behind Quest Health Solutions, a national DME supplier that has processed tens of millions of dollars in Medicare and Medicare Advantage claims across all four MAC jurisdictions. The platform was purpose-built to validate documentation against healthcare-specific coverage rules, with a particular focus on Local Coverage Determinations (LCDs), National Coverage Determinations (NCDs), and Medicare Advantage plan-specific policies. Our team has extensive, direct experience interfacing with Medicare Administrative Contractors (MACs), including CGS, Noridian, Palmetto, and NGS. Through Quest and our DME partners, we've handled thousands of orders governed by LCDs such as: LCD L33822 – Continuous Glucose Monitors (CGM)

Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	LCD L33718 – Positive Airway Pressure (PAP) Devices LCD L33800 – Insulin Infusion Pumps LCDs governing urological, ostomy, and other high-scrutiny DME categories We know our approach works because it has been tested. Quest Health Solutions has undergone multiple Targeted Probe and Educate (TPE) audits across Jurisdictions A, B, and D—and in each instance, passed the first round with zero deficiencies. Medicare auditors have consistently praised the quality and completeness of our documentation, which is directly enabled by the CompliantRx platform. These results are a testament to our ability to apply LCD and payer policy criteria operationally, at scale. (b)(4) (b)(4) (b)(4) In summary, CompliantRx has been built from real operational experience applying CMS policy in the field. The platform enables scalable, defensible, and compliant documentation workflows that align directly with MAC expectations. Our proven track record with TPE audits and our success in building documentation pipelines that withstand pre-payment review make us a strong candidate for participation in the WISeR program. 2c)CompliantRx maintains a robust data privacy and security program aligned with the HIPAA Privacy, Security, and Breach Notification Rules, as well as applicable federal and state data protection laws. Our policies, infrastructure, and access controls are designed to safeguard protected health information (PHI) at every stage of data flow, from intake to review to claims submission. (b)(4) (b)(4) (b)(4) Identity and access management is enforced via Okta, enabling secure single sign-on (SSO), multi-factor authentication (MFA), and granular, role-based access permissions. (b)(4) (b)(4) (b)(6) All system access is logged and reviewed. Access Controls: All users are subject to least-privilege access policies with MFA required for all privileged accounts. Okta governs identity lifecycle management to ensure that employee access aligns with current roles and responsibilities. Monitoring and Audit Logs: All PHI access and system activity are logged and retained for auditability. Our logs are reviewed regularly to identify anomalous activity or unauthorized access attempts. Employee Training: All employees undergo HIPAA and cybersecurity training during onboarding and annually thereafter. Additional training is provided for engineering and support staff handling PHI. BAAs and Vendor Oversight: We execute Business Associate Agreements (BAAs) with all relevant vendors, including AWS, and any partners who process PHI or support compliance functions. Incident Response Plan: We maintain a formal, multi-step incident response plan, which includes: Immediate containment and root-cause investigation Risk analysis to determine whether PHI was accessed or exfiltrated Notification of affected parties and regulators per HIPAA Breach Notification Rule Remediation and preventive measures, including system patching and user re-education Third-Party Security Reviews: Our security and compliance program is reviewed through external audits and gap assessments conducted via (b)(4) to ensure continuous improvement and preparedness for enterprise and federal partnerships. We take data protection seriously not only to meet regulatory requirements, but also to earn and maintain the trust of the providers, suppliers, and patients who rely on our platform every day.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	CompliantRx was built by a team with deep, hands-on experience in clinical documentation review, medical necessity validation, and coverage determinations at scale. Our leadership team also operates Quest Health Solutions, a national DME supplier that handles tens of thousands of claims per month, many of which require detailed chart review, prior authorization, and occasional peer-to-peer engagement with Medicare Advantage plans and commercial payers. Current Clinical Review Capabilities Our current clinical review process leverages our operational experience combined with AI-powered technology to streamline documentation analysis. (b)(4) (b)(4) Through Quest Health Solutions we have developed expertise in: • Pre-claim medical necessity reviews for all documentation associated with products governed by CMS LCDs (e.g., CGMs, PAP devices, insulin pumps) • In-line quality assurance to verify that physician assessments, HPI, and treatment plans clearly document qualifying conditions for coverage • Preparation of records and clinical summaries for peer-to-peer or appeals processes when denials are issued based on medical necessity • Internal review protocols where our MAs identify documentation gaps and coordinate with providers for additional information or clarification Technology-Enhanced Review Process CompliantRx has operationalized this process through its AI-powered platform, which (b)(4) (b)(4) (b)(4) Our workflow supports: • Chart abstraction and documentation summarization conducted by our MA team for clinical rebuttals • Review of denial rationales to determine clinical and technical root causes • Coordination with ordering providers to supply additional documentation or complete addenda to support coverage • Structured tracking of outcomes by payer, reason, and product category—feeding back into our AI and compliance logic Staffing Structure for WiseR Implementation Building on our current foundation of Medical Assistants conducting documentation reviews, CompliantRx is prepared to expand our clinical team to meet the enhanced requirements of the WiseR model. (b)(4) (b)(4) (b)(4) Scalable Clinical Infrastructure Our approach combines the operational efficiency we've developed through Quest Health Solutions—including our current MA-supported review process—with the enhanced clinical expertise required for sound coverage determinations under WiseR. This hybrid model allows us to: • Handle high-volume routine reviews through our AI-enhanced platform with MA oversight • Escalate complex cases to qualified clinical professionals • Maintain consistent application of coverage criteria across all reviews • Provide rapid turnaround while ensuring thorough clinical evaluation This structure positions CompliantRx to excel in the WiseR model by ensuring that coverage determinations are both clinically sound and administratively efficient. Our technology-first approach, combined with our existing MA team and planned clinical oversight expansion, prevents inappropriate denials while identifying inappropriate utilization before claims submission. Our experience managing thousands of medical records monthly with our current MA-supported infrastructure, combined with our commitment to establishing enhanced clinical staffing, creates a foundation for delivering the clinical review capabilities that WiseR requires while maintaining the efficiency and scalability that CMS seeks.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall	CompliantRx was designed with an open, modular architecture that supports API-based integration with multiple software platforms across the healthcare ecosystem, including Electronic Health Records (EHRs), revenue cycle systems, and patient intake tools. While we do not currently maintain live integrations with major EHRs, our platform is fully capable of supporting EHR interoperability and prior authorization workflows via standardized protocols and modern API infrastructure. (b)(4) (b)(4) (b)(4) 4b) Future Plans & CMS Interoperability Support: CompliantRx is built to align with CMS's broader vision under the Interoperability and Prior Authorization Final Rule (CMS-0057-F). Our current roadmap includes structured enhancements that will: Support real-time, standards-based data

payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	exchange with EHR (b)(4) (b)(4) (b)(4) We see interoperability as essential not only to prior authorization efficiency, but also to improving clinical decision-making and reducing documentation friction across the healthcare ecosystem. CompliantRx is well-positioned to support CMS's goals of increased data sharing, greater transparency in coverage requirements, and a reduction in provider and patient burden associated with the prior authorization process. As we expand provider adoption through our upcoming physician portal, EHR integration will become a critical focus area, and we have the technical foundation to deliver on that vision.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	CompliantRx is built on a foundation of deep experience applying artificial intelligence (AI) and machine learning (ML) to real-world compliance, documentation, and healthcare operations. Our leadership and technical teams have been building AI-driven tools for regulated, documentation-heavy environments for nearly a decade, (b)(4) (b)(4) and achieving demonstrable improvements in documentation accuracy and claims success rates. The CompliantRx platform is the direct result of this experience—engineered from the ground up to support medical record review, coverage determination, and policy alignment with Medicare and Medicare Advantage plans. Our AI models have been trained on extensive datasets including over (b)(4) claims with known outcomes, complete LCD libraries from all four MAC jurisdictions, historical TPE audit records, and documented denial patterns with successful appeals. Our (b)(4) (b)(4) (b)(4) Our knowledge base includes: • (b)(4) (b)(4) (b)(4) This keeps the system grounded and prevents hallucinations or unsupported logic. Our AI-driven reviews are validated through: • (b)(4) (b)(4) (b)(4) We are building toward WISeR requirements including: • (b)(4) (b)(4) (b)(4) We understand the importance of trust, transparency, and restraint when deploying AI in healthcare. Poorly managed automation can result in over-denials, patient access delays, and erosion of provider confidence. CompliantRx was designed to mitigate these risks through a human-centered design philosophy with specific safeguards: (b)(4) (b)(4) (b)(4) Our system errs on the side of caution to protect both providers and patients. Clear AI vs. human separation: All (b)(4) preserving transparency for audits and appeals. Bias minimization and monitoring: We (b)(4) across provider type, diagnosis, and geography, and avoid

	introducing coverage logic that disproportionately affects specific populations. Our system (b)(4) Continuous validation: We perform A/B testing of AI recommendations against human reviewers and conduct quarterly model retraining based on new policy updates and outcome data. CompliantRx is designed to support human decision-making not replace it. All AI-generated insights are reviewed and confirmed before downstream action is taken. We believe AI's role in prior authorization and coverage determination should be to illuminate policy logic, reduce administrative burden, and help staff work more confidently not to act as gatekeeper or adjudicator. WISeR Implementation and Unique Value Proposition CompliantRx is uniquely positioned to contribute to WISeR because our AI model is trained on what really matters; coverage rules, clinical evidence, and operational experience and it's deployed in a way that reflects the complexity and seriousness of healthcare decisions. Our platform can be rapidly deployed across MAC jurisdictions with jurisdiction-specific policy customization within (b)(4) (b)(4) We see WISeR as a natural extension of what we already do: applying technology to solve compliance and documentation challenges at scale, while preserving ethical, explainable decision-making. Our combination of proven operational experience through Quest Health Solutions, sophisticated AI technology under enterprise-grade security, and unwavering commitment to human oversight creates the ideal foundation for supporting CMS's goals of reducing inappropriate utilization while maintaining appropriate access to care. Our approach ensures that technology enhances rather than replaces clinical judgment, that every decision is transparent and auditable, and that the system continuously learns and improves while maintaining the highest standards of patient protection and provider support.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Part A: Quality Assurance for Utilization Management and Claims Processes** CompliantRx operates under a comprehensive ethics and quality framework designed to ensure fair, transparent, and patient-centered utilization management decisions. Our approach is built on the principle that technology should enhance, never replace, human judgment in healthcare decisions, and that every stakeholder deserves clear, consistent, and defensible processes. Utilization Management Decision Making: Our utilization management approach centers on evidence-based, policy-driven decision support rather than autonomous determinations. Every recommendation generated by our AI platform includes: • Clear policy citations from applicable LCDs, NCDs, or plan-specific coverage criteria • Confidence scoring with automatic escalation to human review for borderline cases • Detailed documentation of clinical evidence supporting or contradicting coverage • Transparent reasoning that can be easily understood by providers and patients We maintain strict separation between AI-generated insights and final human decisions. Our Medical Assistants and clinical staff review all flagged cases. Complex determinations are escalated. No coverage determination is made without human oversight and approval. Quality Assurance Framework: • Inter-rater reliability testing: Regular calibration exercises ensure consistent application of coverage criteria across all reviewers • Continuous training: Monthly training sessions on policy updates, ethical decision-making, and patient advocacy principles • Performance metrics: We track turnaround times, accuracy rates, and stakeholder satisfaction to ensure quality service delivery Complaints and Grievances Process: CompliantRx maintains a formal complaints and grievances process that includes: • Rapid response protocol: All complaints acknowledged within 24 hours, with resolution target of 5 business days • Appeals support: We provide detailed documentation and clinical rationale to support provider appeals of adverse determinations • Root cause analysis: Every complaint triggers a review of our processes to identify and address systemic issues • Stakeholder feedback integration: Regular surveys of providers, patients, and payers to identify improvement opportunities Claims Billing and Dispute Resolution: Our approach to claims billing emphasizes prevention over correction: • Pre-submission validation: Claims are reviewed for compliance before submission, reducing downstream disputes • Clear documentation standards: We provide detailed guidance on documentation requirements to prevent denials • Dispute resolution support: When disputes arise, we provide

	comprehensive clinical and policy documentation to support resolution Part B: State and Federal Regulatory Compliance CompliantRx maintains rigorous compliance with all applicable state and federal regulations through a multi-layered approach that includes proactive monitoring, regular training, and continuous process improvement. **HIPAA Compliance:** • Comprehensive BAA framework: Business Associate Agreements with all technology partners, including OpenAI • Data encryption: All PHI encrypted in transit and at rest using AES-256 encryption • Access controls: Role-based access with multi-factor authentication and regular access reviews • Audit logging: Complete audit trails of all PHI access and system interactions • Incident response: Formal breach notification and response procedures meeting federal requirements • Regular risk assessments: Annual HIPAA risk assessments with third-party validation Medicare Program Integrity: • Anti-fraud protocols: Systematic monitoring for unusual patterns that might indicate fraud, waste, or abuse • Compliance training: Regular training on Medicare program integrity requirements for all staff • Documentation standards: Adherence to CMS documentation requirements and medical necessity standards • Audit readiness: Comprehensive documentation and process controls to support regulatory audits • Whistleblower protections: Clear policies protecting employees who report compliance concerns State Regulatory Compliance: • State-specific privacy laws: Adherence to state privacy regulations that may exceed federal requirements • Professional licensing: Ensuring all clinical staff maintain appropriate state licenses and certifications • Regulatory monitoring: Continuous monitoring of state regulatory changes affecting our operations Quality and Safety Standards: • SOC 2 Type II certification: Annual third-party audits of our security, availability, and confidentiality controls • Clinical quality standards: Adherence to evidence-based clinical guidelines and professional standards • Continuous improvement: Regular internal audits and process reviews to identify enhancement opportunities Governance and Oversight: • Compliance committee: Regular meetings of senior leadership to review compliance metrics and address issues • External oversight: Independent compliance officer with direct reporting to executive leadership • Documentation and reporting: Comprehensive documentation of all compliance activities and regular reporting to stakeholders Ethics Framework: Our ethical approach is guided by core principles: • Patient-first orientation: All decisions prioritize patient welfare and access to appropriate care • Transparency: Clear communication about our processes, limitations, and decision-making criteria • Fairness: Consistent application of standards without bias based on provider type, geography, or patient demographics • Accountability: Clear responsibility chains and regular performance reviews • Continuous learning: Commitment to improving our processes based on outcomes and stakeholder feedback CompliantRx recognizes that participation in WISeR requires the highest standards of ethical conduct and regulatory compliance. Our comprehensive framework ensures that we can meet these requirements while delivering the innovative technology solutions that CMS seeks. We view compliance not as a burden, but as a foundation for building trust with all stakeholders and ensuring the long-term success of the program.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	CompliantRx projects substantial and sustainable savings through enhanced prior authorization review of the specialized services included in the WiseR model. Over the (b)(4) (b)(4) as our AI models optimize and provider education reduces documentation gaps. The WiseR model targets high-cost, specialized procedures including neuromodulation devices (deep brain stimulators, vagus nerve stimulators, sacral nerve stimulation), spinal interventions (vertebral augmentation, cervical fusion), pain management procedures (epidural steroid injections), and select orthopedic interventions (knee arthroscopy for osteoarthritis). While these represent lower-volume services compared to traditional DME categories, each procedure carries significant per-unit costs ranging from (b)(4) (b)(4) making documentation accuracy and policy compliance critical for appropriate utilization. Our projections are grounded in systematic analysis of documentation patterns and policy compliance gaps. Based on our operational experience and review of Medicare claims data, we identify documentation deficiencies or policy compliance issues in approximately (b)(4) in these specialized service categories. Through our AI-powered clinical review process, we determine that (b)(4) require additional documentation, alternative treatment approaches, or do not meet coverage criteria as currently documented. CMS and OIG have specifically flagged many of these services as high-risk due to inconsistent documentation, insufficient conservative treatment trials, or absence of clearly indicated medical necessity. Our real-time review engine systematically identifies these issues before procedures are performed or claims are submitted, including lack of documented conservative management or failed prior therapy, repeat procedures outside established coverage frequency limits, missing required physician documentation for bioengineered skin substitutes, inappropriate use of neurostimulation devices without adequate trial periods, and insufficient medical necessity documentation for spinal interventions. Our progressive savings trajectory reflects continuous improvement: (b)(4) (b)(4) CompliantRx delivers comprehensive value beyond direct cost savings through streamlined prior authorization processing (reducing average review time (b)(4) , improved provider satisfaction through clear documentation

	guidance and real-time feedback, enhanced beneficiary protection through systematic identification of potentially inappropriate procedures, and reduced administrative burden on MAC resources through more efficient review processes. These estimates are validated against similar technology-enhanced prior authorization programs in Medicare Advantage plans, where AI-powered review of comparable high-cost services has demonstrated (b)(4) sustained reductions in inappropriate utilization. Our platform's machine learning capabilities ensure continuous improvement, with quarterly model retraining based on WiseR-specific outcomes data and evolving policy requirements, ensuring sustainable savings through improved documentation integrity and policy compliance while maintaining appropriate access to medically necessary care.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	CompliantRx is prepared to meet all CMS privacy and security requirements, including HIPAA, FISMA, and FedRAMP, to interface with MACs and securely manage Medicare beneficiary data. Our implementation plan outlines a strategic, phased approach for readiness with full deployment targeted for January 1, 2026, contingent on CMS award timing and leveraging our existing operational foundation. Phase 1: Immediate Compliance Alignment (Months 1-2 Post-Award) CompliantRx will immediately migrate to AWS GovCloud, a FedRAMP-certified cloud hosting environment, to align infrastructure with federal security standards. We will complete our SOC 2 Type II audit already underway with expected completion within 90 days. Simultaneously, we will initiate engagement with our FedRAMP advisory partner and begin drafting our System Security Plan (SSP) while establishing our internal privacy compliance team and project management structure. Business Associate Agreements with CMS and all four participating MACs will be executed immediately upon award notification. Phase 2: Integration and Compliance Foundation (Months 3-5) We will conduct detailed gap analysis against CMS ARS and FISMA controls while engaging MAC technical teams to accelerate integration timelines and identify jurisdiction-specific requirements. Our team will begin secure API development and data exchange workflows using (b)(4) tandards, implementing comprehensive security protocols including multi-factor authentication, audit logging, and data encryption (AES-256 at rest, TLS 1.2+ in transit). Clinical staff hiring and WiseR-specific training programs will commence during this phase to ensure adequate expertise in neurostimulation, spinal procedures, and pain management specialties. Phase 3: Technical Readiness and Pilot Testing (Months 6-9) CompliantRx will develop jurisdiction-specific integrations with each MAC's technical infrastructure while conducting comprehensive internal penetration testing, compliance validation, and inter-rater reliability checks for clinical reviewers. We will launch limited pilot testing with select providers in one MAC jurisdiction to validate end-to-end workflows and real-time clinical documentation review processes. This phase includes extensive user acceptance testing with MAC staff, provider feedback sessions, and refinement of clinical review protocols to ensure seamless operations at scale. Phase 4: Certification and Go-Live Readiness (Months 10-12) Final system deployment across all four MAC jurisdictions will occur with comprehensive monitoring and support capabilities. Our completed SOC 2 Type II certification will be submitted for CMS review alongside final FedRAMP documentation to our CMS-designated 3PAO. We will validate system performance across all MAC jurisdictions, finalize CMS reporting dashboards, and launch comprehensive provider education programs. Our 24/7 monitoring, security operations, and helpdesk infrastructure will be fully operational before program launch. Critical Security and Privacy Safeguards CompliantRx maintains hosting on FedRAMP-certified AWS GovCloud environment with SOC 2 Type II certification completion within three months of award. Our comprehensive HIPAA-compliant policies include MFA enforcement, complete access logging, and provider audit trails managed by our dedicated compliance officer and technical team aligned to CMS IS2P2 and ARS controls. While CompliantRx does not yet hold full FedRAMP certification, our AWS GovCloud infrastructure and existing security controls position us for conditional authorization to begin operations while pursuing full certification. Risk Mitigation and Contingency Planning Our implementation plan includes comprehensive contingency protocols for technical issues, staffing challenges, and regulatory changes. We have established backup systems, redundant infrastructure, and emergency response procedures to ensure uninterrupted service delivery. Given the compressed timeline between potential award announcement and January 1, 2026 program launch, we have pre-positioned technical resources and established vendor relationships to accelerate deployment regardless of award timing. Operational Readiness Foundation CompliantRx's proven track record demonstrates our ability to navigate complex regulatory environments and maintain compliance with Medicare requirements. Our existing operational experience with TPE audits, MAC interactions, and Medicare documentation standards, combined with our AI-powered platform already processing thousands of Medicare records monthly, provides an unparalleled foundation for immediate WiseR implementation. We are prepared to leverage this operational experience to deliver seamless program launch and ongoing excellence in service delivery while maintaining appropriate access to medically necessary care and supporting CMS's program integrity goals.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	CompliantRx, Inc
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00018

Requested by (b)(6) on 07/28/2025 12:30

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Cohere Health, Inc.
b. Doing Business As (DBA) Name(s)	N/A
c. Street Address	226 Causeway Street, Suite 403
d. City	Boston
e. State	MA
f. Zip Code	02114
g. Tax Identification Number	842393515
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Cohere is a clinical intelligence platform company dedicated to transforming the PA process for health plans, providers, and patients. Launched in 2019, our goal is to improve patient care and health outcomes by addressing PA's significant financial, administrative, and clinical challenges. By reimagining the traditional, transactional approach to UM, our solution fosters greater collaboration, driving improved quality, better outcomes, and reduced costs. As the largest digital PA company by auth volume, we serve 660K+ providers and more than 13M members nationwide (including 6M MA members), managing $10.3B in total medical expense, and driving over $600M in annual savings to our MA clients. Cohere's solutions combine our technology platform and expert clinical services to drive better results in PA. The Cohere Unify™ platform uses advanced, clinically trained AI/ML to center PA decisions on optimal patient care across all clinical specialties, dramatically improving efficiency and reducing inappropriate use. Our innovative technology is paired with clinical reviews, peer-to-peers, and other delegated functions (e.g., letters) as part of our Cohere Complete™ services offering, which we would leverage in WISeR. We are a physician-led organization with a deep clinical bench and extensive technology expertise, including: 70+ board-certified physicians across diverse specialties, with significant clinical practice experience, nearly two-thirds still practicing. Expertise demonstrated through same-specialty peer-to-peer reviews. Broader clinical team includes highly qualified RNs, LPNs, and clinical program leaders 230+ AI and technology experts, including over 15 PhDs and 70 advanced degrees, many of whom have published in their fields Leadership team that brings a distinctive blend of executive experience across healthcare technology, clinical practice, data science, and operations Cohere operates at scale, serving all lines of business (MA, Managed Medicaid, commercial) across all 50 states. We began our journey in transforming PA with Humana, the nation's largest and most

	innovative MA health plan. Today, our growing list of valued clients includes (MA denoted*): (b)(4) (b)(4) (b)(4) and several other MA plans in contracting. (b)(4) (b)(4) Efficiency Processing 12M+ PA requests annually Ingested 43M clinical documents and 5B claims. Managing 4,000 codified policies, including over 450 NCD/LCDs Interoperability & Digital Adoption HIPAA compliant, HITRUST certified, NCQA/URAC accredited FHIR-enabled EMR integrations at 300+ facilities 96% digital adoption
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	Cohere Health, Inc.
Street Address	226 Causeway St., Suite 403
City	Boston
State	Massachusetts
Zip Code	02114

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00018_Ownership_Cohere Health Ownership Interest
Uploaded On	7/24/2025, 12:47 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address Name Title/Position	(b)(6)
Address	226 Causeway St., Suite 403, Boston, MA 02114
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)

Name Title/Position	(b)(6)
Address	226 Causeway St., Suite 403, Boston, MA 02114
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00018_Licensure_Cohere Health Certificate of Incorporation
Uploaded On	7/24/2025, 12:52 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	In connection with providing our services to our clients, who are healthcare payer plans, we access and store Protected Health Information of their member patients. As a result, we have entered into Business Associate Agreements with each of our customers: - (b)(4) (b)(4)

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Cohere Health is a clinical intelligence platform company dedicated to transforming the prior authorization (PA) process for health plans, providers, and patients across all clinical specialties. Launched in 2019, our goal is to improve patient care and health outcomes by addressing the significant financial, administrative, and clinical challenges of PA. Cohere pioneered the responsible use of AI, ML, NLP, and generative AI. Cohere's models are trained in close partnership with clinicians before production and receive oversight from clinician leaders throughout their lifecycle. We have tested and optimized best practices for intelligent PA that truly have the potential to transform the system. We would be thrilled to bring this innovation to the WISeR Model. Cohere brings unparalleled expertise in managing UM functions for health plans, serving as both a cutting-edge technology provider and a trusted delegated services partner, with a robust infrastructure that supports prior

authorizations for over 13 million members nationwide, including more than 6 million MA members. Our platform empowers over 660,000 providers nationally to process more than 12 million digital authorizations annually, making us the country's largest AI-enabled prior authorization company. Cohere already serves providers and members in all MAC jurisdictions in scope for the WISeR Model. Therefore, if selected as a Participant, we are well-positioned to partner with CMMI in any of the four jurisdictions. We are uniquely equipped to serve this jurisdiction based on the high volume of providers we are already serving in JH Novitas and the deep relationships we have established in that jurisdiction. However, we will drive impact in any of the regions. We would like to offer our stack-ranked preferences: 1. JH Novitas (9,000 providers in OK & 50,000 providers in TX); 2. JF Noridian (16,000 providers in AZ & 16,000 providers in WA); 3. J15 CGS (41,000 providers in OH); 4. JL Novita (15,000 providers in NJ). We began our journey in transforming PA with Humana, the nation’s largest and most innovative MA health plan. Today, our growing list of valued clients includes (MA denoted *): (b)(4) (b)(4) and several other MA plans currently in contracting. The primary functions we perform for these clients via our Cohere Unify™ platform and delegated services include: Intake: Cohere’s Unify™platform can digitize prior authorization requests across all channels, including provider portals/EMR, fax, and phone, to reduce administrative burden, speed up decision-making, and improve the provider experience. Provider Portal: Our web-based portal experience is the primary channel for PA submission, with a 96% digital adoption rate. Providers can easily submit requests (via SSO from payer portals or EMR integration), leveraging pre-filled data and ML-driven information extraction, with real-time status updates. Integrated into the workflow, our real-time clinical "nudges" deliver dynamic, evidence-based care recommendations and administrative prompts that equip providers to make optimal decisions. These nudges not only recommend the most appropriate sites of service but can also alert providers to any missing documentation, ultimately leading to lasting changes in practice patterns and more efficient, higher-value care submissions. When criteria are met, auto-approvals are delivered instantly, with an average submission time of 3.5 minutes. Fax: Providers can also submit authorizations by faxing documents, which is especially important for providers in rural communities. Cohere’s ML and OCR technology extracts member and provider information, segments documents, and attaches supporting documentation to the correct request. The system can automatically fax notifications back to providers if additional information is needed or if no authorization is required. Administrative nudges and directions are sent to encourage digital submission methods. 95% of faxed clinical notes are automatically attached to authorizations. Phone: Providers can also call Cohere for authorization submissions or edits. Our onshore customer service team includes cross-trained representatives, 200+ non-clinical staff, and 170+ RN/LPNs. Decisioning: Our Unify™ Decisioning rules engine, built on modern cloud technology, uses AI, NLP, and ML to automate and optimize PA decisions in real time. The platform digitizes medical policies into configurable rules, and upon submission, it builds a comprehensive patient profile from multiple data sources (clinical notes, claims, etc.). This enables instant auto-approvals for 50-90% of requests, depending on specialty. We also provide administrative and clinical nudges pre-submission to ensure completeness and appropriateness, boosting real-time approvals. For auditability and traceability, our platform maintains comprehensive audit trails of all interactions and data events, ensuring accuracy and integrity. These logs are accessible and support detailed reporting for compliance and quality improvement. Review: Cases not auto-approved proceed to our Clinical Review process. Licensed RNs/LPNs first evaluate clinical information. If they cannot approve, the case escalates to a physician for a final decision. Cohere offers same-specialty peer-to-peer reviews, ensuring subspecialist expertise, which providers consistently appreciate for its collaborative nature, reduced burden, and positive impact on our 93% provider satisfaction scores. Analytics & Reporting: Cohere provides comprehensive, ongoing reporting on our UM program performance, aligning with clients on specific KPIs and targets from implementation. We offer real-time, daily, monthly, and quarterly reports across key categories, ensuring complete transparency and support for model performance measures. We would work with CMMI to ensure sufficient reporting of the Model Performance Measures, all of which are included in our standard reporting as outlined below: Process Quality: Tracks operational efficiency via metrics like volume processed, time to decision, auto-approval rates, denial rates, appeal rates, and SLA performance. Clinical/Quality Outcomes: Measures clinical impact through non-denial nudge acceptance rates, withdrawal rates, total impact rates, use of alternative services, clarity of explanation of request determination, and actuarially validated total cost of care savings, alongside appeal and complication rates. Beneficiary Experience: Focuses on patient impact, including average time to decision, auto-approval rates, appeal rates, faster care scheduling, and clarity of request determinations. Provider Experience: Monitors provider engagement and satisfaction using digital adoption rates, provider satisfaction scores, auto-approval/denial rates, and authorization completion times. Post-Payment Reconciliation: Cohere offers claims-to-authorization intelligence as part of our post-payment reconciliation services. This solution leverages advanced analytics to reduce mismatches, payment delays, and administrative costs. Key features include an advanced match engine that analyzes standard and context-specific data fields, integration of UM data to prevent payment delays, and the ability to re-process previously submitted clinical information to determine the appropriateness of claims that do not match 1:1 with the original authorization. Cohere can also manage retrospective authorizations when existing authorization information is

	insufficient to justify payment. CMS Audit Support: Cohere maintains its audit readiness through a robust internal audit program, including simulated regulator audits. We routinely conduct mock CMS ODAG audits, source system data validation (SSV) checks, and clinical decision-making audits. Cohere's platform provides detailed audit trails and reporting to support CMS audit and reporting requirements. We provide comprehensive audit services for our delegated clients, including pre-audit readiness, client and external audits support, and robust internal auditing and monitoring programs. Our compliance team manages all aspects of the audit process, from verifying audit details to preparing and reviewing data submissions, and collaborates closely with our clients' audit teams to meet all requirements. Member and Provider Letters: Cohere's solution includes robust member and physician communications capabilities, offering customized letters and voice notifications. Our platform generates and mails letters on behalf of clients or integrates with their mailing systems. Most verbal and letter notifications are fully automated, requiring no manual intervention. We support complete customization of letter templates to meet unique jurisdictional and letter type requirements across all 50 states, with extensive experience in Medicare letter requirements. We manage, produce, and routinely audit these templates to ensure accurate and compliant execution. Provider Support: Providers can submit authorization requests 24/7 via our portal, including expedited requests, and receive real-time status updates. After hours, voicemails and emails receive a response within one business day. The portal also offers in-app support and a dashboard for tracking authorizations. For self-service, a 24/7 Learning Center provides guides and training. Providers can contact our support teams during business hours by phone or email for additional assistance. Our onshore, cross-trained staff aim for first-call resolution for all inquiries. Cohere has delivered strong outcomes to our clients, including: $600M annual savings to MA clients 93% provider satisfaction 70% faster access to patient care 96% digital adoption 50-90% auto approval rates (depending on clinical category) 47% administrative expense savings 15-20% incremental reduction in med expense
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Cohere Health has extensive experience working with healthcare-specific data. Our platform manages prior authorizations for over 13 million members and growing, including more than 6 million Medicare Advantage members across all 50 states. It supports all lines of business, including Medicare Advantage, Managed Medicaid, commercial, and self-insured groups. We have implemented delegated UM services, including clinical review services, and are both NCQA and URAC-accredited for all lines of business, ensuring compliance with CMS requirements. Our solution uses NCDs and LCDs to execute business rules. Our Unify™ Decisioning rules engine allows us to automate any policy, including NCDs/LCDs, and custom policies, to achieve high auto-authorization rates and ensure compliance with coverage guidelines. We codify health plan medical policies by decomposing each policy into a set of indications from which rules are built to allow real-time decisioning when clinical information is present or pend for manual review. Our rules engine is highly configurable to manage different policies and prior authorization requirements across and within lines of business. Cohere has over 450 NCDs and LCDs codified in our platform today, and another 80 launching this quarter (Q3 2025). These policies cover key clinical areas across all specialties such as anesthesiology, PM&R, cardiology, orthopedics, pain, neurology/neurosurgery, spine surgery, therapy, sleep, gastroenterology, diagnostic imaging, general surgery, vascular surgery, etc. Cohere has a dedicated policy management team that monitors CMS for LCD/NCD updates every week, and completes updates to LCD/NCDs within ten business days of notification. Importantly, we leverage the expertise of our in-house team of clinicians to determine how to configure CMS policies in our platform best and write rules for real-time clinical decisioning. Cohere Health also has robust experience ingesting and utilizing administrative claims data from CMS and other payers/plans. We build 360-degree member profiles using historical claims data, enabling claims lookback capabilities to pull relevant member context (e.g., diagnosis codes, procedure codes) and reduce manual data entry for providers. Our platform uses medical and pharmacy data feeds to support automated decisioning, treatment history, and previous diagnoses. We regularly perform claims analyses to drive the design of UM programs, uncover opportunities to improve the quality and affordability of care, and refine our rules and approval criteria. We request a one-time extract of three years of historical medical claims during implementation, followed by monthly updates. While we do not provide delegated claims processing, our claims-to-auth intelligence solution leverages advanced analytics to reduce mismatches, payment delays, and administrative costs and integrates UM data to support claims reconciliation. For delegated clients, we can also manage retrospective authorizations when existing authorization information is insufficient to justify payment. a. (b)(4) (b)(4) (b)(4) With our track record of successful projects and highly integrated implementations, we're incredibly confident in our ability to seamlessly integrate with the MACs from a technology and working relationship standpoint. As a clinical intelligence platform, our software is underpinned by its ability to interface with software and services across the healthcare domain. We maintain this capability through the rigorous build of standards-based APIs, deep integration with EMR software, and broad support for digitizing first—and third-party clinical policies and

	guidelines. Not only is Cohere capable of integrating with the MACs in support of the WISeR model, but we are also in the best position to do so. b. Cohere Health is fully HIPAA compliant and is certified against the HITRUST framework, which, due to being built on NIST SP 800-53, has many commonalities with the FedRAMP standard. We are also NCQA and URAC-accredited. Regarding FedRAMP adherence specifically, we are engaged with our partners at Amazon Web Services and NCC Group (3PAO), assessing our posture against the FedRAMP security framework. We are ready and willing to work with CMS to prove our rigorous commitment to security and compliance as the detailed requirements for the WISeR model are made available. c. Cohere Health is fully HIPAA compliant, HITRUST certified, and NCQA and URAC accredited. We monitor compliance with HIPAA and other privacy and security laws through a comprehensive Compliance Program based on the OIG Seven Elements of Compliance, which has been reviewed and approved by both NCQA and URAC. We have a documented Incident Response Plan and Breach Investigation and Notification Policy in case of a data incident or breach. These outline critical processes, roles, responsibilities, and escalation steps to limit the scope and impact of a security incident. The plan is comprehensive, reviewed and updated at least annually, and includes procedures for incident investigations and breach response. We commit to notifying affected parties without unreasonable delay, and in no event later than seven (7) days following discovery of a reportable event, in accordance with HIPAA and applicable state laws.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Technology Designed with Evidence-Based Medicine at the Forefront Cohere is transforming prior authorization through advanced clinical-in-the-loop AI, placing patient care at the forefront of our mission. We are moving beyond traditional, transactional approaches to establish a more collaborative system that serves the needs of patients, providers, and sponsors alike. Our platform uses AI to align UM with evidence-based clinical guidelines, including leveraging guidelines developed in partnership with leading specialty societies such as the American Academy of Orthopedic Surgeons (AAOS) and the American College of Cardiology (ACC). This translates to faster, real-time approvals for appropriate patient care, ensuring patients get the care they need without delay. By fostering greater collaboration, we improve care quality, achieve better patient outcomes, and reduce costs. Our specialized language models can automate over 85% of medical necessity evaluations by efficiently extracting patient information. Cohere's AI models are developed in a multidisciplinary manner in which clinicians and engineers work in lock-step throughout the development lifecycle, and we also continuously improve our models with learning loops from millions of real-world clinician reviewer feedback. Cohere never denies authorizations based solely on AI guidance. Authorizations that cannot be automatically approved are sent for clinician review, ensuring human oversight in all critical decisions. Cohere's approach to technology-based reviews, paired with clinician reviews and a robust physician peer-to-peer review process, enhances patient safety and optimizes the entire system. Cohere's Clinical Staffing Model for Reviews: Cohere Health is a physician-led organization with over 70 physicians, ensuring deep clinical expertise across our specialty program offerings. Our physicians are board-certified in 30 medical specialties and subspecialties (e.g., anesthesiology, PM&R, cardiology, orthopedics, pain, neurology/neurosurgery, spine surgery, therapy, sleep, gastroenterology, diagnostic imaging, general surgery, vascular surgery, etc.), licensed in multiple states, have multiple years of clinical practice experience, and are members and leaders of their respective medical specialty societies. We provide same-specialty reviews, which distinguishes Cohere from other first-level reviewing platforms. Our clinical review technology features intelligent queue routing and management capabilities to ensure cases are assigned to clinicians with the appropriate skill sets and licensure requirements, enforcing a same-specialty reviewer policy for all reviews. In addition to our physician team, we have a team of over 170 licensed RNs and LPNs with

clinical experience in the specialty areas we review. Our nursing team is licensed across all 50 states, with every RN required to have a minimum of three years of hands-on clinical experience, and on average, our nurses have ten years of specialty clinical experience. All UM reviewers regularly complete clinical knowledge, compliance, and ethics training. Licensure is source system-verified before onboarding, tracked for timely renewals, and audited monthly by our Compliance team. Peer-to-Peer Consultation: Cohere believes peer-to-peer consultation is essential to ensure appropriate and safe clinical care. Oftentimes, peer-to-peer reviews can be regarded as adversarial or burdensome on physicians, but there is unlocked potential in leveraging this process if treated as a collaborative process. Cohere takes the approach of ensuring the conversation is always held between physicians of the same sub-specialty. We ensure that a true sub-specialist consult always occurs before a denial is issued. This allows ordering physicians to collaborate with a peer on the case and ensures denials are not issued for simple informational or communication-related issues. Our peer reviewers utilize the Cohere Unify™ platform, which provides access to the complete set of information (e.g., medical records, prior claims history) to inform their decisions. This structure supports clinically sound coverage determination decisions and high-quality medical review outcomes. Access to specialist reviewers improves provider communication and demonstrates higher physician satisfaction, as evidenced by Cohere's provider NPS of 67. We also believe treating peer-to-peer consultations as an opportunity for a conversation ensures that the latest and most effective treatments, clinical protocols, and evidence can be applied to patients even in the most remote and rural settings, ensuring that no matter where a patient lives, they can have access to evidence-based medicine and quality, safe outcomes. Cohere's physicians complete more than 3,300 peer-to-peer conversations a month. Gaps in provider knowledge in remote and rural areas can be addressed by peer conversations, which often lead to educational opportunities, particularly with mid-level providers. Cohere has demonstrated that our specialized approach using AI/ML to assess relevant clinical information from records provided, paired with the CPT code and clinical guidelines, results in real-time decisioning. Adding in provider characteristics, we can identify wasteful care and intervene before services occur and/or are claimed, which is an effective intervention with demonstrated savings. Cohere Case Studies Spinal Cord Stimulators: Patient safety is paramount and showcased by Cohere's decisioning rules built using evidence-based criteria. In procedures such as spinal cord stimulators, which are invasive and have unpredictable and variable outcomes, we take great care to look for all the indications and ensure all clinical criteria are met before approving. Cohere's data validates the need for stringent review; only 50% of patients receiving spinal cord stimulators have positive outcomes. This aligns with the guidelines requirement that this is a treatment of last resort. In Cohere's solution, if any gaps in the clinical record indicate a patient may not meet all the criteria for appropriateness and effectiveness based on the guidelines, the case will always pend for clinician review. Inappropriate Implantable Loop Recorder (ILR) Implants: A Cohere Health analysis of a large MA program revealed $14 million annually spent on replacement of Implantable Loop Recorders (ILRs) without proper medical documentation. Our audit found 90% of ILR replacements lacked medical necessity, with some providers replacing devices simply due to brand preference. Preventing these unnecessary implants saves the device cost and an additional $3,500 for 3-4 years of monitoring with each device. The audit also uncovered providers failing to disclose existing, functionally equivalent devices (like pacemakers or defibrillators) or simultaneously requesting ILRs and other duplicative rhythm monitoring devices. These redundant and unnecessary implantations can be identified and prevented at the prior authorization stage. Mobile Cardiac Outpatient Telemetry: A Cohere audit revealed billing abnormalities for Mobile Cardiac Outpatient Telemetry (MCOT) devices (CPT 93229) by a Medicare Advantage plan. The audit found 20,000 MCOT device claims without the needed physician order or corresponding reports (CPT code 93228). Specifically, 86% of claims for CPT code 93229 lacked a physician order or indicated a lesser device was requested. This resulted in over $20 million in annual waste for the client. Further investigation uncovered that certain providers engaged in widespread, unnecessary billing for MCOT and other remote services, including cardiac rehabilitation, echocardiography, and sleep studies. This highlights Cohere's comprehensive capability to identify and intervene in complex patterns of unnecessary care, surpassing the limitations of typical single-service, paper-based programs. Defibrillator Implants: Cohere discovered that many defibrillator implants were being inappropriately approved due to misrepresented ejection fractions, a key criterion that must be below 30% or 35% for primary prevention according to LCD guidelines. On January 29, 2025, Cohere implemented an AI-powered rule to flag requests for manual review when clinical documentation showed an ejection fraction greater than 35%. This led to a significant surge in manual review requests in February 2025, which returned to baseline by April. While the number of auto-approved defibrillators remained consistent, withdrawn, denied, or voided cases rose 8-fold during this period, with no increase in appeals. This dramatic shift, representing 32% of all submissions, points to a crucial change in provider behavior. Through our mandatory peer-to-peer phone calls, providers either realized or became aware that the ejection fraction didn't meet NCD requirements and subsequently withdrew these unnecessary cases. This insight is stunning, yet consistent with published findings on fraud, waste, and abuse (FWA) in this area. Our approach, which combines AI/ML models with highly qualified peer review, represents the ideal scenario. It allows us to auto-approve legitimate cases in real-time while simultaneously identifying unnecessary care and fostering educational discussions with medical specialists.

4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Cohere Health's integration with EHR platforms is built on a flexible, standards-based approach to interoperability, enabling seamless deployment of prior authorizations across various EHR vendors and provider types. We support Da Vinci FHIR APIs (including CRD, DTR, PAS) that comply with CMS-0057-F, and can also support 278 transactions. Our experience includes direct integrations with Epic and athenahealth, with our first EHR app launched in the athenahealth marketplace in July 2022. In early 2024, we launched a point-of-care Epic integration with a large Midwest health plan and an academic medical center in Ohio, and we have also integrated with Epic Payer Platform for a national health plan. As part of that partnership, Cohere is now embedded in the EHR at nearly 30 health systems, and growing rapidly with plans to be in over 100 health systems in the next 12 months. Our EHR integration capabilities are designed to alert providers about prior authorization requirements and enable submission at the point of care. The integration triggers are based on orders in the EHR, streamlining the workflow by checking authorization requirements in real time using the CRD standard. If authorization is required, data is pulled from the EHR to pre-fill the authorization request, reducing manual and duplicative entries. Many authorizations can be auto-approved within the EHR workflow in a touchless manner. We also support third-party interoperability enablers like Rhyme, Moxe, Waystar, and others, and provide our own SMART on FHIR workflow app. Our solution is designed to meet providers where they are, whether through direct EHR connections, interoperability solutions already in use at health systems, or integration with Epic Payer Platform. Additionally, Cohere offers a prior auth check API and supports integration with health plan and provider systems to verify prior authorization requirements. Our roadmap includes expanding integrations, building our broader EHR connection network, and enhancing current capabilities to reduce administrative burden and create a touchless experience for providers. Finally, Cohere acknowledges that while interoperability is key to ensuring advancements in technology can modernize processes like PA, today, most healthcare organizations, especially smaller individual physicians in both urban and rural areas, still use fax machines and phones. In fact, across the market in the United States, about 50 percent of all PA submissions are non-electric (e.g., fax or phone). This means that, despite best efforts, interoperability with EMRs will not unlock all of the potential, and the healthcare system must find new ways to migrate from fax to simpler apps and portals. Cohere uses a 'no wrong door' approach to supporting providers where they are. Across Cohere's book of business, we have over 96% portal adoption, significantly higher than the national average. However, serving the 10 percent who don't submit electronically is critical. Fax conversion, which Cohere deploys, is another key strategy that ensures that, regardless of the means of submission (e.g., phone, fax, portal). Our platform uses ML models to extract member and provider information from faxed documents regardless of the template or format. We leverage OCR to extract text, which NLP models then process to identify and triage documents as new authorizations or supporting documentation. The digitization process occurs in real time, and our rules engine can automatically fax notifications back to providers when additional clinical information is needed or no authorization is required. This solution automates intake, case building, and routing, supporting seamless integration with client UM systems via standard transactions or APIs. a. Cohere has active integrations with Epic and athenahealth. We are expanding these integrations to support Meditech by EOY, with Oracle and others to follow. This is in addition to complete product support for direct CMS-0057-F support for ANY EHR vendor by early 2026. b. Cohere Health actively supports payers in meeting the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F). Cohere is one of the earliest PA companies to meet the requirements of CMS-0057-F, and we have had the requirements in place since 2023. Our platform provides FHIR-based APIs (Da Vinci CRD, DTR, and PAS) that are already developed and in production, enabling health plans to achieve compliance with interoperability coverage requirements, document requests, rules, and status updates for patients and providers. To date, we've processed 15 million transactions through FHIR APIs We ensure compliance with turnaround time (TAT) requirements by automating decisioning to auto-approve 50-90% of clinically appropriate prior authorization requests, depending on specialty. Our technology is leveraged to adhere to all state and federal TAT requirements, and we have robust experience monitoring and meeting these standards as a decisioning vendor across all 50 states. The Cohere Unify™ platform integrates with existing health plan UM ecosystem workflows to share prior authorization submission data (278 + API) and decisioning information (approve or pend) in real time. For transparency, we provide decision and denial reasons in our portal notifications, including case review status updates and clinical data requirements with ML-driven missing information check capabilities. All clinical criteria and the evidence used in creating them are available for review on our public-facing website. Additionally, we publish prior authorization lists and data/metric reports quarterly with our clients, supporting the requirement to publish prior authorization rate metrics, including a complete list of authorizations, decisioning statistics, and TAT reporting. To reduce administrative burden for payers, providers, and patients, we leverage automation, machine learning, and EMR integration to streamline the prior authorization process, minimize manual data entry, and enable touchless, real-time authorization at the point of care. Our platform provides transparency through decision and denial reasons, status updates, and clinical data requirements, and publishes prior authorization metrics for accountability.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine	With over 5 years of experience, Cohere leads the industry in transforming PA through advanced AI. As the largest provider of digital PA by transaction volume, we've meticulously

Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers.

a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met.

b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.

refined our models in production. (b)(4)

(b)(4)

(b)(4) Our models undergo extensive internal and external audits with compliance leadership, CMS, NCQA, state regulatory agencies, and clients ensuring accuracy and ethical standards. Cohere follows 3 core development principles to ensure the most effective and responsible use of AI: 1Clinically Grounded: Cohere solutions are developed multidisciplinary, in which clinicians and engineers join forces at every step of the development lifecycle. We also continuously improve our models with learning loops from millions of real-world clinician reviewer feedback. 2Performance-Driven Innovation: We leverage an evaluation-driven development framework and benchmark our models against our proprietary and market-leading AI/ML capabilities to ensure the highest accuracy. Our composable platform allows us to adopt best-in-class models to stay on the cutting edge.3Responsible & Trustworthy: Our team ensures all AI outputs are traceable to source and clinically explainable. We also couple continuous monitoring with proper safeguards to protect against accuracy degradation and eliminate hallucinations. We host our custom and fine-tuned models within the Cohere infrastructure on AWS with the proper security and compliance controls. Cohere's solution is designed to uniquely meet the goals of WISeR by streamlining the PA process for all parties. (b)(4)

(b)(4)

(b)(4) The key product features and underlying model types that we would deploy if selected as a WISeR Model participant include: Combatting FWA: (b)(4)

(b)(4)

(b)(4) Not all waste is intentional; sometimes it's from well-intentioned physicians whose orders don't align with the latest evidence. Our intelligent PA system avoids waste by focusing on evidence-based guidelines and clinical care pathways, ensuring appropriate care. (b)(4)

(b)(4)

(b)(4) Policy Digitalization & Management: (b)(4)

(b)(4)

(b)(4) Today, over 450 NCD/LCD policies are digitized in our portal. Clinical Policy specialists use this tool in over 90% of their policy ingestion tasks, track changes, and ensure the highest fidelity in coverage requirements for case determinations. Case Intake: (b)(4)

(b)(4)

(b)(4) This drives substantial financial and clinical impact, avoiding burdensome denial processes and supporting timely clinical decisions. (b)(4)

(b)(4)

(b)(4) This dramatically streamlines documentation review. (b)(4)

(b)(4)

(b)(4) This approach reduces provider abrasion, enables timely delivery of appropriate care, reduces administrative burden, and improves care quality. Our rigorous quality control processes, continuous model evaluation, and collaboration between clinical experts and technologists ensure that our AI solutions remain accurate, compliant, and aligned with clinical standards. a. Cohere employs a comprehensive approach to verify, validate, secure, and regulate our enhanced technology software: Verification and Validation: (b)(4)

(b)(4) Automated testing precedes phased deployments, and every client configuration undergoes thorough QA with logged, approved, and tested changes for robust change management. Clinicians are integral to this process, collaborating closely with technical teams to ensure rules are clinically sound and continuously monitored for effectiveness. Security: Cohere is HITRUST CSF R2 Certified (initial certification in February 2022 and 2-year recertified March 2024), demonstrating adherence to leading industry practices for handling PHI within our technology platform. We also maintain NCQA and URAC accreditations for all LOBs. We implement comprehensive security protocols, encrypting all sensitive data (PHI, PII, etc.) in transit (TLS 1.2+) and at rest (AES-256). Access is strictly controlled via least privilege and

	Role-Based Access Control (RBAC). All employees receive annual HIPAA and ongoing Security Awareness Training. We conduct regular internal and external audits, including annual third-party penetration tests and continuous vulnerability management. Regulation & Quality Assurance: The Cohere Compliance Committee, chaired by the CMO and C-suite leadership, oversees all UM programs and meets quarterly to review performance, KPIs, and SLAs. To ensure accurate data and decisions, we continuously audit our automated rules, conduct random clinical reviews, and have our Compliance team review cases regularly. Cohere's Compliance & Quality team tracks changes to state and federal laws and regulations that may impact our business. Compliance distributes summaries of the law or regulation to key business partners and works with them to implement any changes necessary to meet the new requirements. Cohere ensures and monitors the quality of its ML models through a rigorous, multi-step process involving clinical and technical expertise. Models are tested with extensive offline simulation, & clinician sign-off prior to production implementation. (b)(4) (b)(4) Auditability & Transparency: Cohere ensures auditability & transparency of our ML models through a rule-based, AI-driven approach that extracts structured clinical data for auto-approval. We continuously monitor model performance for drift & effectiveness, with a robust system for detecting changes and ensuring accuracy. A percentage of PAs are regularly audited to compare auto-approval decisions against human review. Internal audit trails are routinely reviewed, feeding into a rigorous quality improvement program. We also conduct quarterly fairness and bias audits for AI models and can provide in-depth audit reports to clients upon request. Ethical Standards: Cohere's approach ensures AI/ML models are never used to deny authorizations, upholding ethical standards and reducing provider friction. Our principles guide us: Accountability, Transparency, Fairness & Equity, Privacy & Security. b. Cohere manages AI & automation with a comprehensive framework built on compliance, ethics, and strong operational controls. No AI Denials: We never deny authorizations based solely on AI; clinicians review all non-auto-approved cases. Clinician-Validated AI: Cohere's AI/ML models undergo rigorous, clinician-validated testing from training to deployment. Physicians lead data labeling and rule sign-off, with models extensively simulated and tested against "golden" datasets. Deployment requires clinician approval & strict QC, followed by continuous monitoring of auto-approval decisions against human review. Robust Deployment & Monitoring: Rule simulation precedes deployment, and a dedicated governance committee continuously monitors all models in real time for efficiency, quality, data drift, and bias. Hallucination-Free: Clinical extraction models use structured output & strict guardrails to prevent AI "hallucinations. " Ensure findings are directly attributable to clinical data.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	Yes

Accreditations or Certifications Document

File Name	WISeR-00018_Accreditations_Cohere Health NCQA Certificate
Uploaded On	7/24/2025, 1:04 PM
File Name	WISeR-00018_Accreditations_Cohere Health URAC Certificate
Uploaded On	7/24/2025, 1:05 PM

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers.	Cohere Health maintains a comprehensive approach to ethics, compliance, and quality standards to ensure the safety, ethical integrity, and partnership support for patients, providers, and payers. Ethics: Our ethical standards for artificial intelligence and machine learning are grounded in accountability, transparency, fairness, equity, privacy, and security. We ensure responsible use of AI through collaboration between clinicians and technologists, guided by evidence-based clinical practices. All AI/ML decisions are traceable and observable, with proper disclosures and documentation. We uphold consistent standards to prevent erroneous or biased care denials and maintain equity for vulnerable populations. Sensitive patient and business information is safeguarded, and only necessary data is used

a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	in AI model development and operations. Compliance: Cohere Health maintains a robust compliance program that encompasses the following elements: - Our program is led by our Chief Compliance Officer, who has over 20 years of experience in healthcare compliance, including in-depth knowledge of Medicare Compliance. - The program is overseen by a Compliance Committee chaired by our Chief Medical Officer, including most of our executive leadership team. - Our policies and procedures are based on a written compliance plan annually reviewed by the Compliance Committee. - Associates can access the compliance team through various internal channels and a hotline maintained by an independent third party for anonymous reporting. - Monitoring and auditing by first-line business teams and second-line compliance and quality staff. - Thorough root cause analysis and corrective actions to address any identified gaps. - Disciplinary guidelines that are both clear and readily accessible throughout the organization. Cohere Health is NCQA- and URAC-accredited for all lines of business and HITRUST-certified. Our Compliance team ensures adherence to all relevant regulations and privacy laws, including HIPAA. We regularly validate against regulatory standards, maintain ongoing communication with clients and regulatory bodies, and perform routine audits of our systems and processes. We monitor regulatory updates through the HPMS listserv, third-party vendors, and state agency websites. Our platform is designed to support compliance through features such as reporting, case prioritization, and configurable turnaround time rules. Quality Standards: Our platform enhances quality measures by reducing unnecessary care variation, improving adherence to evidence-based care, and accelerating access to care. We leverage clinical decision support to guide providers to high-value, clinically appropriate services, resulting in improved health outcomes, reduced denials, and high provider satisfaction. Our solution is interoperable, integrates with various EMR brands, and supports CMS mandates. We continually inform and train our AI/ML models with real experience data, deploy new automation capabilities, and extend our digital authorization footprint. Cohere's guidelines are developed and validated by our internal physicians and Cohere's external Medical Advisory Board (MAB) across various specialties, which comprises practicing physicians who are experts at some of the most prestigious medical institutions. Our physicians (both internal and MAB) are members of specialty medical societies, and our Executive Clinical Leadership team maintains regular dialogue with the MAB regarding current clinical issues. The internal Utilization Management Committee (UMC) comprises specialty physicians with diverse clinical backgrounds who offer expertise to the policy review process. For policy approval, each new or updated policy undergoes a two-physician review process: one subject matter expert in the relevant medical field and one internal specialty medical director. After this review, the policy is presented to the UMC for final approval. The standard UMC meeting cadence is biweekly, with ad-hoc meetings as needed. Partnership Support Payers: Cohere takes a strategic partnership approach to account management and client success. Each client is assigned a dedicated Strategic Account Manager who works closely with the client to set the overall program strategy, identify additional opportunities, and refine a shared roadmap. Alongside the Strategic Account Manager, a dedicated Client Success Manager is responsible for ongoing operational components, performance reporting, and issue resolution. We engage with clients through regular communication, collaborative program enhancements, and transparent reporting. Providers: Cohere has a Provider Success team dedicated to the successful onboarding, ongoing education, and support of providers using our services. During implementation, we deploy a full provider onboarding initiative, including workshops and webinars to educate provider staff on system capabilities and operational processes. We also offer one-on-one training sessions with high-volume groups, and 24/7 access to an online Learning Center. Ongoing support is provided via self-service resources, live support by phone and email, the provider success team, IT/issue support, and continuous communication. Patients: Cohere helps members by streamlining and automating the PA process, resulting in 70% faster access to patient care. We also provide members with access to an authorization status check tool, which enables members to look up the status of their prior authorization at any time. This feature benefits members by providing real-time visibility into the status of their authorizations, reducing uncertainty and administrative burden. a. Our Compliance Committee, chaired by the Chief Medical Officer and including C-suite leadership, oversees all internal UM programs. The committee meets quarterly to review clinical and operational KPIs, service level agreements, and performance against internal quality metrics. Areas needing improvement are addressed through internal corrective action plans, which are monitored to closure. Monthly audits are conducted on clinical and intake staff, focusing on process adherence and clinical decision accuracy. End-to-end audits evaluate all aspects of the UM process, including timeliness, guideline adherence, decision appropriateness, and notification quality. A bi-annual Inter-rater Reliability (IRR) assessment is performed, exceeding NCQA requirements. Analysts and clinicians continuously review accuracy metrics to adjust decision rules and ensure high-quality auto-approval decisions. The Compliance team also partners with health plan audit teams to ensure comprehensive reporting and successful audits. For complaints and grievances, Cohere Health supports clients by providing documentation support, physician explanations, and subject matter feedback. Upon notice of an appeal or grievance, our Service Operations team compiles all relevant information, including decision steps, rationale, supporting clinical material, and physician communication notes. This information is delivered to a client-specified secure location within a predetermined turnaround time, and the requestor is notified upon delivery. Our physicians are available to explain decisions and provide clinical guidance. This process supports all levels of appeal, including ALJ hearings, and is supplemented by regular

	meetings with clients' G&A departments to inform and improve our processes. Cohere routinely conducts claims analysis for claims billing and dispute issues to identify quality opportunities and inappropriate care. Industry-recognized clinical guidelines inform claims analysis, and the clinical team further reviews identified cases. Insights from claims analysis are used to enhance rules and approval criteria. Cohere partners with clients' quality assurance teams to configure and provide transparency in quality assurance processes. Our platform supports claims sampling for quality assurance, and business users can configure quality assurance processes to meet specific needs. b. Our solution is designed to maintain compliance with all federal and state regulations and NCQA and URAC industry standards. Our experience as a technology vendor and a delegated entity gives us firsthand knowledge of meeting turnaround times and compliance requirements. Proactively, our Compliance team tracks changes to federal and state standards through HPMS, a third-party monitoring vendor, and state agency websites. Compliance distributes summaries of legislation to key business partners and works with them to implement any changes necessary to meet the new requirements. Oversight of Cohere's UM program includes several layers of quality assurance to ensure adherence to regulations and quality standards: Department-level reviews - operational teams monitor activities in their unit to ensure compliance. Business area oversight - Training and Quality Management (TQM) conducts routine audits of operational and clinical teams. Compliance and Quality oversight - CQ performs end-to-end auditing of Cohere processes from automation through clinical review. Inter-Rater Reliability (IRR) testing - Bi-annual assessments of clinicians to monitor quality, identify gaps, and implement corrective actions. Our technology platform supports compliance through features such as: Reporting and visibility into the full lifecycle of authorizations, including timeliness. Case prioritization, flagging cases with turnaround time considerations (e.g., expedited cases). Configurable turnaround time rule management based on state, line of business, and other factors.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	As previously discussed, our technology proactively identifies and successfully intervenes fraudulent behavior in real time using AI, ensuring appropriate care and significant cost avoidance. This is especially valuable in areas like skin substitutes which have been ripe with fraud, waste, and abuse and are a key target for CMS. This capability underscores our commitment to not just efficiency, but also the integrity of Medicare health expenditures. Given the below modeling, we also recognize there could be additional savings gains due to our model's focus on commercial and Medicare Advantage data which typically sees less fraud, waste, and abuse than Original Medicare. Finally, there are other indirect savings that we have seen due to prior authorization, such as total cost of care impact, population health improvement, value-based care impact, etc. and this analysis does not take into account the broader population health impact (e.g., services, conditions, etc., avoided in the future). (b)(4) (b)(4) (b)(4) The lower end of savings represents impact on a well-managed population, and the upper end reflects expected impact on a less-managed population, based on our deep experience in MA. As these code sets are currently unmanaged by CMS in the traditional Medicare program, we would expect to see impact on the much higher end. We conducted our analysis using an assumed gross spend of $439 PBPY in these categories based on publicly available Medicare data and Cohere's MA experience. With access to comprehensive claims data, we can unlock even greater savings estimates, including the identification of fraudulent and abusive claims. We would welcome the opportunity to refine our analysis with true claims data, should CMMI be able to provide this information. Please see below for Cohere's full savings methodology utilized by our team of actuaries in partnership with our clinical leadership: - Developing estimates of FFS utilization per 1,000 and PBPY using Cohere benchmark claims datasets. - Quantifying the cost of each procedure, using Cohere's encounter grouper. This analytic methodology calculates the cost of a surgical procedure by identifying the related Part A and Part B claims and assigning a primary procedure code for the event. For example, a lumbar decompression procedure would include add-on codes on the Part B and Part A claims related to the hospitalization stay for both the professional and facility charges. - Estimating authorization volume for the CPT codes in scope in each service category. - Calculating the expected impact from the Cohere program, measured as the "impact rate" (a percentage of authorizations). This includes denials and non-denial interventions, like changing the service site or educating the provider to withdraw an authorization that does not meet medical necessity guidelines. - Calculating the savings from the denial determinations and non-denial impact. - When no Cohere experience exists for a specific code, best actuarial and clinical judgements were applied together to determine the final model input assumptions. (b)(4) (b)(4) (b)(4) This savings analysis reflects expected impact in each of the eleven clinical categories. For example, the following represents Cohere's expected savings impact and gross savings in the Cervical Fusion category. Cohere has deep experience managing musculoskeletal care, in addition to other key specialties, for one of the nation's largest MA plans, and we would be thrilled to bring comparable impact to the Medicare FFS program, preventing unnecessary and inappropriate spine surgeries which are both costly and

	clinically invasive to the patient, with variable outcomes (b)(4) (b)(4) (b)(4) Across our book of business, Cohere's solution consistently delivers proven cost reduction and minimized provider abrasion. We highlight the following clinical differentiators that drive measurable value for our health plan clients, which we would deploy in the WISeR model as well if we are selected as a participant: (b)(4) (b)(4)
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Cohere is well-positioned to support the WISeR Model across any MAC region by January 1, 2026. Our confidence stems from meaningful experience, leading over 20 successful implementations and expansions across 8 customers. Through this work, we've developed a repeatable, proven approach to planning, designing, and delivering complex solutions on tight timelines. We also understand the importance of stakeholder coordination in a model like WISeR, and we're fully prepared to engage collaboratively with CMMI, MACs, and any subcontracted agency partners. The Cohere Complete solution is designed for speed and scalability. A typical implementation can be completed in three to four months, depending on the clinical scope (e.g., volume, service categories) and the availability of key client resources on the clinical and technology side. This approach allows for rapid deployment while laying a strong foundation for future expansion. Our implementation process is anchored in nine core work streams, which we tailor to each engagement's unique needs and structure. While we operate from a proven framework, we adapt our methodology, timeline, and resource allocation to fit the specific requirements of CMMI and the broader WISeR initiative. From day one, we develop and manage a detailed project plan that guides each work stream through completion. Implementation begins with the activation phase, a 30-day period during which Cohere and CMMI work together to finalize the scope, confirm key deliverables, and align on launch timelines. Once requirements are defined, we enter the delivery phase, which covers system configuration, testing, and go-live preparation. This includes setting up technology integrations, aligning workflows to client specifications, security and compliance alignment, integration with the MACs, and implementing prior authorization lists and medical policy configurations. As implementation progresses, we focus on configuring auto-approval rules, developing and executing the provider engagement plan, preparing operations teams, and finalizing reporting capabilities. We conduct rigorous user acceptance testing and end-to-end validation to ensure the platform is ready for launch. To reduce the burden on client teams, Cohere provides a dedicated Implementation team that drives day-to-day execution, manages provider outreach and education, and oversees IT integration and project tracking. We also bring in cross-functional subject matter experts at key points to address the project's clinical,

	operational, compliance, and technical elements. We take pride in making the implementation process as efficient and collaborative as possible—and in delivering high-quality solutions that are operationally sound, clinically rigorous, and built to scale. Cohere's implementation is tailored to each client, driven by a dedicated, cross-functional team of subject matter experts. These experts ensure seamless integration, covering security, IT, clinical policies, compliance, actuarial analytics, service operations, solution engineering, and provider success. Our leadership team actively supports implementations and account management, including our Chief Client Experience Officer, Chief Growth Officer, and Chief Digital & Technology Officer. The broader team brings extensive, diverse experience from healthcare technology, clinical practice, data science, and operations, ensuring a smooth launch and strong, ongoing partnership focused on maximizing client value.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	☑
Company/Organization Name:	Cohere Health, Inc.
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00040

Requested by (b)(6) on 07/28/2025 12:31

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Virtix Health LLC
b. Doing Business As (DBA) Name(s)	Virtix Health LLC
c. Street Address	13835 N. Tatum Boulevard Suite 9277
d. City	Phoenix
e. State	AZ
f. Zip Code	85032
g. Tax Identification Number	830593025
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	For all intended purposes, in all other responses and references, we will refer to CorroHealth and Virtix Health LLC collectively as "the company". CorroHealth and Virtix Health LLC Overview CorroHealth and Virtix Health LLC are sister companies under a shared holding structure, functioning as a unified organization with a tightly integrated infrastructure. While we operate as distinct entities externally, this separation is purely strategic—designed to optimize our go-to-market approach across the healthcare ecosystem. Unified Purpose & Mission Together, we are committed to improving healthcare outcomes and financial performance through innovation, clinical expertise, and scalable technology. Our shared mission centers on delivering high-impact solutions that empower both providers and payers to operate more efficiently and effectively. Shared Values We are guided by a common set of values: • Integrity in every interaction • Innovation that drives meaningful change • Collaboration across teams and partners • Accountability to our clients and each other • Compassion for the people and communities we serve Shared Infrastructure & Technology We leverage the (b)(4) integrated with Epic Systems via SMART on FHIR®, enabling rapid clinical chart retrieval from over 24,000 hospitals and 45,000 clinics nationwide. We jointly invest in AI/ML technologies to support provider coding, risk adjustment, prospective reviews, and clinical documentation improvement (CDI)—all built on a shared infrastructure and aligned product strategy. Strategic GTM Division (b)(4) (b)(4) (b)(4) This strategic division allows each brand to specialize and tailor its offerings, while benefiting from shared innovation, resources, and operational synergy. In essence, we are one company with two market-facing identities, working in concert to

	deliver comprehensive, complementary solutions across the healthcare continuum. As part of our commitment to ethical and compliant business practices, we have rigorous internal policies in place to protect the confidentially of partner data between to the two go to market strategies. Unified Clientele We proudly serve a broad spectrum of healthcare stakeholders, including: • Hospitals, health systems, and clinics • Medicare Advantage and commercial health plans • Payers, providers, and administrative contractors • Technology partners and regulatory bodies
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	Virtix Health LLC
Street Address	13835 N. Tatum Boulevard Suite 9277
City	Phoenix
State	Arizona
Zip Code	85032

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00040_Ownership_Virtix Health LLC
Uploaded On	7/23/2025, 9:34 AM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Contact Type	Secondary
Email Address Name Title/Position Address	(b)(6)

Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00040_Licensure_1.3.6_Articles Incorporation - Virtix Health
Uploaded On	7/22/2025, 12:49 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Our organization maintains Business Associate Agreements (BAAs) with a wide range of HIPAA-covered entities across both the payer and provider landscape. These include national and regional health plans, integrated delivery networks, hospital systems, and physician groups.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	The company has extensive experience working with Medicare Advantage plans and other payers on all aspects of prior authorization since 2021. We manage the entire prior authorization process, including eligibility verification, coverage criteria determination, documentation support for medical necessity, clinical review, dedicated authorization teams to minimize errors and delays, peer-to-peer consultations, and appeals of denials. We have supported a broad range of services with prior authorization requirements, including wound and skin products, blepharoplasty, Botulinum toxin injections, panniculectomy, rhinoplasty, vein ablation, cervical fusion, spinal neurostimulators, facet joint interventions, knee arthroscopy, incontinence control devices, and sleep medicine procedures. Our program uses advanced analytics to adapt to evolving payer requirements and ensure compliance. We recognize that prior authorization impacts provider cash flow, revenue, operational efficiency, and, importantly, patient access to care. Our approach integrates technology, payer-specific workflow expertise, and clinical knowledge. Custom dashboards provide real-time status updates, minimize claim holds, and reduce days in accounts receivable, helping to prevent revenue leakage. We prioritize expedited processing for high-value procedures and ensure seamless integration with payer portals and EMR systems to avoid duplicate entries and lost documentation. By leveraging historical denial data, our finance and business teams inform contract negotiations, support authorization waivers, and develop value-based arrangements. Key performance metrics include prior authorization

	denial rates, days in accounts receivable, and denial appeal overturn rates. In summary, our financial and operational expertise in prior authorization enables increased net revenue capture, reduced administrative overhead, decreased payer friction, faster payment cycles, improved patient access, and actionable strategic insights for our partners. Other Payor work performed: We are a nationally trusted partner in medical record retrieval, coding, and auditing—serving over 100 health plans across the country. Our tailored, collaborative approach fosters genuine partnerships and consistently delivers measurable results. We support (b)(4) with deep experience across Medicare Advantage, Commercial ACA, ACO, Managed Medicaid, and Original Medicare programs. Our risk adjustment services include: • Medical Record Retrieval • Coding & Auditing • RADV Retrieval & Coding • HEDIS/Quality Abstraction Each year, we process over (b)(4) chart reviews, with retrieval volumes exceeding (b)(4) demonstrating our ability to scale and perform reliably. We work closely with integrated health systems and provider groups to support value-based care and risk adjustment initiatives. Our technology-enabled workflows and experienced teams help clinicians improve documentation accuracy while reducing administrative burden. Our compliance-first approach identifies both missed and delete opportunities—averaging 1.6 missed codes and 0.7 deletions per member review. WISeR Alignment: Claims & Payment Integrity The company offers a robust Payment Integrity solution tailored to the complexity and scale of national health plans. Our services span the full payment continuum: • Pre-Payment Prevention • Post-Payment Auditing & Recovery • Data Mining & Analysis In support of WISeR's goals, we offer: • Dedicated Nurses & Certified Coders • Exclusive Facilities & Operational Sites • Coordinated Provider Education Our teams review both inpatient and outpatient documentation and claims data to validate diagnosis and procedure codes, ensuring accurate and timely adjudication. Differentiators That Matter • (b)(4) certified medical coders with deep expertise in documentation and coding accuracy • Hundred of nurses, clinicians , physicians with extensive clinical expertise • HiTrust-certified infrastructure and rigorous data security protocols • NCQA certification anticipated in 2026 • Domestic and global delivery capabilities • State-of-the-art facilities designed for high-performance operations • Proven cost savings exceeding (b)(4) for our partners We are proud of the flexible, co-development environment we've built with our clients—an approach that aligns seamlessly with WISeR's mission to drive integrity, efficiency, and innovation in claims and payment operations. COMPREHENSIVE CLIENT PORTFOLIO of our Payer Business. 2.1 Medicare Advantage Organizations: • (b)(4) (b)(4)
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	The company is deeply rooted in healthcare expertise, with a team composed of physicians, registered nurses, clinical coding professionals, and compliance specialists. This collective experience is dedicated to maintaining a thorough and current understanding of hospital regulatory guidance. While the Centers for Medicare & Medicaid Services (CMS) initiates prior authorization and pre-claim review programs, it is the Medicare Administrative Contractors (MACs) who are responsible for implementing and administering these programs. This includes the development of Local Coverage Determinations (LCDs) that provide essential medical necessity guidance within the framework of National Coverage Determinations (NCDs). To deliver the most effective compliance support to our provider and payer partners, the company brings deep expertise in CMS Medicare, Medicaid, and Managed Care coverage criteria. Our team excels in identifying and applying relevant guidance and, most critically, in navigating the regional rules established by CMS Contractors. This includes interpreting LCDs, NCDs, prior authorization requirements, and associated Local and National Coverage Articles that offer timely billing guidance. Our core competency positions us to engage strategically with CMS contractors—including (b)(4) (b)(4) (b)(4) We are adept at advocating for the merits of claims based on a sound and current understanding of CMS coverage criteria. The company has assembled a multidisciplinary team of clinicians, coding experts, and compliance professionals who are supported by proprietary technology. This team is highly skilled in assessing clinical documentation and aligning it with NCD criteria to substantiate the medical necessity of services covered under Medicare. Our

	emphasis on accuracy, compliance, and proper application of CMS policies ensures that we uphold the integrity of the Medicare program. Furthermore, our team is recognized for its commitment to continuous education and training, ensuring a deep and evolving understanding of NCDs and their real-world application. This dedication enables accurate billing and reinforces our ability to support CMS's goals of equitable, compliant, and efficient healthcare delivery. The company currently undergoes several audits and certifications to ensure compliance with data security standards, including HITRUST r2, SOC 2 Type 2, and PCI DSS. However, at this time, we do not have FedRAMP or similar authorization specific to operate directly with a federal agency. The Company maintains a formal compliance and ethics program which includes our HIPAA compliance program. A Chief Compliance & Privacy Officer and a Chief Information Security Officer have been designated and have responsibility for oversight of the compliance and information security programs, respectively. These individuals are supported by their teams who help to monitor compliance with the HIPAA Privacy, Security, and Breach Notification Rules through periodic monitoring, formal gap or risk assessments, training and education, and issue investigations/response. In addition, the Company undergoes several third-party assessments/certifications which evaluate compliance with privacy and security controls. The Company has a documented incident response plan and breach notification procedures which are followed in the event of a data incident or breach. The response actions may vary depending on the nature and severity of the incident; however actions will include swift containment and mitigation of the risk and reporting in compliance with federal and state laws and contractual obligations.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

File Name	WISeR-00040_Authorizations_Virtix Health 2024- HITRUST i1 Cert. Ltr. (Final).pdf[70]
Uploaded On	7/24/2025, 11:57 AM

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Clinical Review Process Overview The company's clinical team currently consists of (b)(4) nurses and (b)(4) physicians who span multiple specialties and averages (b)(4) of experience in managing payer-provider interactions. All cases are reviewed by licensed clinicians who are specifically trained in the assigned review type. This specialized training includes handling complex and frequently denied diagnoses, staying current with regulatory updates, and managing outlier cases. The company's clinicians employ a rigorous, evidence-based methodology to conduct medical reviews that support accurate and clinically sound coverage determinations. This process includes a comprehensive evaluation of clinical documentation, medical records, and relevant patient history to assess whether a treatment or procedure is medically necessary and compliant with current clinical and regulatory standards. The review begins with accessing the patient's electronic medical record (EMR) to gather detailed clinical information and establish a complete understanding of the case. Clinicians with relevant specialty expertise apply established clinical guidelines from national medical societies, payers, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and other regulatory sources. These guidelines ensure that requested services align with best practices and standard-of-care protocols. In addition to these frameworks, clinicians apply their professional judgment to evaluate the appropriateness of care, considering any unique patient-specific factors that may influence clinical decision-making. The company recognizes the importance of peer-to-peer engagement. A dedicated team of expert clinicians conducts (b)(4) peer-to-peer reviews daily. These collaborative discussions facilitate clarification of clinical details and foster mutual understanding, ensuring alignment in clinical decision-making. Peer-to-peer reviews enhance transparency and reinforce respect for clinical judgment, contributing to informed and equitable coverage determinations. Beyond peer-to-peer interactions, the company's clinicians may consult with other specialists to ensure a holistic understanding of complex

	cases. Upon completing the review, the clinician documents the key findings and rationale supporting the determination. All clinical reviews are subject to quarterly quality and performance audits. Selected cases are reviewed by a supervising physician to ensure documentation, evaluation, and outcomes meet regulatory and contractual standards. All clinicians receive intensive onboarding education focused on regulatory compliance and clinical evaluation, followed by ongoing training and re-education. Any performance variances are investigated for root cause, and corrective actions—such as performance improvement plans or process adjustments are implemented to ensure consistency and compliance across the team. From an operational standpoint, the company employs a robust set of validation rules to prevent errors and ensure process integrity. Each step in the review workflow is monitored and evaluated for accuracy and efficiency. Ultimately, the company's physicians are committed to delivering coverage decisions that are grounded in sound clinical evidence—promoting optimal patient care while maintaining strict adherence to regulatory and payer requirements.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Integration and Future Plans Overview Current Integrations Our company is actively supporting payers in alignment with the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F), focusing on reducing administrative burden and improving data exchange in the healthcare ecosystem. We are already integrated with: • Epic and Oracle—facilitating seamless data exchange according to HHS-adopted interoperability standards, including the HL7® FHIR® R4 profiles, OAuth 2.0, and SMART on FHIR protocols for real-time chart retrieval and clinical and administrative data exchange. • Athena—leveraging their API infrastructure to ensure efficient and secure data connectivity across systems. • A wide range of EHR systems—utilizing both FHIR framework, HL7, and other established interoperability protocols to enable broad clinical data exchange. Future Plans Looking ahead, we are committed to expanding our technology-driven solutions to further support compliance with regulatory requirements and enhance care delivery. Our future plans include: • Implementing and refining API technologies aligned with the technical specifications and HHS-adopted standards in the CMS-0057-F rule—including HL7® FHIR® R4 profiles, OAuth 2.0, and SMART on FHIR protocols—to support Patient Access, Provider Directory, Payer-to-Payer data exchange, and Prior Authorization workflows. • Continuously improving interoperability and real-time access to information for payers, providers, and patients, with the goal of reducing administrative work and accelerating appropriate authorizations. • Exploring additional integrations and partnerships that further streamline data exchange and improve patient outcomes. Our organization is dedicated to ensuring that our solutions not only fulfill evolving regulatory requirements but also drive measurable improvements in healthcare delivery by minimizing delays and fostering effective collaboration among all stakeholders. To alleviate the administrative and patient burden associated with the prior authorization process, we prioritize innovation and continuous enhancement informed by a comprehensive understanding of provider and patient challenges—including excessive administrative workload, lack of transparency and communication barriers, care delays, and payer-related administrative complexities. Our technology solutions are strategically designed to address workflow bottlenecks, thereby enhancing efficiency, accuracy, and timeliness throughout the prior authorization process. Our automation and technology initiatives are designed to support a standardized submission process and adherence to clinical guidelines, enabling real-time submission and tracking of authorization requests with enhanced accuracy and efficiency. Seamless interoperability with EHR systems significantly reduces administrative burdens and fosters transparency through timely, clear communication among patients, providers, and payers. The integration of Artificial Intelligence (AI) for data validation and decision support accelerates the review process by automating eligibility checks, applying clinical criteria and treatment guidelines, and flagging exceptional requests that require further human assessment. By leveraging advanced data analytics, our solutions anticipate the likelihood of authorization approvals or denials, enabling proactive interventions that streamline approvals for high-probability cases. Ongoing monitoring and evaluation of program impacts—including provider workload, patient wait times, treatment delays, and patient satisfaction—allow for continuous, data-driven optimization. This approach ensures that our initiatives remain responsive, effective, and aligned with the evolving needs of all stakeholders.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the	The Company brings a proven track record in deploying advanced Artificial Intelligence (AI) and Machine Learning (ML) solutions across the healthcare ecosystem, particularly in medical coding, clinical documentation improvement (CDI), and compliance. Our experience positions us as a strong partner for CMS and Medicare Administrative Contractors (MACs) in implementing the WISeR initiative to reduce wasteful and inappropriate services while streamlining the prior authorization process. In addition to our experience with training ML models on complex datasets, The Company's end-to-end medical coding pipeline exemplifies enterprise-grade performance and scalability. Our system currently processes over (b)(4) charts per day—each potentially containing multiple encounters—across both payer and provider environments. The Company is equipped with robust capabilities for ingesting patient charts through multiple secure channels, including SFTP, mail, and fax. For mail and fax submissions, The Company maintains a dedicated locker room facility to ensure all documents are stored securely and handled in full compliance with healthcare data regulations. Additionally, The Company has developed a FHIR-compatible application that is ready for integration with leading EHR systems such as EPIC, Oracle, and Athena.

prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	This integration enables the secure retrieval of only the required chart information via API, ensuring both data minimization and operational efficiency. The AI coding pipeline is designed using an (b)(4) (b)(4) Scalability is achieved through auto-elastic virtual machines, massively parallel processing, and dynamic functions, allowing the system to adapt in real time without human intervention. The entire AI flow—from OCR initiation to final output—takes (b)(4) chart. Our GenAI models deliver over (b)(4) accuracy for all charges, including levels, procedures, and medication administration, and over (b)(4) accuracy for diagnosis coding. These results are achieved even with unstructured charts; when charts are delivered in clean, structured formats (e.g., via API), performance is significantly enhanced. This operational scale and accuracy underscore The Company's deep expertise in AI-driven medical coding, robust ML model development, and secure, compliant infrastructure. Our capabilities make us an ideal partner for CMS and MACs in delivering measurable value through the WISeR initiative. Experience in Training AI/ML Models on Complex Data Sets and Coverage Determinations The Company has successfully trained and deployed ML models on (b)(4) patient charts (with masked PHI), enabling precise opportunity identification in our CDI services. These models leverage classification algorithms and Random Forest frameworks to detect patterns in clinical documentation that indicate potential gaps in care or coding accuracy. For WISeR, The Company will develop a custom ML model trained specifically on documentation related to the selected services identified by CMS (e.g., skin substitutes, nerve stimulators, knee arthroscopy). This model will be designed to: - Detect potential abuse or overutilization of these services. - Classify the type of service and flag documentation inconsistencies. - Trigger a GenAI-powered prompting flow to extract relevant clinical facts and indicators for human review. This hybrid approach—combining deterministic ML with generative AI—ensures both scalability and clinical nuance in identifying inappropriate service use. To maintain the highest standards of security and compliance, all Protected Health Information (PHI) will be masked before any documentation is processed by our models. This includes processing within private LLM environments, with only non-identifiable PHI (e.g., age, sex) exposed at any stage of the AI pipeline. Importantly, clinical coders and nurses will be actively involved in reviewing the outputs of both the ML models and GenAI prompting flows during the training and tuning phases. Their domain expertise ensures that the models are clinically sound, contextually accurate, and aligned with CMS policy objectives. AI Algorithms and Frameworks for WISeR Implementation Our WISeR-specific solution will utilize: - Sectioning and tagging of clinical documents to structure data for accurate classification and clinical indicator extraction. - Training on approximately (b)(4) charts with masked PHI to ensure robust model performance and generalizability. - Random Forest and Gradient Boosting classifiers for abuse detection. - Natural Language Processing (NLP) models fine-tuned on clinical text to extract contextual indicators. - Custom GenAI prompting flows, where each prompt builds on the previous output to extract layered insights from unstructured EHR data. - Secure, private LLM environments to ensure data never leaves our controlled infrastructure. - Certified medical coders, providers, and nurses reviewing 100% of outputs during training until 90% accuracy is achieved, with continued oversight through audits and feedback loops. These models will be integrated into a modular pipeline that interfaces with MACs, enabling seamless chart triage, documentation analysis, and decision support. Unique Value to WISeR Goals The Company's approach aligns directly with WISeR's objectives: - Streamlining prior authorization by automating the identification of high-risk services. - Reducing administrative burden through intelligent chart triage. - Enhancing transparency and fairness by surfacing clinical justifications for human review. - Our proprietary PHI Masking AI safeguards patient data by masking all identifiable elements (e.g., name, ID) prior to any processing. Only minimal, non-identifiable PHI (e.g., age, sex) is retained—and only for as long as necessary—before any interaction with large language models, even within private server environments. - Ensuring clinical accuracy through the involvement of experienced coders and nurses in model development and validation. Our combination of AI talent, clinical domain expertise, and operational scale makes us uniquely positioned to support CMS and MACs in achieving measurable improvements in utilization management. a. Verification, Validation, Security, and Ethical Oversight The Company follows a rigorous ML lifecycle governance framework that includes: - Model validation using stratified test sets and cross-validation. - Bias detection and mitigation through fairness audits and explainability tools. - Security protocols including PHI masking, encryption at rest and in transit, and role-based access controls. - Ethical oversight via an internal AI Ethics Committee that reviews all models for compliance with CMS guidelines and healthcare equity standards. We also maintain SOC 2 Type II and HITRUST certifications, ensuring our infrastructure meets the highest standards of data security and compliance. b. Managing Potential Adverse Effects of Automation and AI The Company proactively addresses the risks of automation through: - Human-in-the-loop (HITL) workflows, where flagged cases are reviewed by clinical experts before final decisions. - Continuous model monitoring to detect drift, false positives, or unintended consequences. - Transparent audit trails for every AI decision, enabling traceability and accountability. - Stakeholder training and change management to ensure smooth adoption and responsible use of AI tools. By combining automation with clinical oversight, we ensure that AI enhances—not replaces—human judgment in utilization management. Post-Live Calibration Following deployment, The Company will collaborate closely with CMS to review program performance metrics and outcomes. We will use this feedback to continuously calibrate and refine our AI models and

	GenAI prompting workflows, ensuring that the system adapts to evolving clinical practices and policy requirements while maintaining high accuracy and fairness. The Company is deeply committed to eliminating waste and abuse in the healthcare system. Our mission aligns closely with CMS's vision for the WISeR initiative, and we are ready to bring our proven AI-driven solutions, clinical expertise, and scalable infrastructure to support this transformative effort. With confidence in our ability to deliver measurable results, we stand prepared to partner with CMS and MACs to implement and operationalize WISeR by the end of 2025.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	All clinical reviews undergo quarterly quality and performance audits. A supervising physician selects and evaluates clinical cases to ensure that documentation, assessment, and outcomes meet regulatory and contractual standards. Upon hire, all clinicians receive comprehensive training in regulatory requirements and clinical case evaluation, followed by ongoing educational updates. Performance variances are promptly identified, analyzed for root causes, and addressed through targeted improvement plans or process adjustments. This approach ensures regulatory compliance, team consistency, and immediate access to educational resources. From an administrative standpoint, validation rules are in place at each process stage to alert staff and prevent errors. Every step is systematically monitored and assessed. We are dedicated to upholding the highest standards of service and care for our clients. Recognizing that concerns may occasionally arise, we have established a transparent and structured process for addressing complaints and grievances. Clients can easily report issues via phone, email, or online submission, and our staff is trained to respond with empathy and professionalism. Each complaint receives a prompt initial response and is investigated thoroughly, considering all relevant factors. We strive for fair, timely resolutions that meet the needs of all parties involved. If a client is dissatisfied with the outcome, an appeal process allows for a comprehensive second review to ensure all concerns are fully addressed. We view complaints and grievances as opportunities for continuous improvement. After resolution, we analyze each situation to identify service, procedure, or policy enhancements. This feedback is integral to elevating the quality of our offerings. Our complaint resolution process reflects our core values of integrity, compassion, and professionalism, ensuring a fair and responsive mechanism for all stakeholders and fostering ongoing enhancement of the client experience. Given frequent federal and state regulatory updates regarding prior authorizations, our compliance procedures include continuous monitoring and analysis of evolving legislation and agency guidance. Upon onboarding new clients, our Regulatory Affairs Team conducts an initial assessment of relevant state statutes and remains vigilant for updates. The team is dedicated to tracking, interpreting, and communicating regulatory or statutory changes, ensuring our guidance remains current and compliant across all jurisdictions.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Executive Summary: WISeR Model Cost Forecast – Texas & Oklahoma Overview This analysis estimates Medicare Fee-For-Service (FFS) outpatient spending on select high-cost procedures identified in CMS's WISeR pilot, and forecasts potential savings from implementing machine learning–enabled prior authorization. The forecast focuses on Texas & Oklahoma and excludes emergency room and inpatient settings. Scope of Services Sixteen services were analyzed, based on the Request for Applications (RFA) for the WISeR pilot: • Electrical Nerve Stimulators • Sacral Nerve Stimulation • Phrenic Nerve Stimulator • Deep Brain Stimulation • Vagus Nerve Stimulation • Induced Lesions of Nerve Tracts • Epidural Steroid Injections • Percutaneous Vertebral Augmentation • Cervical Fusion • Arthroscopic Knee Debridement • Hypoglossal Nerve Stimulation • Incontinence Control Devices • Diagnosis and Treatment of Impotence • Percutaneous Lumbar Decompression • Skin Substitutes for Wounds • Wound care using skin/tissue substitutes These services are drawn from National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) included in the CMS WISeR pilot. Methodology Summary Component Approach Geography Texas and Oklahoma only Population Medicare Fee-for-Service only Setting Outpatient services only (excludes ER and inpatient) Data

	Sources (b)(4) Medicare Part B & OPPS claims data (b)(4) internal Charge Master data obtained from CMS Volume Estimation Scaled from national service volumes based on regional Medicare share (b)(4) Payment Estimation Based on (b)(4) average allowed amounts from CMS and (b)(4) internal Charge Master data obtained from CMS Formula Total Spend = Estimated Volume × Average Payment Savings Forecast Forecasted Savings = Total Spend × Avoidable Utilization Rate (b)(4) Key Findings • (b)(4) Estimated Medicare FFS Outpatient Spend (TX + OK): (b)(4) Avoidable Spend at (b)(4) Reduction: (b)(4) - Avoidable Spend at (b)(4) Reduction: (b)(4) • (b)(4) Estimated Medicare FFS Outpatient Spend (TX + OK): (b)(4) - Avoidable Spend at (b)(4) Reduction: (b)(4) - Avoidable Spend at (b)(4) Reduction: (b)(4) million Strategic Impact Deploying advanced automation and ML-based decision support for prior authorization can significantly reduce low-value or unnecessary utilization. For high-cost procedures with clinical variation, such as those in the WISeR pilot, this model supports the case for: • Lower administrative burden • Faster provider decisioning • Material FFS savings at scale • Potential policy expansion beyond pilot states Conclusion Based on our calculations for the Medicare outpatient spend in (b)(6) we believe that with our AI/ML models—custom-built for the WISeR framework—we can capture savings in the range of (b)(4) for Texas and Oklahoma. The cost savings we forecasted for Texas and Oklahoma under the WISeR model are also relevant and applicable to other states and regions. These projections are based on scalable efficiencies—such as AI/ML-powered automation, streamlined workflows, and reduced administrative burden—that are not geographically constrained. As such, we expect similar financial and operational benefits as the model is extended nationally Lastly, deploying advanced automation and ML-based decision support for prior authorization can significantly reduce low-value or unnecessary utilization as well as identify trends to detect fraud, waste and abuse. Source: CMS
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	This project outlines the strategic implementation plan for enabling secure, compliant integration with Medicare Administrative Contractors (MACs) to support prior authorization workflows. The initiative is designed to ensure our systems are fully aligned with CMS requirements and HIPAA regulations while maintaining operational efficiency and interoperability. The project spans from August 18, 2025, to Jan 31st, 2026, and includes key phases such as discovery, architecture and security setup, API development, sandbox testing, go-live readiness, and post-launch support. A core focus is on expanding our existing R4 FHIR framework and ensuring seamless bi-directional data exchange between providers, our platform, and MACs. To ensure the highest level of execution and accountability, a dedicated cross-functional team will be assigned to this initiative. This team will include: • A Project Manager to oversee timelines, dependencies, and stakeholder communication. • Developers to lead API enhancements and integration efforts. • Quality Assurance (QA) specialists to validate functionality, security, and interoperability. • Business Owners to ensure alignment with strategic goals and regulatory expectations. • Executive Leadership to provide oversight, remove roadblocks, and ensure organizational support. • Providers and Nurses to ensure clinical alignment with prior authorization workflows and CMS guidelines, and to represent frontline perspectives in the design and validation process. Additionally, a comprehensive review of our existing security protocols—already established within the organization—will be conducted to validate compliance with CMS and HIPAA standards. This includes infrastructure, access control, encryption, secure APIs, and incident response readiness. The plan is structured to minimize risk, ensure audit readiness, and deliver a scalable, secure solution that meets the evolving needs of both CMS and healthcare providers. Timeline & Implementation Plan Phase Key Activities Start End 1. Discovery & Gap Analysis Review CMS/MAC specs, compliance policies, integration specs Aug 18, 2025 Aug 18, 2025 2. Architecture & Security Set up GovCloud, review RBAC, encryption, secure APIs, OAuth 2.0, and SMART on FHIR protocols Aug 18, 2025 Aug 19, 2025 3. API Development & Interoperability Testing Expand current R4 FHIR framework to support prior authorization with MACs and/or build new APIs as needed to ensure seamless integration Aug 25, 2025 Nov 3, 2025 3a. Testing in Sandbox Thorough bi-directional testing with MACs to support both provider our company MAC and provider MAC our company workflows, ensuring alignment with CMS and provider needs Nov 4, 2025 Dec 19, 2025 3b. CMS-Facing Integration Support Nov 4, 2025 to Dec 19, 2025 If SMART on FHIR is not a viable option for integration, we are fully prepared to support MAC connectivity through our existing client-facing portal and/or X12 EDI. Our portal is already in active use for submissions today, ensuring we can meet CMS expectations through either method as needed 3b. CMS-Facing Integration Support Nov 4, 2025 to Dec 19, 2025 Confirm readiness to support MAC integration via Portal or X12 EDI. Our client-facing portal is already in use for submissions, ensuring alignment with CMS expectations for either method. 4. Go Live Readiness Final readiness checks Dec 22, 2025 Dec 26, 2025 5. Go Live Launch interface with MACs Dec 29, 2025 Dec 29, 2025 6. Post Go Live Support Validation and ongoing support Jan 1, 2026 Jan 31, 2026 The following checklist outlines key security protocols that are already established within our organization. This review is intended to validate alignment with CMS and HIPAA requirements and ensure readiness for integration with MACs. Internal Actions for HIPAA & Security Compliance To ensure readiness and compliance with HIPAA and CMS security requirements, the following internal actions are critical: Policy & Procedure Review • Review and update internal policies to align with CMS and MAC requirements. • Ensure documentation reflects HIPAA-compliant practices for data access, storage, and transmission. Security Architecture • Provision Azure

	Government or AWS GovCloud environments as required. • Implement Role-Based Access Control (RBAC) and data encryption protocols. • Validate secure physical locations for mailroom if data handling and storage is needed API & Interoperability • Ensure APIs support R4 FHIR and SMART on FHIR authentication. • Conduct bi-directional testing with MACs in a sandbox environment. • Validate secure and compliant data exchange mechanisms. Testing & Validation • Perform end-to-end testing with MACs. • Document test results and remediation steps for any issues found. Documentation & Audit Readiness • Maintain detailed logs of all compliance checks, security reviews, and testing outcomes. • Prepare for potential audits by CMS or other regulatory bodies. Security Compliance Checklist Security Component Compliance Requirement Cloud Infrastructure Compliance Provision Azure Government or AWS GovCloud environment (FedRAMP, HIPAA compliant) Role-Based Access Control (RBAC) Implement least privilege RBAC with identity provider integration (e.g., Azure AD) Data Encryption Protocols Use AES-256 for data at rest and TLS 1.2+ for data in transit Secure API Integration Use OAuth 2.0, SMART on FHIR, token expiration and refresh mechanisms Portal & X12 EDI Data Exchange Ensure secure authentication, encrypted transmission (TLS 1.2+), and audit logging for all portal and X12 EDI transactions. Validate role-based access and endpoint security for MAC-facing workflows. Physical Security Controls Ensure controlled access, surveillance, and secure physical locations for mailroom as required Audit Logging Enable immutable logging for access and data exchange events Security Testing Conduct penetration testing and vulnerability assessments Incident Response Plan Document and test incident response procedures for data breaches

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Virtix Health LLC
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00043

Requested by (b)(6) on 07/28/2025 12:31

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Innovaccer Inc.
b. Doing Business As (DBA) Name(s)	Innovaccer Inc.
c. Street Address	101 Mission Street Suite 1950
d. City	San Francisco
e. State	CA
f. Zip Code	94105
g. Tax Identification Number	300839073
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Innovaccer is a privately held corporation, founded in 2014. We have a global presence and a leadership-driven corporate structure centered around our executive team. Our co-founders Abhinav Shashank (CEO) and Sandeep Gupta (COO), along with our executive leadership team which includes our Chief Medical Officer, Chief Innovation Officer, Chief Population Health Officer, Chief Technology Officer, Chief Financial Officer, and President of Customer Success, oversee the strategic direction and overall operations. These leaders collaborate across specialized domains: product, operations, clinical, technology, finance, and business development, to drive Innovaccer's mission to activate the flow of data to advance health outcomes for everyone, everywhere. Innovaccer has the following core values: -Always Do the Right Thing: Our commitment to ethical behavior is unwavering and foundational to our success. -Be a Collaborative Team Member: We prioritize the team over ourselves and collaborate to ensure long-term success. -Be Accountable: We own every task, commit fully, and follow through. -Be Purposefully Ambitious: Our ambition drives us to pursue even greater goals, pushing the boundaries of what's possible. -Making Our Customers Heroes: By building quality products, implementing effectively, providing thorough training, and offering unwavering support, we ensure their success and make them the stars of their own stories. These values reflect Innovaccer's commitment to effective, accessible, and equitable healthcare through teamwork, bold thinking, empathy, transparency, and customer-centric innovation. Innovaccer's primary line of business is healthcare technology. We specialize in delivering comprehensive health tech solutions, including data integration, analytics, and population health management. Our core product is the Innovaccer Health Cloud, a platform that unifies member data across multiple systems and care settings, enabling healthcare organizations to improve clinical, financial, operational, and experiential outcomes. Since 2014, our platform has integrated data

	from 60+ payers across lines of business (Medicaid, Medicare, Commercial) and 80+ EMRs; Our purpose-built platform seamlessly integrates Medicaid claims, clinical (EMR and HIE), and SDoH data into a normalized longitudinal member record and is engineered not only for high-fidelity data unification, but also to serve as the foundation for analytics, risk stratification, and interactive dashboards that drive population health management and targeted intervention planning. We are headquartered in San Francisco, California, with additional offices in Noida and Bangalore, India and Abu Dhabi, enabling global delivery and cross-time zone collaboration. In addition to these office locations, we maintain a distributed workforce across the United States, with remote employees located in various state, to ensure national coverage and local responsiveness.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	Alternate Site
Street Address	201 Mission St, Suite 2900
City	San Francisco
State	California
Zip Code	94105

Location Name	Headquarters
Street Address	101 Mission Street, Suite 1950
City	San Francisco
State	California
Zip Code	94105

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00043_Ownership_Innovaccer Inc Ownership Interest Listing- June 2025-CONFIDENTIAL AND PROPRIETARY
Uploaded On	7/25/2025, 12:26 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	

Title/Position	(b)(6)
Address	201 Mission Street, Suite 2900, San Francisco, CA 94105
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	201 Mission Street, Suite 2900, San Francisco, CA 94105
Business Phone Number	(b)(6)

Contact Type	Tertiary
Email Address	(b)(6)
Name	
Title/Position	
Address	201 Mission Street, Suite 2900, San Francisco, CA 94105
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00043_Licensure_Innovaccer_Incorp Document
Uploaded On	7/25/2025, 12:53 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Innovaccer Inc. has Business Associate Agreements (BAAs) in place with all of our clients, which include healthcare providers, health plans (including governmental agencies), and healthcare clearinghouses. See below for a full list of these entities (b)(4) (b)(4)

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Innovaccer's comprehensive suite of AI-powered tools and integrated workflows can transform the Original Medicare prior-authorization process from a cumbersome administrative hurdle into an efficient, transparent, and compliant operation. AI-powered solutions embed automation directly into clinical workflows, leverage advanced data aggregation, and provide real-time visibility to reduce administrative burden and control costs. These tools help providers and payers reduce manual effort, improve compliance, minimize denials, and enhance patient care coordination. Innovaccer's AI-powered tools and integrated workflows can simplify, automate, and accelerate the Original Medicare prior-authorization process. EXPERIENCE WITH MEDICARE ADVANTAGE PLANS Innovaccer services extend to approximately 630,000 people enrolled in Medicare Advantage (MA) plans. We provide analytics for risk, quality, and cost and also support compliance with interoperability for CMS-9115-F and soon CMS-0057. For example, Innovaccer collaborates with (b)(4) to support their MA and value-based care initiatives. Our platform integrates claims, clinical, and SDoH data to create a unified patient record, enabling (b)(4) to enhance care coordination and quality improvement efforts. Innovaccer's analytics tools provide insights into cost and utilization trends, supporting (b)(4) efforts to optimize performance and achieve better health outcomes. Our Prior Authorization leadership team has previous experience working with MA plans provided by Aetna, Anthem, BCBS AZ, BCBS MA, BCBS MN, BCBS NC, BCBS TN, Blues Association, Bright Health, Centene, Cigna, Devoted, Evernorth, Florida Blue, Geisinger, Health First, HCSC, Highmark, Humana, Independent Health, John Hopkins, Kaiser Permanente, Medical Mutual, Molina, MVP HealthCare, Oscar, Presbyterian, SCAN Health, UHC, and Wellmark. In addition, our clinical review partner, KFMC, works with several states to provide external review services, including MA plan determinations: Colorado Department of Regulatory Agencies Delaware Department of Insurance Kansas Department of Health and Environment Kansas Insurance Department KS Workers Compensation Missouri Department of Commerce and Insurance Montana State Auditor Commissioner of Securities & Insurance North Dakota Insurance Department Oklahoma Insurance Department Oregon Division of Financial Regulation Virginia State Corporation, Bureau of Insurance PROVIDER COPILOT: AI-POWERED WORKFLOW AUTOMATION At the heart of Innovaccer's prior-authorization solution is Provider Copilot, an AI-driven digital assistant embedded directly into the provider's workflow. Provider Copilot is designed to automate multiple steps in the provider journey, reducing administrative overhead for clinical staff and improving accuracy. Pre-Visit Preparation: Before a patient visit, Provider Copilot reviews the patient's insurance coverage, including MA plan or Original Medicare details, to determine if any services or procedures require prior authorization. This proactive identification helps avoid surprises during or after the visit. Real-Time Authorization Requirements: The tool cross-references payer-specific rules and clinical guidelines to confirm whether prior-authorization is necessary for the planned service. It provides real-time alerts to clinicians and staff, ensuring they are aware of authorization needs before ordering tests or procedures. Clinical Documentation Improvement (CDI): Provider Copilot supports providers by suggesting documentation improvements that align with payer requirements. It helps capture the necessary clinical details in the patient's chart, which is essential for successful prior authorization approval. Automated Authorization Packet Assembly: Once authorization is required, Provider Copilot automatically compiles the complete authorization packet. This includes clinical notes, relevant lab results, imaging reports, and any other documentation mandated by the MA plan or CMS guidelines. Multi-Channel Submission: Innovaccer's platform submits authorization requests through multiple channels—direct electronic data interchange (EDI) with payers, payer portals, or

	even fax—depending on payer capabilities. This flexibility ensures timely submission regardless of payer infrastructure. Real-Time Status Tracking: Providers receive continuous updates on the status of each authorization request, from submission to approval or denial. This transparency helps clinical teams manage follow-ups and avoid treatment delays. AI-DRIVEN PRIOR AUTHORIZATION AGENT Innovaccer also offers a specialized AI Prior Authorization Agent (with a human in the loop option) that integrates seamlessly with Electronic Health Records (EHR) systems and payer. This agent leverages machine learning, Robotic Process Automation (RPA), Optical Character Recognition (OCR) and Large Language Model (LLMs) to streamline the prior authorization workflow. Insurance & Prior Authorization Determination: Automatically verifies if the patient's insurance is active and checks coverage details. Once eligibility is confirmed, the agent determines whether prior authorization is required based on the patient's plan and the ordered CPT code. Clinically Indexed Knowledge Base of Payer Guidelines: We extract and clinically index payer medical necessity guidelines into a centralized, structured knowledge base. This enables the system to apply nuanced, payer-specific approval criteria during the prior authorization process and stay current with frequent policy changes. Automated Data Extraction and Clinical Review: An AI agent automatically extracts relevant clinical data from the patient's EHR, such as diagnosis codes, procedures, lab results, and physician notes, and validates it against payer specific criteria. It then reviews this data to determine if the patient meets medical necessity requirements and generates a confidence score to predict prior authorization approval. Proactive Missing Documentation Flagging: Our system intelligently identifies and flags any missing documentation required for approval, preventing common denial reasons upfront. Seamless Prior Authorization Submission and Status Updates: After review, the completed Prior Authorization packet is submitted electronically to the appropriate payer. Status updates are surfaced within the system to ensure timely tracking and follow-up. If the payer doesn't support electronic submission, the agent pre-fills the payer-specific forms for submission, eliminating manual entry errors and saving time. Caller Agent Support: AI-powered agents that perform outbound communication tasks traditionally handled by prior authorization specialists. They make phone calls to support with checking status, gather missing information, and support follow-ups when electronic options are not available Self-Learning Decision Support and Workflow Adaptation: The AI agent continuously learns from historical prior authorization outcomes and payer responses. Over time it predicts the likelihood of approval, recommends modifications or documentation when needed, and dynamically adjusts workflows, prompting the care team when payers request additional information and helping complete submissions faster. UNIFIED DATA PLATFORM FOR COMPREHENSIVE INFORMATION ACCESS A major challenge in Medicare prior-authorization is the fragmentation of data across multiple systems, EHRs, claims databases, payer portals, and others. Innovaccer addresses this with its Data Activation Platform (platform), which aggregates and harmonizes data from diverse sources into a single, comprehensive patient profile. 360-Degree Patient View: This unified view ensures that all relevant clinical, administrative, and insurance data is readily accessible to the care team when preparing prior authorization requests. Real-Time Data Updates: The platform continuously ingests real-time data feeds, enabling up-to-date eligibility verification and authorization status tracking. Interoperability: Innovaccer's platform supports industry standards such as HL7 FHIR APIs, facilitating seamless data exchange between providers, payers, and other stakeholders. ENHANCED COMPLIANCE AND REPORTING Innovaccer's tools also help MA plans and providers maintain compliance with CMS regulations and payer-specific policies related to prior-authorization. Audit-Ready Documentation: The platform ensures that all submitted authorization packets are complete, accurate, and stored securely, facilitating audits and post-payment reviews. Analytics and Insights: Innovaccer provides dashboards and reports that analyze authorization turnaround times, denial reasons, and approval rates, enabling continuous process improvement. Denial Management: When denials occur, the system flags them promptly and assists in preparing appeals with the necessary supporting documentation. BENEFITS TO PROVIDERS, PAYERS, AND PATIENTS By leveraging Innovaccer's prior-authorization tools, MA plans and providers experience multiple benefits: Reduced Administrative Burden: Automation of manual tasks frees up clinical staff to focus on patient care rather than paperwork. Faster Approvals: Streamlined workflows and real-time submission reduce delays in obtaining prior authorizations. Improved Compliance: Accurate documentation and adherence to payer rules minimize denials and audit risks. Better Care Coordination: Timely authorizations enable smoother care delivery and reduce treatment interruptions. Increased Revenue Capture: Optimized risk adjustment and coding accuracy ensure appropriate reimbursement.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with	2. Innovaccer combines a powerful data platform, rich payer-provider insights, and strategic clinical partnerships to deliver solutions for managing healthcare-specific data, automating prior authorizations, supporting pre-payment reviews, and implementing complex coverage determinations. Our Data Activation Platform (platform) integrates, normalizes, and harmonizes data from diverse sources, providing a comprehensive view of patient and population health critical for payer operations. Health Care-Specific Data Expertise Innovaccer's platform processes diverse healthcare data: Clinical Data: EHRs, labs, notes, medications, vitals, imaging. Claims Data: Professional, institutional, pharmacy, dental. Enrollment Data: Demographics, eligibility, plan info. Provider Data: Directories, credentialing, network details. SDOH Data: Social, economic, environmental health factors. PROs: Patient input on health and quality of life. Data governance ensures quality, security,

administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	and compliance with HIPAA, HITRUST, SOC 2. Experience with Applying Prior Authorizations Innovaccer automates prior authorization (PA) workflows: Data Extraction: Pulls clinical data from EHRs to reduce manual input and errors. Workflow Automation: Pre-fills forms, flags gaps, routes to reviewers. Policy Integration: Embeds guidelines to assess necessity, flag early denials. Real-Time Tracking: Dashboards for PA status visibility. Analytics: Reveals denial patterns, bottlenecks, and process improvement areas. Experience with Pre-Payment Reviews Supports utilization validation and fraud prevention: Rules Engine: Applies payer rules, coding edits (e.g., NCCI), necessity checks. Anomaly Detection: Uses ML to flag suspicious patterns. Clinical Validation: Cross-checks claims with diagnoses, treatment plans. Audit Trail: Documents review decisions for compliance and appeals. Implementing Coverage Determinations (LCDs/NCDs): Innovaccer operationalizes CMS and commercial coverage rules: Policy Digitization: Structures LCDs/NCDs for platform use. Automated Rule Application: Applies rules during PA, reviews, and claims workflows. Point-of-Care Support: Alerts providers to coverage limits to avoid denials. Compliance Monitoring: Tracks adherence, flags issues, supports appeals. EXPERIENCE WITH ADMINISTRATIVE CLAIMS DATA FROM CMS OR OTHER PAYERS/PLANS Innovaccer handles CMS and payer claims data at scale. Data Ingestion and ETL Scalable Pipelines: Ingest 837 I/P/D, flat files, APIs, and CMS formats. ETL Processes: Clean, normalize, enrich data (ICD-10, CPT, HCPCS, NDC). Data Harmonization and Linkage Unified Patient Record: Links claims, clinical, and enrollment data. MPI: Matches patient records across systems using advanced logic. Analytics and Reporting Cost & Utilization: Identify trends and service patterns. Risk Stratification: Create risk scores from claims. Performance Metrics: Evaluate providers by quality and cost. Population Health: Identify care gaps and manage chronic conditions. FWA Detection: Detects billing anomalies. Contract Monitoring: Track outcomes in value-based models. Experience with CMS Data Medicare A–D & Medicaid: Manage claims across CMS programs. Compliance: Adhere to DUA and federal privacy rules. Quality Programs: Support MIPS, ACOs, and claims-based submissions. SUBJECT MATTER EXPERTISE AND STRATEGIC PARTNERSHIPS The platform's strategy is guided by a Sr. Director of Product, Payer with: (b)(4) (b)(4) (b)(4) KFMC's advisory work with hospitals, practices, and state agencies enhances Innovaccer's real-world applicability of coverage policies and prior authorization tools. 2a Innovaccer's clinical review partner, KFMC, is CMS-certified as a QIO-like entity for Kansas under Section 1154 of the SSA. KFMC performs reviews aligned with MAC and CMS standards, including DRG validations, coding reviews, and quality assessments using LCD/NCD criteria and MCG guidelines. KFMC's work regularly interfaces with MAC policies and supports or challenges prior claims adjudication decisions. Innovaccer's Sr. Director of Product, Payer (b)(4) (b)(4) (b)(4) 2b. Innovaccer has implemented several security controls to monitor compliance with data security standards, described below. Annual Audits and External Reviews: Innovaccer undergoes annual audits and engages external consultants to assess its information security controls. These audits review policies and practices to ensure compliance. Security Awareness Training: All employees and contractors must complete mandatory annual security awareness training. This ensures adherence to protocols and helps safeguard operations. Public Cloud Security Standard: Innovaccer maintains a Public Cloud Security Standard to ensure confidentiality, integrity, and availability of data. This includes defined security requirements and controls for cloud services. Identity and Access Management (IAM) Controls: IAM controls secure the public cloud environment through centralized authentication, authorization, multifactor authentication, and privileged ID management. Data Encryption and Key Management: Innovaccer manages encryption keys per regulatory, client, or internal policies. This includes key rotation and adherence to encryption standards. Logging and Monitoring: Event logging is supported in cloud environments, with logs routed to management platforms like SIEM for analysis of security, access, and application events. Penetration Testing and Vulnerability Management: Penetration tests are conducted for cloud applications. Cloud provider patching procedures align with Innovaccer's Threat and Vulnerability Management Standard. Security Tools and Automation: Tools like DAST, SAST, and endpoint protection are used to monitor and enforce compliance with data security standards. Security Automation & DevSecOps: Security checks are embedded in CI/CD. Code fails on git push if vulnerabilities or policy violations exist. Innovaccer follows OWASP, SANS Top 25, NIST, and CIS benchmarks, using Infrastructure as Code (IaC). These controls collectively ensure Innovaccer maintains compliance with data security standards and manages information security risks effectively. Innovaccer's solution is now deployable in Amazon's AWS GovCloud (US) regions. Innovaccer's Data Security Architecture is designed in accordance with NIST guidelines and CIS benchmarks, ensuring compliance with various industry standards, including the Federal Risk and Authorization Management Program (FedRAMP). However, Innovaccer is undergoing compliance as part of the roadmap, starting with State/Gov RAMP in 2026 &

	FedRAMP in 2026/27. 2c. Innovaccer monitors compliance with HIPAA Privacy, Security, and Breach Rules through a combination of mandatory HIPAA training for individuals handling Protected Health Information (PHI), annual updates, and adherence to HIPAA security guidelines. The company ensures that all employees managing customer PHI sign a confidentiality statement and integrates this requirement as a legal clause within the Business Associate Agreement. Innovaccer has a strict data privacy policy and a formal policy regarding security breaches, overseen by a dedicated 24/7 Security Incident Response Team (SIRT) responsible for incident management. In the event of a data incident or breach, Innovaccer follows a structured response plan: 1. All employees are responsible for reporting potential security incidents to the identified SIRT members, manager, CISO, Administrative team, Security team, Corporate IT, or Infrastructure team. 2. The SIRT lead informs stakeholders about the probable incident. 3. The Chief Information Security Officer (CISO) follows guidelines for identifying the severity of the incident. 4. The CISO and SIRT investigate incidents and identify potential remediation. 5. The SIRT lead invokes the Emergency Response Plan if required. 6. The SIRT tests the systems for security and integrity. 7. The SIRT conducts a root cause analysis of the incident. 8. The SIRT prepares an incident report. 9. The SIRT lead informs stakeholders about the resumption of services. 10. The CISO collects, retains, and maintains all incident-related evidence for future use, ensuring the confidentiality and integrity of the evidence. Innovaccer ensures that all teams are knowledgeable about their respective policies and procedures, ready to act according to established protocols in the event of a breach.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	CLINICAL EXPERIENCE IN MEDICAL REVIEWS FOR COVERAGE DETERMINATIONS AND RESUBMISSIONS Through our partnership with KFMC, Innovaccer brings over five decades of review experience to ensure sound coverage determinations and credible reconsiderations. KFMC offers a valuable layer of external validation and insight through a real-world understanding of how coverage determinations and clinical guidelines are implemented in everyday care settings. KFMC has been an External Quality Review Organization (EQRO) since 1995 (30years). KFMC has been a quality improvement organization (QIO) for Medicare beneficiaries from 1982-2014 (32 years) and then became a certified QIO-like entity (11 years). KFMC has been the Utilization Review/Independent Review Organization for the Kansas Insurance Department since 2000 (25 years). Our model emphasizes specialty-matched, peer-reviewed, and evidence-based evaluations, backed by ongoing performance oversight and a credentialed reviewer network. This enables Innovaccer to deliver high-quality, defensible medical reviews that support payer and regulatory compliance. A. CLINICAL EXPERTISE IN COVERAGE DETERMINATIONS Our approach is backed by five decades of experience providing clinical medical reviews, which are essential in determining whether services are medically necessary, appropriate, and compliant with applicable coverage policies such as: Medicare National Coverage Determinations (NCDs) Medicare Local Coverage Determinations (LCDs) State Medicaid Guidelines Health Plan Medical Policies We apply evidence-based guidelines (including MCG guidelines) and payer-specific requirements to assess the clinical appropriateness of services. These reviews encompass: Inpatient and outpatient service utilization DRG validation Admission and discharge appropriateness High-dollar and outlier claim reviews Experimental/investigational procedure evaluations Pharmacy/therapeutic appropriateness Payment accuracy is automated, reviewing claims against CMS-defined standards and assisting Medicaid agencies with policy implementation that aligns with federal regulations. B. EXPERIENCE IN PEER-TO-PEER AND RESUBMISSION REVIEW MODELS Our reconsideration process for adverse determinations functions similarly to peer-to-peer review in commercial insurance settings: Reconsideration requests are accepted within 30 days of a determination. New or clarifying clinical documentation is reviewed to reassess

	medical necessity or appropriateness. The case is reassigned to a different peer reviewer with comparable specialty and clinical expertise, who was not involved in the original determination. This approach ensures objectivity, mirrors the peer-to-peer review process, and promotes confidence in the reconsideration outcome. KFMC's process adheres to URAC IRO standards, requiring that the secondary reviewer has no prior knowledge of or involvement in the original decision and is actively practicing in the relevant field. STAFFING STRUCTURE AND ACCESS TO CLINICAL EXPERTS We offer a well-structured and scalable model to provide timely, qualified clinical reviews. This includes: A. CASE REVIEW TEAM CORE MEMBERS Medical Directors: Provides clinical leadership, oversees peer reviewers, validates determinations, and reviews reconsiderations. Clinical Care Reviewers (CCRs): Nurses or other licensed clinical professionals who conduct initial case reviews and prepare clinical summaries. Review Coordinators (RCs): Verify peer reviewer credentials, manage case assignments, and ensure conflict-of-interest protocols are followed. B. PEER REVIEWER NETWORK KFMC maintains a diverse panel of more than 150 credentialed peer reviewers across 65+ specialties, including: Internal Medicine (33) Family Practice (23) Pediatrics (14) Psychiatry (13) Surgery (8) OB/GYN (8) Pain Medicine, Cardiology, Oncology, Radiology, Neurology, and others Each peer reviewer: Is board-certified and actively practicing in the relevant specialty Has a minimum of 5 years of clinical experience Has provided direct patient care within the last 3 years Undergoes primary source verification, credentialing, and re-credentialing every three years Is monitored monthly for licensure status, sanctions, or disciplinary actions KFMC also maintains credentialing and quality improvement committees to oversee reviewer performance, address complaints, and implement corrective actions as needed. C. SPECIALTY MATCHING AND ASSIGNMENT PROTOCOL KFMC rigorously matches reviewers by specialty and care setting to the case in question. Assignment protocols ensure: Reviewer expertise aligns with the clinical content of the case No organizational or personal conflict of interest exists Reviewers are not involved in claims processing, benefit administration, or plan decision-making These protocols are aligned with URAC standards for IROs, and KFMC exceeds minimum expectations wherever possible. PERFORMANCE MONITORING AND QUALITY ASSURANCE KFMC maintains a robust internal quality control (IQC) program to ensure medical review quality and integrity: Quarterly audits of peer and non-physician reviewers Tracking of clinical consistency, rationale quality, and documentation standards Performance improvement actions when issues are identified Quarterly performance summaries shared with credentialing and leadership committees KFMC's commitment to ongoing performance improvement reinforces its ability to deliver reliable, clinically sound, and defensible coverage determinations.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	4. Innovaccer's prior authorization solution integrates seamlessly with leading EHR platforms, like Epic, offering in-workflow submission, tracking, and management of authorizations through a flexible, EHR-agnostic interface. Supporting HL7 v2 and CDS Hooks standards, it ensures broad interoperability across clinical settings. Built on the Innovaccer Data Activation Platform (platform), the solution leverages standards-based, scalable, and intelligent automation to reduce administrative burden, enhance provider efficiency, support CMS-0057-F compliance, and enable timely, clinically appropriate care. STANDARDS-BASED INTEROPERABILITY Innovaccer's integration strategy adheres to industry and CMS-mandated interoperability standards, ensuring seamless data exchange between EHRs, payer systems, and CMS/MACs: FHIR APIs and HL7 v2.x interfaces enable standards-aligned access to clinical data elements (e.g., demographics, problem lists, labs, clinical notes, imaging). X12 278 EDI support ensures compatibility with payer-side systems for electronic submission and tracking of prior authorization requests and responses. This standards-first framework enables integration with major EHR platforms including Epic, Cerner, Allscripts, eClinicalWorks, Athenahealth, and others, while also supporting bidirectional communication with MACs as required by the Wasteful and Inappropriate Service Reduction (WISeR) model. ROBUST EHR INTEGRATION AND DATA NORMALIZATION Our platform is equipped with pre-built APIs and connectors to extract and normalize key data required for accurate prior authorization. Capabilities include: Automated extraction of diagnosis and procedure codes, clinical notes, and supporting documentation via rule-based logic. Mapping and transformation of data into a payer-aligned unified schema that ensures conformance with LCDs, NCDs, and other Medicare documentation and coding guidelines. Innovaccer's ability to standardize data across disparate EHR systems ensures that all submissions are accurate, complete, and audit-ready, aligning with WISeR's expectations for documentation quality and downstream clinical outcome tracking. AUTOMATED WORKFLOW AND INTELLIGENT SUBMISSION Innovaccer automates the full prior authorization lifecycle in alignment with WISeR's operational flow: Rule-based automation pre-populates authorization forms and determines supporting documentation requirements. Requests are submitted electronically to payers or routed to MACs via secure, standards-compliant interfaces. Providers receive real-time alerts and status notifications directly within their EHR, enabling prompt clinical decision-making and reducing administrative delays. This end-to-end automation reduces manual effort, supports timely decisions, and minimizes unnecessary denials—consistent with WISeR's goals for reducing waste and ensuring quality. REAL-TIME MONITORING AND STATUS TRACKING Innovaccer provides providers and administrators with a centralized dashboard to track and manage prior authorization requests across facilities, specialties, and payers. Metrics surfaced include: Affirmation and denial rates Turnaround times Resubmissions and appeal activity Common causes of non-affirmation This reporting

	layer enables providers to identify workflow inefficiencies, supports quality assurance, and can be leveraged to support CMS-required process quality metrics reporting. SCALABLE, CONFIGURABLE, AND CMS-ALIGNED The Innovaccer platform is architected for horizontal scalability and operational flexibility, essential for multi-state, multi-jurisdiction programs like WISeR: Scalable architecture to support high-volume, concurrent prior authorization transactions Configurable workflows based on payer-specific or jurisdictional requirements (including LCD/NCD variations across MACs) Support for multiple submission modes (API, portal, fax, mail), in line with CMS's requirement for backup options COLLABORATIVE ECOSYSTEM INTEGRATION Innovaccer maintains active partnerships with EHR vendors, payers, and regulatory stakeholders to ensure tight integration, rapid deployment, and continuous alignment with CMS objectives. We offer tailored implementation support to help provider organizations adapt workflows, integrate data sources, and comply with the prior authorization process as outlined in the WISeR model. 4a. We have successfully integrated with over 70 EHRs and related systems, through a variety of modalities ranging from HL7 FHIR APIs to database-level file extract and load processes. Our platform is designed for EHR-agnostic flexibility, and we are eager to connect with other EHRs with which we haven't previously integrated. Innovaccer previously integrated with the following EHR platforms: Acumen, AdvancedMD, Agastha, Allscripts, Amazing Charts, Amkai, Aprima, Athenahealth, Care Cloud, Care360, Cerner, CompuGroup Medical, Compulink Advantage 11, Criterions, CureMD, DigiChart, Echo, eClinicalWorks, Elation, eMDs, eMedPractice, Epic, Eye Care Leaders, Falcon Physician, Flatiron, Freedom EMR, GE Healthcare, GEMMS ONE, GlaceEMR, Greenway Health, Healthpac EHR powered by Sevocity, I-heal, InSync EMR/PM 9.0, Intelidox, IPatientCare, Inc., Kareo, Lifepoint health, Lytec, Lytec MD, MacPractice, Mastermind EHR V.5, McKesson, MDoffice 10.3, Medent, Medhost, Medical Transcription Billing Corporation, Medinformatics, Meditab IMS, Meditech, Meditouch, MicroMD, Modernizing Medicine, Mosaiq, Nehii, Netsmart Homecare, NexTech, NextGen, Office Practicum, OneTouch, OpenEMR, Practice Administrator, Practice Fusion, Pulse Systems, Quanum, QuestCare 360, Sevocity, SRS EHR 9, SRS Soft, STI Chartmaker, Uow, UroChartEHR, and Xolis. 4b. Innovaccer is committed to supporting CMS's vision of advancing interoperability and reducing administrative burden through full compliance with the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F). Our strategy directly supports the goals of the WISeR Model by enabling technology-driven prior authorization processes that are secure, standards-aligned, and responsive to the operational complexities of Original Medicare. API-DRIVEN COMPLIANCE AND DATA EXCHANGE To align with the interoperability mandates of CMS-0057-F and the expectations outlined in the WISeR model, Innovaccer is enhancing its FHIR-native API infrastructure to support: Patient Access API, Provider Directory API, and Payer-to-Payer Data Exchange API, as required under CMS-0057-F. FHIR R4, SMART on FHIR, OAuth 2.0, and OpenID Connect protocols to enable secure, authorized, and standards-based access to clinical and claims data. These APIs enable seamless communication between model participants, MACs, providers, and payers, ensuring transparency, timeliness, and alignment with CMS's technical expectations for data exchange and prior authorization determinations. FHIR-BASED PRIOR AUTHORIZATION AUTOMATION Innovaccer is actively developing FHIR-enabled workflows for prior authorization that are consistent with both WISeR and CMS-0057-F. These workflows include: Real-time data exchange to reduce delays in affirmations and improve turnaround times. Structured data retrieval from EHRs to populate prior authorization submissions in alignment with Medicare's NCD and LCD requirements. Integration with both provider-facing tools and MACs, ensuring streamlined operations in accordance with WISeR's dual submission path (direct or MAC-routed). This allows participants to achieve WISeR's intended balance of automation, clinical oversight, and provider communication efficiency. SECURITY, PRIVACY, AND REGULATORY CONFORMANCE Innovaccer's platform is engineered for full compliance with the HIPAA Privacy, Security, and Breach Notification Rules, and CMS security policies, as required under WISeR: FedRAMP-certified infrastructure (Deployed on AWS FedRamp Authorized GovCloud). FISMA-aligned practices. CMS Acceptable Risk Safeguards (ARS). Audit logging, encryption, and breach response protocols per CMS Risk Management Handbook (RMH) Chapter 8. These protections ensure responsible handling of Medicare beneficiary data, particularly when interfacing with MACs and managing prior authorization transactions. CONSULTATIVE COLLABORATION AND READINESS Innovaccer engages in collaborative implementation planning with payers and provider systems to support: CMS-0057-F readiness assessments. Customization of authorization workflows based on jurisdictional LCDs and MAC-specific integration. Alignment with provider outreach and "gold carding" policies outlined in the WISeR model. This approach enables efficient onboarding, streamlined coordination with MACs, and a frictionless experience for providers submitting requests. FUTURE EXPANSION AND STANDARDS SUPPORT Innovaccer is continuously investing in the expansion of its interoperability and prior authorization capabilities, in support of: Emerging standards such as USCDI+, TEFCA, and Da Vinci Implementation Guides. Expanded payer-to-payer exchange beyond the initial scope. Scalable and configurable solutions that accommodate broader Medicare administrative use cases and cross-model integration.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data	5. AI/ML TRAINING ON COMPLEX DATA SETS Innovaccer specializes in healthcare data integration and analytics. Our AI/ML capabilities involve training models on: Claims data Clinical EHR data Patient demographics Patients insurance & eligibility information

sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers.

a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met.

b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.

Payer's clinical/medical necessity rules (both commercial and government) Provider and Payer performance metrics Population health data Social determinants of health (SDOH) Prior authorization outcomes These complex, high-dimensional datasets enable the development of models for risk stratification, care gap identification, and decision support. COVERAGE DETERMINATION APPLICATIONS Innovaccer's existing AI platforms could extend to: Predicting coverage likelihood based on historical claims + MAC/LCD logic. Automating benefit verification via NLP and rules-based engines. Semantic search + clustering to align patient needs with covered services. Mapping conditions to MAC LCDs/NCDs using ontology-based matching. PLANNED AI ALGORITHMS AND FRAMEWORKS FOR WISER The following frameworks and tools would likely be used for WISeR to assess items/services coverage eligibility in near-real time, leveraging historical MAC adjudication patterns. AI Algorithms Gradient Boosted Decision Trees (XGBoost, LightGBM) – for structured claims/patient data. Transformer-based NLP models – for policy text and clinical notes (e.g., BERT variants). Graph Neural Networks (GNNs) – for modeling relationships between patients, providers, and services. Reinforcement Learning – for optimizing decisions around prior authorization and appeals. Self learning models - Based on denials and prior PA outcomes, models adapt to new learnings. Frameworks and Platforms PyTorch or TensorFlow – for model development and training. Spark MLlib / Databricks – for large-scale data processing. Scikit-learn – for baseline models and pipeline integration. ONNX / TorchScript – for model deployment. FHIR-compatible APIs – for integration with MAC systems. Data Sources Typically Utilized CMS claims and encounter data. HCPCS, CPT, ICD-10 codes. MAC-specific policy rules and LCDs (Local Coverage Determinations). Clinical decision support documents. Utilization management datasets. Supports longitudinal, rule-based, and adaptive modeling. VERIFICATION AND VALIDATION Industry Certification: Innovaccer has achieved certification from the National Committee for Quality Assurance (NCQA) through the Data Aggregator Validation (DAV) program. This ensures that its data ingestion, processing, and export meet high standards for accuracy, reliability, and compliance with programs such as HEDIS® and other quality reporting initiatives. Data Stream Integrity: Innovaccer's Health Cloud undergoes end-to-end validation, from primary source ingestion to output, ensuring the accuracy and trustworthiness of clinical data streams. This process requires adherence to rigorous NCQA process, system, and data standards. AI-Driven Analytics: The company uses advanced AI and analytics to enable real-time monitoring and risk-adjusted benchmarking, promoting high-quality, accurate, and actionable utilization management metrics. SECURITY Multi-Layered Data Protection: We use AES 256 encryption at rest, TLS 1.2 in transit, data masking, access controls, and strong endpoint/network safeguards. Compliance Certifications: Innovaccer's platforms are HITRUST CSF, HIPAA, SOC II Type II, and EHNAC certified, ensuring compliance with global and U.S. regulations on privacy, confidentiality, and security. Cloud Infrastructure: Data is securely stored in AWS and Azure regions to maintain sovereignty and local compliance. Continuous Monitoring: SIEM tools like QRadar, GuardDuty, and web firewalls ensure proactive threat detection, with RBAC and two-factor authentication in place. REGULATION AND COMPLIANCE Rigorous Audit Trails: All access to PHI is logged and retained for at least six years per HIPAA. Governance & Policy: Innovaccer maintains strict security governance with internal/external audits, vendor risk reviews, evidence tracking, and compliance frameworks aligned with NIST and CIS standards. Standardized Frameworks: Regular audits and reviews ensure ongoing alignment with evolving laws and best practices. ETHICAL AND HIGH-QUALITY UTILIZATION MANAGEMENT Metrics & Transparency: Our analytics dashboards track key metrics like readmission rates, avoidable use, cost drivers, and engagement, enabling transparent decision-making. Gap Closure & Quality: AI tools identify and close care gaps, drive performance, and support CMS-aligned quality reporting. Standardization & Interoperability: Our FHIR-enabled platform supports ethical, secure, cross-system data 5a. ENSURING ETHICAL AND HIGH-QUALITY UTILIZATION MANAGEMENT METRICS To ensure that our company's enhanced technology software meets ethical and high-quality utilization management metrics, Innovaccer's systematic approach encompasses verification, validation, security, and regulation. By integrating the strategies listed below, we ensure that our technology software is not only high-quality and efficient but also secure, ethical, and compliant with all relevant standards and regulations. 1. VERIFICATION AND VALIDATION Requirements Analysis: We thoroughly analyze and document software requirements to align with business goals and ethical standards, involving stakeholders and expert reviews. Design Verification: The design phase includes peer reviews and simulations to validate architectural soundness and workload handling. Testing Protocols: A multi-layered testing approach—unit, integration, system, and UAT—identifies and resolves defects to ensure expected functionality. Continuous Feedback: Ongoing input from end-users drives iterative updates, keeping the software relevant and effective. 2. SECURITY MEASURES Data Protection: We use advanced encryption and secure storage to safeguard sensitive data. Access Control: Robust access mechanisms limit functionality and data access to authorized personnel. Audits: Regular security audits and vulnerability scans uncover risks and enable corrective action. Incident Response: A well-defined plan ensures swift response to security threats or breaches. 3. REGULATION AND COMPLIANCE Standards Adherence: Development aligns with ISO, GDPR, and other applicable frameworks to ensure legal and ethical compliance. Ethical Governance: Established guidelines ensure responsible software development and deployment. Training: Ongoing sessions keep staff informed of regulatory changes and ethical practices, supporting a strong compliance culture. 4. QUALITY ASSURANCE Performance

	Monitoring: Real-time tools measure efficiency and ensure quality benchmarks are met. User Feedback: Surveys and direct input help identify satisfaction trends and improvement areas. Continuous Improvement: We leverage analytics and user feedback to enhance functionality and user experience. 5b. To assess and mitigate potential negative impacts of AI/ML, Innovaccer focuses on fairness, bias mitigation, data security, transparency, and continuous monitoring. Bias Detection and Mitigation Fairness Evaluation Framework: Integrated into model-building pipelines to identify and address biases. Bias Mitigation Techniques: Uses stratified sampling and oversampling to ensure diversity in training data and correct class imbalances. Labeling Bias Control: Employs multiple annotators and feedback loops for NLP-based clinical evidence extraction. Fairness Metrics Monitoring: Leverages IBM's AIF360 toolkit to measure statistical parity and equal opportunity, ensuring consistent model performance across different demographics. Historical Bias Management: Models trained on data from specific timeframes (e.g., COVID-19) undergo careful review to prevent bias from skewing predictions. Data Security and Compliance HIPAA-Compliant Data Handling: Ensures strict compliance with regulatory standards. Secure Infrastructure: Uses dedicated AWS tenants, role-based access controls (RBAC), and Access Control Lists (ACL) to restrict data access. De-Identification Techniques: Follows Safe Harbor Method and additional safeguards like data masking and tokenization to protect sensitive information. Transparency and Explainability Clinician-Centric AI Models: AI solutions are designed to support, not replace clinicians, ensuring transparent and evidence-backed recommendations. Explainable Predictions: Provides risk scores, contributing factors, and visualizations (e.g., feature importance charts) to clarify how predictions are made. Customer Visibility: Offers model performance reports and comparison files for independent validation. Continuous Monitoring and Improvement Ongoing Model Evaluation: Conducts retrospective and prospective testing to identify biases and improve performance iteratively. AI Governance & Compliance: A Strategic Advisory Board oversees best practices and policy alignment with evolving regulations. Bias Testing Before Deployment: Every model undergoes bias assessments and fairness validation before release. Feedback Loops and Collaboration Customer-Driven Refinements: Actively incorporates feedback from Customer and other partners to align AI models with real-world needs. Transparent Communication: Maintains clear updates on model performance, technology changes, and impact assessments through structured meetings and detailed release documentation. By integrating these measures, Innovaccer ensures its AI/ML tools are accurate, fair, secure, and transparent, minimizing potential negative impacts while optimizing outcomes for our customers.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	Yes

Accreditations or Certifications Document

File Name	WISeR-00043_Accreditations_#6. Accreditations and Certifications 7.25.25
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7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues.	7. Our partner's URAC-accredited review framework ensures qualified reviewers adhere to rigorous standards for fairness, timeliness, and objectivity. A robust conflict-of-interest policy requires annual disclosures from staff and reviewers, ensuring impartiality. Our corporate compliance program includes mandatory training, whistleblower protections, and regular monitoring aligned with OIG guidance. PATIENT SAFETY STANDARDS All determinations follow evidence-based guidelines (e.g., MCG, Medicare policies). Actively practicing, board-certified clinicians—matched by specialty—perform reviews to ensure accuracy. Immediate safety risks trigger escalation via a structured process involving clinical leadership and emergency coordination. Staff are trained to recognize abuse, neglect, and unsafe discharge. SUPPORT FOR PROVIDERS We ensure transparency through evidence-based decisions and a fair reconsideration process. Denials with new documentation are reassigned to a new peer reviewer. Our network of 150+ clinicians across 65+ specialties supports peer-aligned evaluations. Provider feedback is used to improve processes and inform education. PAYER ACCOUNTABILITY & PERFORMANCE MONITORING All reviews comply with CMS and Medicaid requirements. Secure systems

b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	enable full auditability. Quarterly performance reviews track reviewer accuracy, timeliness, contract compliance, and client satisfaction, supporting ongoing training and continuous improvement. QUALITY STANDARDS FOR SECURE SYSTEMS & DATA PROTECTION Our ethical framework aligns with HIPAA, HITECH, CMS rules, and Section 504. We implement the seven OIG-recommended compliance elements, with frequent audits and training to uphold CMS IS2P2 and ARS mandates. Our Quality Management System (QMS) supports: Metric-based tracking Tech-enabled workflow reviews Alignment with WISeR performance indicators (e.g., affirmation rates, timeliness, appeals) AI GOVERNANCE & CUSTOMER EXPERIENCE Innovaccer's Responsible AI Governance framework ensures: Transparency and explainability Bias detection and mitigation Human oversight for non-affirmed decisions per WISeR standards Customer experience is enhanced through: Feedback loops with providers and beneficiaries Surveys aligned with CMS expectations Complaint resolution and grievance tracking SAFETY, ETHICAL PRACTICES & INCIDENT RESPONSE We operate in FedRAMP-certified environments and comply with FISMA, HIPAA, and CMS ATO. Our incident response protocol ensures: Reporting within one hour Audit trail maintenance Root cause analysis and corrective action PATIENT-CENTRIC DESIGN Innovaccer's evidence-based tools assist providers in delivering high-value care and avoiding low-value interventions, supporting WISeR's care transformation goals. COLLABORATION & INTEROPERABILITY We partner with stakeholders through: Governance committees Design workshops and pilot programs Stakeholder interviews Our platform supports CMS-0057-F rule compliance through: FHIR-compliant APIs Real-time data exchange Automated decisioning with override paths These capabilities reduce burden, improve transparency, and align with WISeR's technology and monitoring priorities. 7a. Innovaccer's platform reflects a deep alignment with WISeR's priorities of ensuring timely, clinically appropriate decision-making, protection of beneficiary rights, and accurate claims processing while promoting transparency and accountability across the care continuum. 1. UTILIZATION MANAGEMENT (UM) DECISION-MAKING WISeR emphasizes technology-enhanced prior authorization based on clinical coverage criteria (NCDs/LCDs) and mandates human clinical review for non-affirmations. Innovaccer's platform is purpose-built to support this mandate through: Data-Driven Insights: Our analytics engine detects trends and outliers in utilization, prioritizing high-impact areas such as pain management, neuromodulation, and spinal procedures outlined in WISeR's scope. Predictive Analytics: AI/ML models trained on clinical and claims data forecast high-utilization or potentially non-compliant services, enabling preemptive intervention and smarter resource use—aligned with CMS's aim to reduce unnecessary care while preserving access. Guidelines Integration: We embed NCDs and LCDs directly into the decision engine to ensure compliance with Medicare coverage—a WISeR core requirement. Review Controls: Automated tools support affirmations; non-affirmed requests undergo clinical review to ensure medical accuracy, per WISeR Section 4 participation requirements. 2. COMPLAINTS AND GRIEVANCES HANDLING Recognizing WISeR's focus on provider and beneficiary experience, Innovaccer ensures transparency and responsiveness in all stakeholder interactions: Centralized Tracking System: A robust issue-tracking module captures all provider/supplier or beneficiary complaints, logs them systematically, and monitors their lifecycle through resolution. Automated Workflows: The platform auto-routes grievances based on urgency, type, or regulatory timelines, helping meet expectations around timeliness, communication, and fairness as highlighted in WISeR's performance measurement criteria. Root Cause Analysis: Each complaint undergoes structured analysis to identify systemic issues. This allows us to implement corrective actions and prevent recurrence, further contributing to continuous improvement and program integrity. 3. CLAIMS BILLING AND DISPUTE RESOLUTION Although WISeR model participants do not process claims directly, they play a critical role in influencing the payment lifecycle through affirmations/non-affirmations and potential prepayment medical review. Innovaccer's platform supports CMS and MACs by: Claims Processing Automation: The platform validates coverage alignment preemptively, reducing downstream denials and streamlining adjudication. Dispute Management: Tools within the platform track appeals and disputes resulting from non-affirmed decisions that lead to denied claims. We support peer-to-peer clinical review workflows and maintain full audit trails, aligning with CMS's outlined appeals and resubmission processes (Figure 1, WISeR RFA page 16). Compliance Monitoring: Built-in logic validates claims against NCD/LCDs and CMS billing standards. Additionally, real-time status tracking and audit histories allow for seamless collaboration with MACs during prepayment reviews or appeals. 4. QUALITY ASSURANCE AND CONTINUOUS MONITORING To meet WISeR's stringent expectations for quality monitoring and model evaluation, Innovaccer embeds the following QA mechanisms: Continuous Monitoring: Key metrics such as affirmation rates, response times, provider satisfaction, and appeal resolution are tracked and benchmarked continuously to inform quality improvement. Feedback Loops: Stakeholder surveys and system-triggered feedback collection are integrated, supporting WISeR's requirement for capturing provider/supplier and beneficiary experience as part of quality scoring. Training and Support: Innovaccer provides ongoing training to internal clinical staff and provider-facing teams to ensure proper interpretation of NCDs/LCDs, streamlined PA submissions, and respectful engagement with all stakeholders. This reinforces CMS's emphasis on minimizing delays and ensuring clinically appropriate decisions. 7b. Innovaccer's compliance framework is built to fully align with WISeR Model requirements, including HIPAA, FISMA, FedRAMP, CMS Acceptable Risk Safeguards (ARS), and other laws governing Medicare data use, protection, and processing. 1. REGULATORY OVERSIGHT AND LIAISON READINESS Aligned with WISeR Sections 4,

	9, and 10, Innovaccer maintains up-to-date liaison channels with: State/federal regulators Law enforcement Legal and compliance authorities This ensures: Timely incident escalation Forensic investigation readiness Direct communication for audits or enforcement actions We review contact points regularly per CMS RMH Chapter 8, reporting incidents within one hour to CMS and WISeR teams. 2. PROACTIVE CAPACITY AND PERFORMANCE PLANNING Innovaccer supports WISeR's integrity goals with: Demand forecasting via capacity models Performance benchmarks for real-time workflows Risk-based thresholds to maintain reliability These actions ensure uptime, resilience, and performance in line with CMS standards. 3. BASELINE SECURITY AND DEPLOYMENT ARCHITECTURE All systems meet baseline security mandates and CMS requirements: Secure by design: Hardened per HIPAA, FedRAMP, and FISMA Single-tenant architecture: Customer-dedicated VPCs reduce risk Cloud compliance: Hosted on FedRAMP-authorized AWS and Azure environments 4. COMPREHENSIVE SECURITY FRAMEWORK a. Perimeter & Network WAF, DDoS protection, IP whitelisting, geo-fencing, real-time monitoring, patch automation b. Product & Data Security Encryption in-transit/at-rest, IDS/IPS, DLP, XDR, role-based access, least privilege, zero trust c. Identity & Access MFA, VPN/IP-based remote access, weekly access audits, real-time deprovisioning d. Infrastructure Micro-segmentation, port protection, geo-fencing, continuous vulnerability scanning 5. SECURE SDLC All software follows a Secure SDLC with: 28-stage CI/CD pipeline Integrated SAST/DAST Code audits and compliance checkpoints 6. MONITORING, RESPONSE, AND PHYSICAL SECURITY 24/7 SOC for asset monitoring Quarterly risk assessments CMS RMH/ARS-aligned incident handling Physical controls: badge access, CCTV, secure visitor logs 7. DATA GOVERNANCE & COMPLIANCE TEAMS Internal teams oversee: Audit readiness and compliance validation HIPAA breach reporting CMS BAA adherence All PHI/PII handling complies with 45 CFR §§ 164.502(e), 164.504(e), supported by rigorous logging and incident documentation.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	This section outlines the actuarial methodology employed to estimate the potential savings from implementing a prior authorization program for specific MAC Jurisdictions, Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) related to Medicare services across selected jurisdictions. There was no data or statistics provided by CMS during this application period so we used data assets from the CMS VRDC as well as publicly available statistics that have been published by reputable organizations for Medicare Advantage Plans, which represent a comparable basis for Original Medicare. We would be happy to revise our estimates with data and assumptions provided by CMS in future application rounds. METHODOLOGY OVERVIEW Step 1: Centers for Medicare and Medicaid Virtual Research Data Center (CMS VRDC) The first phase of the methodology involved analyzing Original Medicare claims data obtained from the CMS VRDC on the six selected states from 2022-2024 for the included items and services based on associated ICD and CPT codes. We utilized a mapping of ICD and CPT to the respective LCDs and NCDs. There was a modest increase year over year from 2022, 2023 (b)(4) 2022), and 2024 ((b)(4) . We estimated that there will be a (b)(4) Year over Year growth in expenditures from 2024 through 2028. Step 2: Initial Non-Affirmation, Appeal, and Overturn Rate Estimation Next, an estimation of the potential denial rate for LCDs and NCDs was conducted. The data from the CMS VRDC indicated (b)(4) of selected LCDs and NCDs (Paid Amounts) did not have a supporting diagnosis, establishing a baseline for potential denial rate. In an effort to support a conservative estimate, the projected savings are based on a 6.4% non-affirmation rate, that was supported by a January 2025 Report by Kaiser Family Foundation (KFF), (https://www.kff.org/medicare/issue-brief/nearly-50-million-prior-authorization-requests-were-se which calculated the non-affirmation rate, appeal rate (11.7%), and overturn rate (81.7%) for Medicare Advantage Plans in 2023. Step 3: Savings Projection Potential savings were projected by applying the 6.4% non-affirmation rate to the total paid amounts to determine an initial non-affirmation rate. With the understanding that there will be a population of these non-affirmations that will be appealed, we then reduced that number by the 11.7% rate calculated by KFF. Then recognizing a portion of these appeals would be overturned, we calculated the amount that would be overturned according to the 81.7% overturn rate provided by KFF and finally subtracted this from the initial non-affirmation amount. Below we provide the total estimated prior authorization non-affirmation savings ranges for all selected states, jurisdictions, and selected LCDs and NCDs for the first Model Agreement Period (2026-2028). We provide a breakdown by year. Since Model Year 1 (2026) will be an implementation period, the figures provided are for Model Performance Year 1 (2027) and Model Performance Year 2 (2028). We then break this down by jurisdiction and by LCD/NCD for the total Model Period. Please note that these figures do not account for previous claim denial rates by MACs prior to the model, the reduction in claim volume anticipated due to a chilling effect on the market by providers, nor the adjustments to these figures for a beneficiary receiving a less costly service. SAVINGS ESTIMATES: TOTAL MODEL SAVINGS (Agreement Period 1): (b)(4) (b)(4)

	(b)(4) (b)(4) Not Available. These were not represented in the 2022-2024 data from the VRDC. Given that the CMS VRDC data indicated that 44.66% of the claims paid didn't have supporting diagnosis codes that would be required for payment, the expectation is that these numbers could be significantly higher than the low end of the range.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	We anticipate the implementation timeframe to be completed within 12 months. This accounts for the dependencies of various stakeholders involved in the implementation such as the MAC, etc. WISER MODEL – IMPLEMENTATION TIMELINE Duration: 12 Months (Phase 1), Optional Extension to 18 Months Start Date: January 1, 2026 (Assumes award notifications and contracting are completed within 5 months of the application deadline) Go-Live Target: January 1, 2027 Phases: Phase 0: Pre-Contract Activities Phase 1: Model Agreement & Technical Setup Phase 2: System Configuration & Pilot Testing Phase 3: Stakeholder Readiness & Soft Launch Phase 4: Go-Live & Post-Launch Monitoring Phase 5: Extended Optimization (Months 13–18, optional) PHASE 0: PRE-CONTRACT PLANNING (4 WEEKS) Internal Kickoff: Align internal teams and identify cross-functional workstreams. Governance Structure: Assign key roles, including the WISeR Program Manager, security lead, compliance officers, and clinical director. Preliminary Gap Assessment: Map CMS RFA deliverables to Innovaccer's existing systems. Identify gaps and define system enhancement and workflow development requirements. Document Preparation: Finalize all preparatory documents including certifications, BAA templates, MAC coordination materials, and data sharing protocols. PHASE 1: CMS CONTRACT EXECUTION & ENVIRONMENT SETUP (8–10 WEEKS) WISeR Participation Agreement Signed: Execute the CMS contract and Business Associate Agreement (BAA). HIPAA Compliance Readiness: Conduct final security audits and confirm alignment with FedRAMP, FISMA, ARS, and IS2P2. MAC Onboarding Coordination: Identify and coordinate with the assigned MAC point-of-contact. Align on APIs, file formats, and submission workflows. System Enhancements: Develop and test enhancements to support secure environment integration and API compatibility. Infrastructure Provisioning: Set up Virtual Private Clouds (VPCs), configure secure environments on AWS/Azure, and isolate MAC regions. EHR and Claims Integration Mapping: Define formats such as 837, HL7, and FHIR; map data flows and embed appropriate security layers. API & Interoperability Compliance: Validate authorization, documentation, and response APIs against CMS Final Rule (CMS-0057-F). Technical Test Plan and Training Materials: Draft a validation plan for endpoints, dashboards, and submission modules. Develop training materials based on the plan. PHASE 2: SYSTEM CONFIGURATION, AI TUNING & INTERNAL TESTING (8–10 WEEKS) AI/ML Model Finalization: Refine prior authorization models based on National and Local Coverage Determinations (NCDs/LCDs), such as skin/tissue and neuromodulators. Non-Affirmation Review Logic: Configure routing logic for clinical review and assign board-certified physicians to designated service areas (e.g., orthopedics, neurology). Gold Carding Framework: Implement rules for 90% affirmation rate and logic for periodic exemption review. Test Environment Go-Live: Launch a staging instance connected to MAC systems to validate rule engines and initial data feeds. Security & Privacy Testing: Perform penetration testing, data loss prevention checks, and SOC simulations. Prepare compliance documentation. Training of Clinical Reviewers: Provide clinical training based on NCDs/LCDs and simulate peer-to-peer review scenarios. Preliminary CMS Audit Readiness: Prepare CMS-facing documentation for compliance and audit attestation. PHASE 3: PROVIDER ENGAGEMENT & PILOT OPERATIONS (4–6 WEEKS) Provider Portal Live (Pilot): Open submission access to selected providers via direct portal and MAC-routed pathways. MAC-Participant Communication Protocol: Activate workflows for tracking IDs and claim interception. Pilot Feedback Loops: Collect structured feedback from providers through surveys, support tickets, and usage logs. Expedited Review Process Simulation: Test urgent request flows, especially for life- or health-threatening conditions. Peer-to-Peer Workflow Validation: Conduct live tests of resubmission and peer review communications. Compliance Monitoring Begins: Begin tracking time-to-decision, affirmation rates, denials, and reversals to establish a baseline. PHASE 4: FULL GO-LIVE & PERFORMANCE MONITORING (20–24 WEEKS) Full Regional Go-Live: Expand operations to all providers and suppliers in designated MAC regions. Live Clinical Reviews: Begin full adjudication of non-affirmations by licensed clinical reviewers. Data Reporting to

	CMS: Submit monthly metrics including affirmations, denials, decision turnaround time, reversals, and quality indicators. Model Payment Triggers: Start tracking cost savings from claims denied without resubmission. Appeals & Resubmission Handling: Monitor MAC appeal flows and track resubmission outcomes. Quarterly Threat Modeling & Compliance Checks: Conduct ongoing risk assessments, confirm system integrity, and report any incidents. PHASE 5: OPTIONAL EXTENDED OPTIMIZATION (20–24 WEEKS) Continuous Learning Loop: Retrain AI/ML models using real-world data from prior authorizations and adjudications. MAC/Provider Joint Optimization: Facilitate collaborative learning through webinars, feedback sessions, and performance reviews. Annual CMS Audit Preparation: Compile performance metrics, appeals data, and quality outcomes into documentation packets. Expand Item/Service Coverage: Prepare to support new services and items as CMS updates its NCDs/LCDs. System Optimization & Scalability: Scale infrastructure and clinical staffing in preparation for Year 2 growth. DELIVERABLES CHECKLIST BY CMS PRIORITY AREA The project must deliver on the following CMS priority areas: Technical Integration: Complete APIs for prior authorization submission, MAC routing, and CMS dashboard reporting. Clinical Review: Ensure trained clinical reviewers are available by item/service area with peer review and resubmission workflows. Security & Privacy: Achieve FISMA, FedRAMP, and ARS compliance. Maintain a one-hour incident response capability. Compliance & Quality Assurance: Conduct audits, provider surveys, and submit program metrics in accordance with 42 C.F.R. § 403.1110(b). Model Payment & Reporting: Provide detailed analyses of cost savings, appeals outcomes, and quality scoring. Stakeholder Engagement: Facilitate provider onboarding, MAC coordination, and monitor patient impacts. KEY INTERNAL ACTIONS FOR DATA READINESS & MAC INTEGRATION 1. Security & Privacy Compliance Sign HIPAA-compliant BAAs with CMS and/or MACs. Validate systems against HIPAA Security Rule, IS2P2, ARS, and RMH Chapter 8. Submit FedRAMP and FISMA documentation. Implement an incident response plan with alerts to CMS within one hour. Enforce encryption (AES-256), MFA, IP whitelisting, VPN access, and zero trust. Conduct security audits and pre-launch penetration testing. 2. MAC Interface Readiness Coordinate with each MAC region (J15, JL, JH, JF) and conduct onboarding. Set up routing layers for direct and indirect prior authorization submissions. Align on HL7, FHIR, 837 formats and Unique Tracking Codes. Enable claims matching logic for real-time adjudication. Activate workflows for appeals, peer reviews, and denial response processes. 3. Infrastructure & Platform Readiness Provision single-tenant VPCs for each MAC region. Establish secure ingestion pipelines for provider and MAC data. Deploy clinical review systems with real-time decision support. Configure dashboards to monitor affirmations, denial reasons, and processing times per CMS requirements. 4. Training, Governance & Attestations Establish a WISeR governance team spanning compliance, security, clinical, and data functions. Deliver HIPAA and CMS-compliance training to all team members. Train board-certified MDs on NCD/LCD usage in prior authorization workflows. Assemble annual audit and attestation packets including access logs, data maps, breach history, and compliance sign-offs. DEPENDENCIES AND RISK MITIGATION For potential MAC workflow delays, set up joint workgroups and manual fallback routing. To mitigate provider onboarding lag, offer early education, technical help, and Gold Carding incentives. To address system scaling constraints, implement a high-availability cloud architecture with auto-scaling and redundancy by November 2025. Assign a regulatory monitoring lead to stay updated on CMS and ONC changes and adapt workflows accordingly.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Innovaccer Inc.
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00066

Requested by (b)(6) on 07/28/2025 12:33

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Abridge AI, Inc.
b. Doing Business As (DBA) Name(s)	Abridge
c. Street Address	30 S 15th St, Suite 1550 PMB41901
d. City	Philadelphia
e. State	PA
f. Zip Code	19102
g. Tax Identification Number	824607710
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Abridge was founded in 2018 to power deeper understanding in healthcare. The enterprise-grade AI platform transforms medical conversations into clinically useful and billable documentation at the point of care, reducing administrative burden and clinician burnout while improving patient experience. With deep EHR integration, support for 28+ languages, and 50+ specialties, Abridge is used across a wide range of care settings, including outpatient, emergency department, and inpatient. Abridge's enterprise-grade AI platform is purpose-built for healthcare. Supported by Linked Evidence, Abridge is the only solution that maps AI-generated summaries to source data, helping clinicians quickly trust and verify the output. As a pioneer in generative AI for healthcare, Abridge is setting the industry standard for the responsible deployment of AI across health systems. Abridge was awarded Best in KLAS 2025 for Ambient AI in addition to other accolades, including Forbes 2025 AI 50 List, TIME Best Inventions of 2024, and Fortune's 2024 AI 50 Innovators.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JL Novitas; JF Noridian
5. Provide street address, city and state for all locations.	

Location Name	Pittsburgh
Street Address	6101 Penn Ave, Suite 6
City	Pittsburgh
State	Pennsylvania
Zip Code	15206

Location Name	San Francisco
Street Address	470 Alabama Street
City	San Francisco
State	California
Zip Code	94110

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00066_Ownership_Abridge Ownership Interest - 07-24-25 - Sheet1 (1)
Uploaded On	7/24/2025, 5:28 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00066_Licensure_Abridge - Series E - Seventh A&R Certificate of Incorporation (FILED) (1)
Uploaded On	7/24/2025, 3:42 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.	
N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	As a commercially available platform working primarily with large health systems, Abridge maintains a business associate agreement (BAA) with all of its customers in compliance with HIPAA. Given the length of this list, we provide a list of the top ten customer covered entities with which we have a BAA: (b)(4) (b)(4) Further disclosures are available upon request.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Abridge has developed a new approach to prior authorization that is intended to resolve requests directly at the point of care. This builds from our existing core product experience, which records a conversation between a provider and a patient, and applies AI to rapidly distill that conversation into a draft clinical note. Our new prior authorization technology applies AI on-the-fly during an encounter, drawing in prior clinical notes, payer approval requirements, and the ongoing conversation between patient and provider to dynamically prepare a prior authorization request in the appointment. Our platform can prompt a provider to collect additional information, resolving any gaps in documentation in the appointment rather than expensively afterwards. With proper integration with a payer, approvals can now happen in minutes during the appointment itself. We have been demoing this technology with a number of national payers and entering co-development relationships with them. We also intend to build on our long-standing relationships with (b)(4) (b)(4) who have benefitted from our core product and would likely be ideal candidates for adopting this new technology for prior authorization. This platform is also extensible, allowing us to flexibly create cross network data integrations that enable Abridge to have a broader picture of patient history and labs that allow more efficient prior authorization request assembly. (b)(4) (b)(4)
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National	(b)(4)

Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	(b)(4)
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	If chosen for the pilot, Abridge would collaborate with one of its existing provider customers with utilization management capacity. This would work to compliment areas where AI will not suffice for automating the prior authorization request. (b)(4) (b)(4)
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior	Abridge is currently integrated with three EHRs: Epic, Cerner, and Athena. We are intimately aware of the APIs and other interfaces supported by these platforms in part because Abridge has required a deep level of seamless integration to be successful. Drawing on existing data from the EHR has enabled the Abridge platform to generate ever richer and more informative clinical notes. Similarly, seamless "push" of Abridge clinical notes into the EHR has made for the best user experience for the clinician. The same is true with Abridge's prior authorization features, which leverage AI to assist a provider in assembling the necessary documentation at the point of care. Some requirements to receive authorization will depend not on actions taken during an appointment between provider and patient, but instead on data logged within the EHR. Our existing relationships and relationships with the leading EHRs will aid us in drawing on this information and building a solution that can facilitate prior authorization for the maximal scope of services over the long run. CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) will serve a major role in helping to accelerate our solution nationwide. As payers implement standardized prior authorization APIs and providers adopt electronic PA workflows, it will become faster to deploy Abridge to facilitate PA at the point of care rather than having to build custom integrations with each participating entity. We will support and build our technology against the standards specified in CMS-0057-F as other players in the ecosystem develop their APIs in response to the Rule throughout 2026.

authorization practices and data exchange practices.	
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	We believe that the objective of WISeR in cutting the waste due to unnecessary or inappropriate services with little to no clinical benefit is impossible without the seamless integration of ambient AI into the conversation between provider and patient. This is simply because the point of care is the best opportunity to gather all the facts relevant to a proper and accurate prior authorization determination. By the time the appointment has ended, gathering and verifying information frequently extends prior authorization processes by days and weeks. However, it has at the same time been historically impractical and burdensome to delegate prior authorization workflows onto the clinician during an appointment: authorization requirements are complex and voluminous, patient histories may not be readily logged or available, and it has been hard to accurately document in real-time all the activity taking place in an appointment. AI promises to dramatically reduce this burden. By integrating prior authorization requirements from a payer or MAC, contextual knowledge about a patient's medical history, and the live activity ongoing in a patient-provider conversation, AI can in real-time prompt a clinician to obtain the necessary information without immense cognitive burden. This "shift upstream" promises to revolutionize how prior authorization is done, resolving requests in minutes by lowering frictions to closing gaps against payer or MAC guidelines. Best of all, the AI can intelligently recognize when a procedure is being recommended that requires a prior authorization, unburdening the provider from having to recognize that this is the case. As one of the leading providers of ambient documentation in the United States, Abridge is uniquely well positioned to take on the challenge of bringing the WISeR model far upstream in the care delivery process. Our $5.3 billion valuation and nationwide footprint in the largest hospital systems in the country reflect a unique mastery of extracting technical insights from unstructured conversations between patient and provider. As mentioned in Question 2, this has included the autonomous generation of accurate ICD-10 and CPT codes leveraging proprietary fine-tuned language models. Based on our experience, (b)(4) (b)(4) (b)(4) This is the technical framework we would apply if selected for the WISeR pilot, adapting such a DAG structure to represent MAC policies. (b)(4) (b)(4) Furthermore, Abridge will bring the best practices it has gained in serving its ambient AI technologies nationwide to ensure that the systems used in the WISeR pilot can be verified, validated, secured, and regulated. We do this primarily in three ways. (b)(4) (b)(4) (b)(4) Together, these methods help us manage and mitigate any potential adverse effects of our technologies.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics,	Abridge maintains a comprehensive approach to focus on fairness, accountability, multilingual accessibility, and robustness in our platform. We have taken measures to ensure that our systems are HIPAA compliant and that we lead the industry in establishing rigorous norms for evaluating, deploying, and monitoring models in production. We focus on

and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	both quality assessment prior to deployment and procedures for monitoring quality in production. We take continued innovation in evaluation methodology just as seriously as improvement of our models. We have engineered our product to incentivize daily feedback from our clinicians and this input constantly brings to light new observations that directly inform product improvements and new desiderata that help us to expand the scope of our evaluations. With regards to state and federal regulation, Abridge ensures compliance through a comprehensive multi-layered approach. Our experienced product counseling team monitors state and federal regulations applicable to our platform and collaborates across the Abridge product, engineering, and commercial teams throughout the software lifecycle to ensure that requirements are “baked in” to the technology stack. This includes integration of legal review at the point of requirements design, as well as legal review prior to the launch of new features and products into production.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	In our preferred MAC jurisdictions of JH Novitas and JF Noridian, we estimate annual savings of $143 million and $68 million, respectively. We calculate this amount by pulling from publicly available numbers on aggregate Medicare FFS Spend within MAC jurisdictions and using NCD/LCD codes within the scope of WISeR to narrow to an addressable spend for each jurisdiction. Then, we estimate savings from this addressable amount by examining the savings typically associated with UM. We draw from several studies in JAMA, The American Journal of Medicine, Health Affairs, and the Journal of Bone and Joint Surgery to land on a benchmark of 16%. This further reduction provides a rough projection of savings, though we believe this to be fairly conservative given the unique efficiencies that might be driven through AI. This estimate additionally assumes that an appropriate arrangement would be viable whereby the Abridge platform was made freely accessible to all providers within a MAC jurisdiction, as the prior authorization solution requires that the core ambient AI product also be deployed. For completeness, outside of our preferred jurisdictions, we estimate annual savings of $31 million and $33 million in JH Novitas and J15/CGS, respectively.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	(b)(4)

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	☑
Company/Organization Name:	Abridge AI, Inc.
Certifying Individual: **Title:**	(b)(6)

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00081

Requested by (b)(6) on 07/28/2025 15:45

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Zyter Inc.
b. Doing Business As (DBA) Name(s)	Zyter Inc.
c. Street Address	2600 Tower Oaks Blvd, Suite 700
d. City	Rockville
e. State	MD
f. Zip Code	20852
g. Tax Identification Number	814088677
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Zyter,Inc. is a healthcaretechnology company whose mission is to cut administrative friction, so every patient receives timely, appropriate care. The cloudbased TruCare® platform delivers AIenabled utilization, care, and populationhealth management in one secure workflow. Who we serve: (b)(4) (b)(4) etc.), plus health systems, ACOs, and public agencies covering MA, Medicaid, Marketplace, TRICARE, and commercial lines. What we do (today): (b)(4) What we will do for CMS: Intake PAs via FHIR, EDI278, portal, or digitized fax; validate completeness; run AI triage against CMS LCD/NCD rules; route autoapprovals; escalate clinical reviews; and manage peertopeer, appeals, and pre/postpayment review with full audit trace. Value delivered: (b)(4) (b)(4) while meeting all CMS/MAC SLAs. (b)(4) (b)(4) boardcertified clinicians continuously refine performance. Governance & accreditation: Ethicsfirst culture; TruCare is NCQA Prevalidated (Health Plans, PHM, MBHO, Management), HITRUST, HIPAA, SOC2TypeII, and FedRAMPready via Palantir. All staff complete annual PHI, FWA, and CMS training. Industry recognition: MedTech Breakthrough "Best Care Management Solution," Everest PEAK Matrix "Trailblazer—Member Engagement," IDC "Leader, Care Coordination&Patient Engagement20242025." Futureready: APIfirst architecture already bidirectional with major EHRs; roadmap includes PAS, CRD, and DTR compliance for CMS0057F by

	Jan2026. (b)(4) (b)(4) These capabilities position Zyter as a proven partner to modernize utilization management, lower administrative burden, and safeguard member outcomes—fully aligned with CMS's vision for a faster, fairer priorauthorization ecosystem.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	Main Office
Street Address	2600 Tower Oaks, Suite 700
City	Rockville
State	Maryland
Zip Code	20852

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00081_Ownership_Zyter Inc COI
Uploaded On	7/24/2025, 10:49 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	2600 Tower Oaks Blvd, Suite 700, Rockville, MD 20852
Business Phone Number	(b)(6)

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	2600 Tower Oaks Blvd, Suite 700, Rockville, MD 20852
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00081_Licensure_Zyter Inc COI
Uploaded On	7/24/2025, 10:59 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.	
N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Zyter is bound to confidentiality and non-disclosure obligations that prevents it from disclosing its customers and the agreements we execute with our customers to third parties. In the event Zyter's services to its customer is subject to HIPAA compliance, Zyter executes a business associate agreement with the customer.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Our consortium unites industry leaders, including an AI-enabled utilization management and care management platform (Zyter), a secure federal-grade software infrastructure provider (Palantir), and nationally trusted clinical review organizations (AllMed and MRIoA), to transform how prior authorization and pre-payment reviews are delivered for Medicare beneficiaries. Collectively, we bring deep expertise in Medicare Advantage (MA), Medicaid, Duals, and commercial payer operations, and have designed, implemented, and operated large-scale prior authorization (PA) and medical necessity review programs across every major payer segment, including national health plans, regional Blue affiliates, and state-based managed care organizations (MCOs). Our solution delivers a comprehensive, end-to-end prior authorization workflow, from multi-channel intake (EDI, portal, fax, FHIR), through authorization request creation and medical necessity determination based on CMS LCD/NCDs and plan-specific guidelines, to final decision communication and provider notification. At the core of this workflow is Zyter SENTRY™ (Secure, End-to-End, Neural Triage & Review System) - our intelligent orchestration solution for utilization management. SENTRY drives real-time triage, surfacing clinical context and guiding next-best actions across the UM lifecycle. Affirmable cases are rapidly processed using AI-based rules, while ambiguous or non-affirmable cases are escalated to appropriate clinical reviewers. The system is trained to detect patterns of unnecessary or misaligned care and delivers clinically grounded recommendations that are defensible, explainable, and transparent. Our team brings to CMS: Proven, AI-enabled prior authorization solutions built on commercial best practices, designed to expedite approvals of medically necessary services and flag potential

low-value care. Deep clinical expertise to review the merits of each flagged case, focused on improving care quality for Medicare beneficiaries by non-affirming services that lack clinical value. Operational readiness by 01/01/2026, leveraging Palantir's FedRAMP-certified software infrastructure to ensure CMS remains on track for a successful go-live. Zyter|TruCare (Prime Contractor) An AI-first utilization and care management platform powering real-time triage and orchestration for 44M+ lives across national and regional payers. (b)(4) (b)(4) Qualifications in MA and Payer Markets: Zyter's TruCare® utilization management platform currently supports over (b)(4) including several Fortune 100 health insurers and Blue-plan affiliates. It is used by MA, Medicaid, Marketplace, TRICARE, and commercial payers to manage complex populations, high-cost procedures, and regulatory reporting requirements. (b)(4) (b)(4) (b)(4) TruCare is also used by health systems, accountable care organizations (ACOs), and public health entities, and integrates bi-directionally with leading EHRs (e.g., Epic, Cerner). (b)(4) (b)(4) that will extend its organizational accreditation to include NCQA Utilization Management across all 50 states, complementing its robust platform quality standards. Differentiating Capabilities: Proven at scale: Manages UM workflows for over 44+M members across diverse lines of business. Platform ready for 1/1/26 go-live: Live across multiple large payers with rapid configuration capability. Multi-channel intake and routing: Supports FHIR, EDI 278, portals, and digitized fax, with built-in validation and provider communication. Embedded AI triage engine: Modular, rules-based, and audit-transparent, configured for CMS and plan policies. Integrated clinical and claims review: Enables prior auth and pre-/post-payment reviews across workflows. Provider experience focused: Reduces friction with self-service tools, structured denial communication, and ABN workflows. Audit and oversight ready: Transparent decision logging with real-time CMS-reviewable dashboards. Palantir (SoftwareInfrastructure & Security) The federal government's data backbone, enabling secure, real-time, and audit-ready integration across CMS, HHS, VA, and national payers. Palantir will provide FedRAMP High–authorized infrastructure to power decision intelligence, audit trails, and end-to-end workflow integration. Qualifications in MA and Payer Markets: Palantir provides mission-critical software infrastructure for CMS, HHS, the VA, and multiple national payers. Its platforms support Medicare integrity, provider performance, claims fraud detection, and quality measurement. Palantir enables secure data integration and decision support for Humana, Aetna, and others. Differentiating Capabilities: FedRAMP High–authorized platform: NIST 800-53 compliant with robust access controls for CMS-facing workloads. Unified decision infrastructure: Integrates structured and unstructured data into immutable audit trails. Real-time interoperability: Seamlessly connects with Zyter TruCare for workflow orchestration and MAC coordination. Flexible deployment: Supports public, private, and hybrid clouds with granular, zero-trust security enforcement. AllMed Healthcare Management (Clinical Review Partner) A nationally trusted IRO with 30+ years of experience delivering high-quality, specialty-aligned clinical reviews for MA and commercial plans. AllMed will deliver peer-matched utilization reviews, appeal support, and clinical policy interpretation with fast turnaround and full CMS compliance. Qualifications in MA and Payer Markets: AllMed is URAC-accredited and supports MA, commercial, and Medicaid payers across all 50 states, delivering clinical reviews for major health plans nationwide. Differentiating Capabilities: 30+ years as a trusted IRO: 100+ specialty reviewers with national reach. End-to-end clinical operations: Nurse screening to MD oversight with 99% of determinations delivered within 24–48 hours. Gold-standard appeals: CMS-compliant internal/external documentation aligned with LCD/NCD guidelines. Scalable network: Maintains 100% internal audit pass rate, able to ramp for large volumes. Embedded compliance: Peer matching, documented rationale, and audit-ready logs. Secure infrastructure: HITRUST-based framework, encrypted VDI, and 24/7 SOC monitoring. Precision reviewer matching: 99% concordance with board-certified specialists. MRIoA (Clinical Review Partner) One of the nation's largest clinical review engines with 1,000+ board-certified reviewers, delivering millions of determinations annually. MRIoA will support rapid, high-volume clinical reviews, second-level appeals, and peer-to-peer support aligned with WISeR focus areas. Qualifications in MA and Payer Markets: MRIoA supports 900+ clients across MA, Medicaid, and commercial markets with scalable review operations and specialty depth. Differentiating Capabilities: High-volume review engine: Millions of determinations annually with 1,000+ specialists. Aligned clinical focus: Neuromodulation, musculoskeletal, chronic pain, and behavioral health. Dual-level support: Peer-to-peer and Level 2 appeals that exceed CMS standards. Advanced escalations: Structured workflows for pre-appeal validation and MAC coordination. Proven audit outcomes: High concordance and low overturn rates in CMS/MAC reviews. Industry-leading turnaround: 81% of reviews in <4 hours; 98% meet SLA, 3x faster than CMS's new benchmark. Together, our consortium offers a CMS-aligned, high-performance model for delivering scalable, accountable, and equitable prior authorization services. Each partner brings tested capabilities, Zyter's AI-first UM platform, Palantir's secure software foundation, and AllMed and MRIoA's clinical rigor. This team is uniquely equipped to help CMS stand up WISeR rapidly, reliably, and responsibly. Our solution is designed to not only identify and reduce fraud, waste, and

	abuse, but also to prevent inappropriate denials and streamline access to medically necessary care. This balance between integrity and equity is essential for a more effective and trusted Medicare system.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Our consortium brings decades of experience working with healthcare-specific data across Medicare Advantage (MA), Medicaid, and commercial payers. We have implemented and operated large-scale prior authorization (PA) and pre-payment review programs anchored in CMS medical necessity criteria and Local and National Coverage Determinations (LCDs/NCDs), managing both structured and unstructured data across eligibility, claims, documentation, and appeals. Zyter: Utilization Management Platform Zyter's AI-first TruCare® platform (b)(4) (b)(4) (b)(4) TruCare integrates AI-enabled workflows for both prior authorization and pre-payment review, (b)(4) (b)(4) (b)(4) TruCare is designed for bi-directional data exchange and integrates seamlessly with partner systems to provide claims context alongside clinical workflows, enabling reviewers to align documentation, policy, and determination in real time. Zyter can interface with MAC systems to transmit decision outcomes, facilitate documentation exchange, and maintain audit-ready logs through FedRAMP-authorized infrastructure powered by Palantir. Palantir: Data Integration, Compliance & CMS Alignment Palantir provides Foundry, i.e. its secure software infrastructure needed for our consortium. The Palantir Federal Cloud Service (PFCS) received FedRAMP High Authorization in December 2024, supporting CMS, HHS, VA, and MAC-facing applications with secure data ingestion, audit logging, and CMS-aligned reporting. Key Experience Highlights: Supports appeals automation for programs covering CMS beneficiaries Ingests and processes administrative claims data for fraud detection, coverage reviews, and savings attribution Powers data infrastructure for healthcare systems managing Medicare and Medicaid populations Transforms LCDs/NCDs into structured ontology objects for automated coding and consistent, policy-aligned decisions Offers 200+ prebuilt data connectors across systems including Epic, Cerner, and others—enabling seamless ingestion of structured and unstructured data (e.g., claims, PDFs, ABNs, clinical notes) Implements row-level permissions, HIPAA-compliant access controls, retention policies, and oversight from a dedicated HIPAA security team Palantir's ability to normalize disparate data sources and support secure analytics and orchestration aligns directly with WISeR's goals—particularly in claims attribution, downstream outcome tracking, and MAC-aligned decision transparency. Data Security & Federal Certifications Palantir: FedRAMP-High authorized (as of 12/03/2024), NIST 800-53 and HIPAA compliant. Operates with real-time audit logging, secure data ingestion, and continuous monitoring. Incident response is governed by a NIST 800-61–aligned framework with a five-step process for prompt containment and client notification. Zyter: HIPAA- and SOC 2 Type II–certified. Maintains encryption, multi-factor authentication, user access logs, annual security training, and a documented, annually tested incident response plan. Zyter operates within Palantir's FedRAMP environment to meet CMS data security expectations. AllMed & MRIoA: Maintain HIPAA-compliant infrastructures with formal SOC oversight, and adhere to federal, state, and payer-specific security protocols through regular review and audit.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	Yes

Authorizations or Certifications Document

File Name	WISeR-00081_Authorizations_Palantir Federal Cloud Service - High _ FedRAMP Marketplace
Uploaded On	7/24/2025, 11:01 PM

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Under WISeR, our consortium will deliver clinically sound and audit-ready medical reviews through a dedicated structure powered by two experienced Independent Review Organizations (IROs): AllMed and MRIoA. Both partners bring established national reach, robust clinical governance, and track records of high-quality medical necessity reviews tailored to Medicare populations. Their capabilities are complemented by Zyter's intelligent routing engine, which ensures seamless distribution of cases to the appropriate clinical resource with transparency and speed. Staffing Structure and Clinical Operations Dedicated Clinical Panels by Specialty: AllMed and MRIoA maintain deep networks of board-certified clinicians across 150+ specialties, including neurology, orthopedics, pain management, and behavioral health, areas aligned with WISeR's initial focus. Dedicated teams will be credentialed and assigned based on MAC region and service type to ensure clinical relevance and consistency. Peer-to-Peer and Appeal Support Workflows: Both organizations offer integrated peer-to-peer consultation and appeal documentation, with staffing and scheduling tools designed to meet CMS timelines and beneficiary notice requirements. Structured scripting and overturn rationales are standardized to ensure audit-ready documentation. Turnaround Time & SLA Adherence: Our partners consistently deliver determinations within 24–48 hours across MA and Medicaid contracts. For WISeR, these SLA expectations will be hard-coded into our platform's triage and escalation logic to ensure compliance. Clinical QA and Overturn Review: (b)(4) (b)(4) (b)(4) Denials that are overturned during peer-to-peer or appeal processes are flagged for internal review to continuously improve clinical guidelines and reviewer performance. Scalable Clinical Capacity: The combined capacity of our clinical partners includes 1,000+ board-certified physicians and hundreds of trained nurses and reviewers, capable of scaling rapidly to meet WISeR demand across multiple MAC regions and service lines. Zyter's platform will triage non-affirmed cases to the appropriate partner based on service type, provider characteristics, and region, while ensuring that escalations, documentation requests, and appeals are routed with audit-ready transparency. Real-time dashboards and quality metrics provide centralized visibility across all clinical determinations, enabling proactive risk mitigation and performance This model ensures that every non-affirmation determination is supported by specialty-aligned, clinically grounded expertise, delivered within tight SLAs, traceable through audit logs, and aligned to CMS and MAC expectations for accuracy, defensibility, and member protections. Importantly, this approach reflects the core of what we already do today, receiving authorizations, applying business rules, routing to the appropriate clinician for review, and leveraging the correct clinical guidelines across all our UM customers, making this a manageable and scalable lift for our team.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Our proposed solution for WISeR is powered by the integrated capabilities of Zyter's TruCare® platform atop Palantir's software infrastructure (Palantir Foundry), enabling secure, scalable, and standards-based interoperability across EHRs, provider workflows, payer systems, and CMS. Together, the platforms support multi-channel intake, real-time status updates, and traceable, structured decision data, aligned with CMS's interoperability and burden reduction goals. a. EHR Platforms and Integration Experience Zyter's TruCare® platform has been successfully integrated with leading EHR platforms, including Epic and Cerner. These integrations have enabled bi-directional workflows for prior authorization submissions, clinical documentation exchange, and real-time status updates between providers and payer systems. In current deployments, Zyter supports multiple intake channels including X12 278, FHIR, HL7v2, and digital fax. Our patented collaboration platform seamlessly integrates with the provider's EHR system, enabling real-time communication between utilization review nurses and the provider's care team. Clinicians can securely request additional information, and providers can upload the necessary documentation directly. This streamlined workflow significantly reduces delays associated with clinical information submission, resulting in faster case determinations and improved operational efficiency. While Epic and Cerner are the two primary systems with live integrations today, Zyter's architecture is API-first and highly configurable, enabling rapid expansion to other EHRs as needed. Palantir complements this with a federal-grade data integration and interoperability software stack that ingests both structured and unstructured content from: EHR systems (Epic, Cerner, Meditech, etc.) Provider and payer APIs (FHIR, CRD, DTR, PAS) Chart notes, attachments, and ABNs via document and image ingestion Palantir has supported HL7, FHIR, and SMART on FHIR integrations across federal and commercial environments and is proven in interoperating with CRD, DTR, and PAS endpoints enabling seamless bidirectional data exchange between providers, MACs, and the CMS adjudication ecosystem. b. CMS Interoperability and Prior Authorization Final Rule (CMS0057F) Readiness Both Zyter and Palantir are actively investing in capabilities aligned to the CMS-0057F mandate, with features that support both technical compliance and operational impact: FHIR Prior Authorization APIs: Zyter is incorporating FHIR-based endpoints to support electronic submission, validation, and decision delivery, reducing reliance on manual intake and fax-based workflows Document Requirement Lookup Service (DRLS): Zyter will integrate with payer coverage policy APIs to preemptively guide providers on documentation needed for specific services Near-Real-Time Determinations: Zyter's workflow engine supports prior authorization requests by delivering structured affirmation or denial responses (with clinical rationale) via FHIR as soon as the determination has been made. This enables faster decision-making and minimizes provider wait times, helping

	ensure timely access to care. Palantir's Role: Provides the secure infrastructure, data normalization, and immutable audit logs required to support FHIR payloads, continuous monitoring, and CMS-aligned reporting Together, the Zyter + Palantir stack supports a full spectrum of prior authorization interoperability, from submission through adjudication, in a way that reduces provider burden, improves accuracy and timeliness, and supports long-term CMS objectives for equity, usability, and transparency. Our architecture is designed to fully support CMS0057F compliance by January 2026, including PAS implementation for applicable services.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	At Zyter, we believe the future of utilization management lies in speed, accuracy, and equity, all delivered through a secure, orchestrated, AI-native approach. Our proposed solution for WISeR introduces Zyter SENTRY™ (Secure, End-to-end, Neural Triage & Review System) - a next-generation orchestration layer designed not only to automate workflow steps, but to create a sentinel effect: detecting inappropriate services with needle-in-a-haystack precision while accelerating affirmations safely and at scale. Unlike conventional point-solution models, (b)(4) (b)(4) that supports both prior authorization and pre-payment medical necessity reviews. This orchestration is embedded within Zyter's TruCare® platform and enhanced by Palantir's FedRAMP-High infrastructure, which securely ingests, processes, and audits structured and unstructured data, including OCR records, chart notes, ABNs, and decision history. AI-Powered Workflow Orchestration (b)(4) (b)(4) Each recommendation is grounded in CMS LCD/NCD policy, denial history, documentation gaps, and provider behavior, all visible to human reviewers in an explainable, audit-traceable format. Key capabilities include: (b)(4) (b)(4) Full integration with Palantir to extract and normalize structured and unstructured data at scale, from EHRs to scanned records Human-in-the-loop support: final decisions are always made by credentialed clinicians with AI assistance, not automation alone (b)(4) (b)(4) (b)(4) Medically necessary services are never deprioritized by automation alone All AI outputs include transparent rationales and are logged with audit trails for compliance Zyter SENTRY™ is designed not only to improve workflow efficiency, but to meet WISeR's broader goals: reduce low-value care, safeguard medically necessary services, and protect patients from delays or inappropriate denials. Our system is built with clinical safety, equity, and auditability at its core, empowered by a platform already deployed at scale, an AI capability with clinical oversight, and a data backbone trusted by CMS. We believe we are bringing in a powerful combination of implementation maturity, technical depth, and commitment to CMS's vision for ethical, AI-powered utilization management.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	Yes

Accreditations or Certifications Document

File Name	WISeR-00081_Accreditations_AllMed Healthcare Management, LLC URAC IRO 6.0_ Comprehensive Review 4.1.28 1
Uploaded On	7/24/2025, 11:05 PM
File Name	WISeR-00081_Accreditations_URAC HUM 2023-2026
Uploaded On	7/24/2025, 11:06 PM
File Name	WISeR-00081_Accreditations_NCQA UM 12.2024-12.2027
Uploaded On	7/24/2025, 11:06 PM
File Name	WISeR-00081_Accreditations_AllMed Healthcare Mangement, LLC NCQA Utilization Managment 9.6.25
Uploaded On	7/24/2025, 11:05 PM
File Name	WISeR-00081_Accreditations_NMR NCQA UM 12-17-2024 to 12-17-2027 (002)
Uploaded On	7/24/2025, 11:05 PM
File Name	WISeR-00081_Accreditations_AllMed Healthcare Management, LLC - URAC Utilization Managment 9.1.27
Uploaded On	7/24/2025, 11:05 PM
File Name	WISeR-00081_Accreditations_URAC Accreditation Certificate NMR LLC 9.1.22 - 9.1.25 (002)
Uploaded On	7/24/2025, 11:06 PM
File Name	WISeR-00081_Accreditations_URAC IRO 2023-2026
Uploaded On	7/24/2025, 11:06 PM

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Our consortium is united by a mission to protect beneficiaries and improve care by ensuring that every utilization decision is both clinically appropriate and operationally accountable. We recognize that preventing fraud, waste, and abuse is essential, but equally important is ensuring timely access to medically necessary services. Under WISeR, our model is designed not only to flag inappropriate or misaligned care but to reduce unnecessary administrative delays and ensure that deserving patients receive care without undue burden. Across Zyter, Palantir, AllMed, and MRIoA, we bring decades of experience operationalizing this balance - embedding ethics, compliance, and quality into every layer of the prior authorization and review process. a. Utilization Management, Complaints, and Dispute Resolution Utilization Management Quality Assurance: AllMed and MRIoA deliver clinically sound determinations based on CMS LCD/NCDs and plan-specific guidelines. Every reviewer is credentialed and specialty-matched; all determinations are supported by tracking mechanisms to ensure accuracy, timeliness, and audit readiness. Zyter's platform includes configurable business rules, turnaround time clocks, and escalation logic that ensures coverage determinations are completed timely, are defensible, and fair. Denials are logged with structured rationale, and overturns trigger internal root-cause reviews for continuous improvement. Complaint and Grievance Handling: All partners follow documented procedures for logging, triaging, and resolving complaints, whether from providers, beneficiaries, or CMS. Issues related to clinical accuracy, fairness, or timeliness are escalated to compliance leads, and findings are incorporated into quarterly QA reviews and corrective actions. Claims-Based Reviews and Appeals: In addition to prospective prior authorization, the WISeR model requires pre-payment review of services that were not subject to PA. Our platform and partners will support this by ingesting claims data, applying coverage logic, and generating documentation to support post-service denial or affirmation. AllMed and MRIoA produce appeal-ready packets with rationale aligned to CMS requirements. MAC submission formats, turnaround times, and clinical escalation protocols are built into their operations. Reviewers are trained to interpret claims-level details (e.g., modifiers, bundling, place of service) to ensure that determinations are accurate and aligned to both policy and billing context. b. Compliance with State and Federal Regulations CMS and Federal Program Alignment: Palantir's FedRAMP-High platform ensures end-to-end data security and compliance, supporting audit logging, traceability, and reporting across CMS and MAC workflows. Zyter's HIPAA-compliant and SOC 2–certified environment

	enforces secure data handling, access control, and vulnerability monitoring. Determination logs, documentation uploads, and appeal packet submissions are tracked in real time, with full auditability and role-based access. State-Level Flexibility and Ethics Governance: All partners bring experience across MA, Medicaid, and commercial lines of business, supporting compliance with state-specific timelines, policies, and patient protections. Annual HIPAA, FWA, and CMS-specific compliance training is mandatory for all clinical and non-clinical associates interacting with member data, including subcontractors. This ethics-first model ensures that CMS can rely on our team not only to prevent waste and abuse, but to uphold access, fairness, and transparency - ensuring that every patient gets the care they deserve, at the right time, for the right reasons.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Across the selected services and geographic regions outlined for the WISeR program, we estimate (b)(4) (b)(4) This estimate is grounded in a transparent and reproducible methodology, aligned with WISeR's core objective: reducing low-value care and improving efficiency in clinical review. Methodology and Assumptions: (b)(4) (b)(4) (b)(4) Within the four pilot regions identified in the RFA, (b)(4) We then applied a 3% downward adjustment to account for current MAC-led fraud, waste, and abuse efforts, as cited in the RFA. To calculate potential savings, we modeled three scenarios based on assumed (b)(4) (b)(4) Factors Influencing Realized Savings: Behavioral Change and Volume Attrition: We anticipate a "sentinel effect" as WISeR implementation progresses. As providers become more aware of CMS oversight and coverage enforcement, treatment patterns are likely to shift, reducing the volume of inappropriate service requests and increasing the use of evidence-based alternatives. This trend may reduce review volume in later years as gold-carding and provider education take hold. AI-Orchestrated Triage and Efficiency Gains: Our platform features an intelligent, AI-driven orchestrator that distinguishes between affirmable and suspect cases in real-time. High-confidence affirmations are routed immediately, while complex cases are escalated with embedded rationale and supporting documentation. This reduces manual review burden, enhances throughput, and improves consistency and accuracy of determinations over time. Dynamic Calibration Post-Launch: Annual savings will be revisited and refined each year, based on actual program performance, including realized denial rates, appeal reversals, provider behavior, and regional MAC-specific trends. Improved MAC Practices: We anticipate opportunities for MACs to expand their role in post-service, concurrent claims review, particularly to flag inappropriate billing and identify patterns of misuse not captured through traditional pre-service authorization. Based on these factors, (b)(4) (b)(4) Our technology-enabled operating model is designed to help CMS achieve meaningful cost savings, while upholding the core values of fairness, timeliness, and clinically appropriate access for Medicare beneficiaries.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Our team understands the urgency and complexity of launching the WISeR model by January 2026 and is fully prepared to meet CMS's expectations for secure integration with Medicare Administrative Contractors (MACs) and access to Medicare beneficiary data. We have outlined a high-level, phased implementation plan that reflects our current approach to technical, operational, compliance, and contractual readiness. This plan will serve as the foundation for a more detailed implementation roadmap that we will co-develop with CMS post-award to ensure alignment with program priorities, timelines, and evolving requirements. Phase 0: Pre-Award Mobilization (August–September 2025) We will finalize teaming agreements, establish WISeR program governance structures, and designate regional points of contact for MAC coordination. Early planning will also include alignment on credentialing and training workflows for clinical reviewers, and initial documentation preparation for HIPAA, FedRAMP, and CMS compliance. Phase 1: Solution Configuration and Test Environment Setup (October–November 2025) Secure sandbox environments will be provisioned across both the Zyter and Palantir platforms. Our teams will configure the clinical rules engine using CMS LCD/NCD mappings and initiate interface development with MAC EDI and data endpoints. This phase will include validation of case routing logic, audit logs, and role-based access controls in accordance with CMS requirements. Phase 2: Clinical and Operational Readiness (October–December 2025) We will complete credentialing and training of our clinical review teams, conduct tabletop simulations of determinations and appeals, and validate service level agreements (SLAs), QA protocols, and reporting dashboards. In parallel, security, privacy, and penetration testing will be conducted across Zyter, Palantir, and our clinical review partners to ensure full audit readiness. Phase 3: Go-Live Enablement (January 2026) We will activate secure production data flows with CMS and the MACs, begin intake of live cases, and launch clinical operations with a phased ramp-up. Early determinations will be closely monitored for audit traceability, timeliness, and quality assurance. Affirmations and denials will be submitted

	with complete, structured documentation in alignment with MAC and CMS expectations. This implementation plan reflects our current understanding of WISeR's launch timeline and technical requirements. We are committed to working closely with CMS and the MACs to refine this plan post-award, ensure coordination across all stakeholders, and deliver a secure, high-quality, and fully operational solution on day one.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	☑
Company/Organization Name:	Zyter Inc.
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00092

Requested by (b)(6) on 07/28/2025 15:46

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	AuditorIQ
b. Doing Business As (DBA) Name(s)	AuditorIQ
c. Street Address	18142 Regents Square Drive
d. City	Tampa
e. State	FL
f. Zip Code	33647
g. Tax Identification Number	334647617
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	AuditorIQ is a HIPAA-compliant AI platform built to enforce Medicare documentation compliance with full alignment to LCDs, NCDs, and CMS Articles. Our mission is to eliminate improper payments and reduce administrative burden by delivering policy-bound, structured audits that verify whether medical records support services billed under Medicare Fee-for-Service — without assumption or clinical inference (b)(4) (b)(4) (b)(4) To ensure seamless scalability and provider adoption, AuditorIQ was also architected for direct integration with electronic health records (EHRs). This allows audits to be conducted in near real-time against source documentation, reducing friction and eliminating the need for manual chart uploads. (b)(4) (b)(4) (b)(4) Across all use cases, AuditorIQ

	functions as a high-fidelity filter, bringing precision, transparency, and defensibility to Medicare audit preparation and prior authorization workflows. As CMS modernizes its documentation and prior authorization infrastructure under the WISER model, AuditorIQ stands ready to operationalize that vision — providing scalable, policy-bound audit intelligence with full clinical oversight and provider feedback mechanisms.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas

5. Provide street address, city and state for all locations.

Location Name	Admin
Street Address	18142 Regents Square Drive
City	Tampa
State	Florida
Zip Code	33647

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00092_Ownership_Board Written Consent for Stock Ownership
Uploaded On	7/24/2025, 8:59 PM
File Name	WISeR-00092_Ownership_AuditorIQ Delaware Articles of Formation
Uploaded On	7/24/2025, 8:58 PM
File Name	WISeR-00092_Ownership_Restricted Stock Purchase Agreement
Uploaded On	7/24/2025, 8:59 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	18142 Regents Square Drive, Tampa, FL 33647
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)

Name	(b)(6)
Title/Position	
Address	18142 Regents Square Drive, Tampa, FL 33647
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00092_Licensure_AuditorIQ EIN
Uploaded On	7/24/2025, 9:02 PM
File Name	WISeR-00092_Licensure_AuditorIQ Delaware Articles of Formation
Uploaded On	7/24/2025, 9:01 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	AuditorIQ is a newly launched platform developed by expert wound care clinicians and wound care revenue cycle management specialists, and does not currently hold active Business Associate Agreements (BAAs) with HIPAA-covered entities.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	AuditorIQ is a newly launched platform but benefits directly from the operational depth and payer-facing experience of its sister companies: (b)(4) (b)(4) Together, these entities have supported thousands of providers across the U.S. in navigating prior authorization workflows with Medicare Advantage plans and commercial insurers. (b)(4) we have worked extensively with major MA plans including (b)(4) various regional Medicare Advantage and Managed Medicaid plans. Our team has managed all aspects of the PA lifecycle, including: • Clinical intake and chart validation • CPT-specific authorization

	submission and tracking • Pre-service documentation review based on payer coverage policies • Peer-to-peer coordination and appeal support • Denial mitigation and root cause trend reporting These experiences have directly shaped AuditorIQ's architecture. The platform is designed to enforce policy-bound documentation validation against MAC-specific LCDs, NCDs, and CMS Articles — identifying documentation gaps that commonly lead to authorization denials or retroactive recoupments. While AuditorIQ itself has not yet contracted directly with payers, it was built from inception to support API-based integration with payer systems. This allows for direct connection to prior authorization and utilization management workflows — enabling real-time, policy-aligned chart review at scale. As CMS advances initiatives like WISER, AuditorIQ is positioned as a modern, interoperable tool for documentation compliance and PA transformation.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	AuditorIQ was designed to replicate the documentation enforcement standards used by Medicare Administrative Contractors (MACs) and is powered by a live, built-in interface with the CMS Medicare Coverage Database (MCD). The platform dynamically maps each provider's ZIP code to the appropriate MAC jurisdiction (e.g., Novitas, Palmetto, CGS) and automatically loads all active Local Coverage Determinations (LCDs), CMS Articles, and National Coverage Determinations (NCDs) applicable to the documented services. This ZIP-to-MAC logic ensures that each audit is jurisdictionally accurate and policy-specific. The system applies these rules at the CPT level per Date of Service, evaluating whether documentation supports Medicare billing and coverage under current guidelines. AuditorIQ's audit engine was developed to mirror the compliance frameworks MACs use for medical review, pre-payment audits, and post-payment claim validation — with transparent audit output, citations to CMS policy, and structured risk scoring. (b)(4) (b)(4) (b)(4) This real-world experience with Medicare Advantage and Fee-for-Service plans ensures that AuditorIQ's policy enforcement engine reflects not only the written requirements of CMS, but the practical expectations of MACs and payers as applied during chart review. (b)(4) (b)(4) our team is uniquely positioned to meet the WISER model's goals of standardizing and scaling Medicare documentation review. AuditorIQ was developed from the ground up with full alignment to the HIPAA Privacy, Security, and Breach Notification Rules. The system is deployed on a HIPAA-compliant Amazon Web Services (AWS) cloud server infrastructure, with all services configured to meet CMS and OCR standards for safeguarding Protected Health Information (PHI). Key security and compliance controls include: • Encryption: All PHI is encrypted at rest (AES-256) and in transit (TLS 1.2+). • Access Controls: Role-based permissions enforce least-privilege access to sensitive data; all user activity is logged and audited. • Audit Logging: All interactions with PHI are tracked and timestamped to ensure full traceability. • Data Segregation: Multi-tenant database structure with strict logical partitioning ensures client data is isolated and secure. • Vendor Oversight: All infrastructure and support vendors are contractually bound by Business Associate Agreements and undergo security risk vetting. • Training & Governance: Every team member undergoes HIPAA training and executes confidentiality agreements prior to accessing systems or PHI. AuditorIQ maintains an incident response and breach notification plan as required by law. Our designated Security Officer oversees this plan. While we do not currently hold FedRAMP certification, our infrastructure, technical controls, and documentation practices are aligned with NIST 800-53 guidelines, and we are actively exploring a FedRAMP compliance roadmap in support of WISER model participation.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	(b)(4)
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	AuditorIQ was specifically built with EHR integration in mind. From its earliest design phase, the platform was developed to include multiple API mapping hooks to support direct interoperability with Electronic Health Records — allowing it to pull structured chart data, push audit results, and ultimately support real-time pre-authorization decision support within provider workflows. The system's architecture includes modular endpoints for patient demographics, CPT codes, ICD-10s, wound measurements, and encounter documentation — making it flexible for integration with a wide range of clinical platforms used in outpatient and specialty settings. We are currently in technical review or API alignment planning with the following EHRs: • Intellicure • WoundExpert (Net Health) • Athenahealth • eClinicalWorks • NextGen • Cerner • Epic (via FHIR-based API) • Kareo / Tebra These integrations will enable AuditorIQ to perform real-time, policy-driven documentation audits and PA readiness scoring directly within the EHR, reducing provider burden and streamlining compliance. AuditorIQ is actively preparing to align with the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F). The platform is built on a modern API-first architecture designed to support the following objectives of the rule: • Use of FHIR-based APIs for seamless data exchange with providers and payers • Standardized representation of prior authorization requests and responses • Automated determination of medical necessity based on payer coverage rules • Timely, traceable communication of PA decisions back into the EHR workflow Our product roadmap includes full support for HHS-adopted standards including FHIR Release 4.0.1, HL7 Da Vinci Coverage Requirements Discovery (CRD), Prior Authorization Support (PAS), and Documentation Templates and Rules (DTR). These capabilities will enable AuditorIQ to function as a compliance intelligence layer between providers, EHRs, and payer systems — improving pre-service documentation quality, reducing administrative burden, and aligning fully with CMS's vision for interoperability. Additionally, AuditorIQ's integration-ready design allows it to serve both provider-side PA readiness and payer-side utilization management, making it ideal for supporting bi-directional data exchange and real-time coverage decisioning under CMS-0057-F.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	AuditorIQ leverages OpenAI's large language model (LLM) infrastructure, integrated into a proprietary policy engine that enforces CMS coverage criteria with transparency and clinical oversight. Unlike generalized AI tools, AuditorIQ was purpose-built to operationalize Medicare LCDs, NCDs, and CMS Articles using AI-assisted chart parsing and structured audit logic. (b)(4) (b)(4)

	(b)(4) (b)(4) As CMS continues to modernize utilization review, AuditorIQ provides a scalable solution that combines the power of LLMs, the precision of policy logic, and the integrity of clinical oversight.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	AuditorIQ was founded on the principle that Medicare compliance must be enforced with transparency, objectivity, and fairness. Our approach to ethics and quality is rooted in the belief that technology should support—not replace—clinical judgment, and that every audit or utilization management (UM) decision must be traceable back to an explicit CMS policy standard. From day one, the platform has been built to align with: • CMS Program Integrity goals • HIPAA security and privacy rules • State and federal audit regulations • Ethical AI and clinical oversight frameworks Our audit results are structured, citation-based, and never speculative. We apply CMS-published coverage standards (LCDs, NCDs, Articles, or "Reasonable and Necessary" if no LCD exists) using a layered clinical governance model that includes both AI logic and licensed human reviewers. a. Quality Assurance for UM Decisions, Complaints, Billing, and Disputes AuditorIQ maintains a strict clinical review protocol for all utilization management-related audits, including those used to support prior authorization (PA) or pre-payment review decisions. Our quality assurance program includes: • Dual-review model: All Red Flags (denial risk) are reviewed and approved by licensed wound care clinicians or specialty reviewers before results are finalized. • Policy traceability: Every audit flag is directly tied to a specific coverage requirement, including LCD/NCD ID, Article citation, and plain-language explanation. • Appeals support: For clients using our audit results to respond to payer denials, we provide structured language referencing applicable policy to support appeals or reconsiderations. • Complaint escalation pathway: AuditorIQ maintains a formal grievance protocol for clients who dispute audit outcomes. Disputes are reviewed by a senior compliance officer and, if needed, escalated to clinical leadership. (b)(4) (b)(4) (b)(4) AuditorIQ does not override medical decisions and does not serve as a diagnostic tool. Our sole purpose is to assess whether the documentation provided supports the service billed under Medicare policy. b. Compliance with State and Federal Regulations AuditorIQ adheres to a robust compliance framework informed by both CMS policy and federal regulations. Our state and federal compliance strategy includes: • HIPAA and HITECH compliance: All infrastructure is hosted on HIPAA-compliant AWS servers. Access controls, breach response protocols, and data encryption standards are enforced. • NIST 800-53-aligned controls: Though we do not yet

	have FedRAMP certification, our architecture is designed in alignment with federal data protection standards. • Legal and regulatory oversight: Our legal team regularly monitors CMS transmittals, MAC updates, and state-specific billing policies to ensure our audit logic reflects the most current regulatory environment. • Conflict of interest protections: As a documentation audit platform, AuditorIQ is firewall-separated from any entity performing direct billing, to prevent any incentive misalignment or ethical conflict. • Policy version control and audit trails: Every audit includes metadata indicating which CMS policies were enforced, versioned at the time of audit. This enables compliance teams to reconstruct logic for downstream disputes or appeals. Where applicable, we also work with external compliance consultants to validate our audit logic and risk scoring framework against current CMS integrity initiatives. AuditorIQ does not make clinical decisions. Our role is to ensure that what has been documented can defensibly support what has been billed — and to do so in a way that empowers providers, reduces payer burden, and ultimately protects patient access to medically necessary care. Our ethical commitment includes: • Transparency in all audit outputs • Respect for provider documentation integrity • Separation of audit from reimbursement incentives • Prioritization of fairness, education, and defensibility We welcome CMS's efforts under WISeR to modernize utilization review, and we are committed to being a compliant, policy-aligned, and ethics-first technology partner in that process.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	AuditorIQ projects substantial cost avoidance potential in the Novitas and CGS MAC regions, where advanced wound care services — including skin substitute grafts, debridement, and NPWT — are highly utilized and strictly regulated under detailed LCDs and CMS Articles. (b)(4) (b)(4) AuditorIQ audit flags, which consistently identify coverage deficiencies in roughly 1 out of 4 wound care charts audited The Financial Impact: Note, these numbers are conservative. The financial exposure is compounded by the high per-unit cost of skin substitute products. Medicare reimbursement is often based on per square centimeter, with prices varying significantly: • Common allografts: $150–$500+ per cm² • Advanced or cellular/tissue-based products: $2,000 to $5,000+ per cm² • Improper use of even 2–4 cm² could result in $1,000 to $15,000+ per claim in overpayments Metric Estimate Annual Claims Audited 20,000 – 40,000 Estimated Non-Compliance Rate 25% (conservatively modeled) Avg. Cost of Improper Payment $500 – $2,500 per flagged claim Projected Annual Savings $5M – $12M across both jurisdictions (most likely much more) AuditorIQ applies MAC-specific coverage criteria based on ZIP-to-MAC mapping, with direct enforcement of: • L35041 & A54117 (Novitas) • L33631 & A53001 (CGS) Audit results are generated at the wound/service level per Date of Service and include: • Policy-cited findings • Denial/Recoupment Risk Scores • Healing trend analysis and SOC validation Our structured audit output allows for real-time feedback to providers and seamless data exchange with MACs or delegated review entities. By targeting high-error services with high-dollar exposure, AuditorIQ is uniquely positioned to generate immediate savings and improve compliance outcomes under WISeR — starting with the regions that need it most.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	AuditorIQ is technically and operationally prepared to support WISeR implementation within a structured 4-phase plan. The platform already includes a live interface with the CMS Medicare Coverage Database (MCD), enabling jurisdiction-specific enforcement of LCDs, NCDs, and CMS Articles by provider ZIP code. As a result, clinical policy integration is already complete, and the remaining steps focus on security scaling, MAC connectivity, and formal authorization to process PHI. Phase 1: Pre-Contract Finalization (Now – Q4 2025) Objective: Finalize partnership scope with CMS, initiate privacy/security review, and document infrastructure readiness. Internal Actions: • Confirm MAC onboarding specifications and data flow expectations • Assign internal Privacy & Security Officer and MAC Integration Lead • Begin CMS Security Questionnaire and DUA documentation • Conduct gap assessment vs. NIST 800-53 moderate controls • Validate AWS-based HIPAA-compliant environment configuration • Document already-live CMS policy interface (ZIP MAC LCD/NCD) Status: Live CMS policy interface (no build needed) HIPAA-compliant cloud infrastructure (AWS) DUA prep and CMS onboarding documentation in progress Phase 2: Infrastructure & Secure Access (Q4 2025) Objective: Establish secure environment and access protocols for CMS/MAC data exchange and PHI handling. Internal Actions: • Finalize DUA submission and credentials for MAC sandbox/test environment • Configure production database segmentation for PHI isolation • Deploy logging, MFA, and audit trails per CMS security specs • Test role-based access controls and breach detection protocols • Define audit output routing for MAC-aligned review and adjudication support Security Focus: • AES-256 encryption at rest / TLS 1.2+ in transit • Real-time access monitoring and anomaly alerting • Full alignment with HIPAA and HITECH Phase 3: Pilot Validation (Late Q4 2025) Objective: Begin processing real-world sample data with MAC review alignment and clinician-supervised audit review. Activities: • Ingest test

	charts (de-identified or CMS-supplied) • Apply live CMS policy logic (already integrated) to generate audit results • Validate audit output per MAC jurisdiction and LCD-specific coverage • Route feedback to internal clinicians for quality assurance • Track compliance flag accuracy and audit traceability Oversight: • Clinical team signs off on all high-risk determinations • Security logs monitored continuously during pilot exchanges • MAC or CMS liaison provides structured feedback Phase 4: WISeR Launch (Q1 2026) Objective: Operationalize live audit deployment and real-time documentation validation at scale in conjunction with MACs. Deliverables: • Live production access for incoming PHI-based chart review • Encrypted, structured audit results shared securely with CMS/MAC endpoints • Continuous model monitoring and clinician validation • Regular CMS reporting (e.g., audit volumes, flag breakdowns, turnaround times) Ongoing Governance: • Quarterly HIPAA compliance audits • Policy refresh schedule synced with CMS transmittals • Formal incident response readiness • Prompt performance tracking to prevent drift or policy mismatch

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	AuditorIQ
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00093

Requested by (b)(6) on 07/28/2025 15:46

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Acrometis LLC
b. Doing Business As (DBA) Name(s)	Adaptive Processing Solutions
c. Street Address	1055 Westlakes Drive, Suite 300
d. City	Berwyn
e. State	PA
f. Zip Code	19312
g. Tax Identification Number	453641748
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	APS delivers decades of experience in trusted workers' compensation claims management expertise and proven technology solutions. By employing claim analytics, bill routing, and a powerful ruleset, we streamline workflow and improve adjuster efficiency. Our programs seamlessly integrate into existing claims systems, allowing us to fit the unique needs of many related businesses
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	Main office
Street Address	1055 Westlakes Drive, Suite 300
City	Berwyn
State	Pennsylvania
Zip Code	19312

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00093_Ownership_Acrometis ownership interest 2025
Uploaded On	7/24/2025, 3:54 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	1055 Westlakes Drive, Suite 300, Berwyn, PA 19312
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00093_Licensure_ACROMETIS LLC - PA GS
Uploaded On	7/21/2025, 2:54 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	(b)(4)

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	ProPeer Resources has been providing best-in-class specialty-matched clinical reviews since 1992. ProPeer has extensive experience working with Medicare Advantage (MA) plans and other commercial payers in support of prior authorization processes. Our team is highly knowledgeable in the regulatory nuances of Medicare Advantage, including strict adherence to CMS guidelines and plan-specific medical policies. We have partnered with a variety of national and regional Medicare Advantage organizations and commercial health insurance plans. While specific plan names may be subject to confidentiality agreements, our portfolio includes collaborations with several regional Medicare Advantage plan administrators as well as national insurers. Our support for Medicare Advantage and other health plans includes best-in-class core functions. ProPeer's intake team does an initial administrative triage of prior authorization request to include conflict of interest verification, appropriate same specialty clinical reviewer assigned, and validation of all components necessary to support a thorough and timely review. ProPeer's clinical reviewers have extensive training in ensuring all clinical documentation, to include medical policy language, diagnosis codes, procedure requests, and patient clinical history is taken into consideration with each clinical determination. By providing same or like specialty clinical reviewers, the highest level of clinical judgement is applied for each determination. The clinical reviewers are well researched and adept in the use of various medical criteria to include evidence-based literature, supported practice guidelines, and evidence-based procedures. ProPeer's team is seasoned in providing outbound communication with providers to obtain missing documentation to ensure the best outcome for all patients ensuring that each case represents our company mission "To improve the quality of life for all people we serve". ProPeer ensures that all determination notifications to include approvals, denials, or requests for additional information are communicated in a timely manner and in full compliance with CMS requirements for Medicare Advantage plans. Our team's experience spans both clinical and administrative components of the prior authorization process, enabling us to provide end-to-end support that improves turnaround times and reduces provider abrasion.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	- Adaptive Processing Solutions has extensive experience working with complex healthcare-specific data sets across the payer and provider ecosystems. Our capabilities span clinical, administrative, and operational data, allowing us to deliver intelligent automation, compliance-driven workflows, and data-informed decision support for our clients in the healthcare industry. Types of Healthcare-Specific Data APS routinely works with the following categories of healthcare data: • Administrative Claims Data Including 837 (institutional, professional, and dental), 835 remittance data, claim edits and denials, utilization patterns, and payer adjudication logic. • Clinical Data Sourced from electronic health records (EHRs), progress notes, diagnostic imaging, lab reports, operative summaries, and discharge documentation—both structured and unstructured. Core Competencies • Data Ingestion & Normalization APS has built robust pipelines to ingest data from diverse sources which can include CMS, payer APIs, clearinghouses, and provider EHRs. We normalize disparate formats (X12, HL7, FHIR, JSON, CSV, PDFs) into unified models for downstream processing. • Data Mapping & Standardization Expert in mapping ICD-10, CPT/HCPCS, DRG, NDC, and LOINC codes for accurate interpretation of services and clinical intent. • Natural Language Processing (NLP) & AI Advanced AI/NLP tools extract key clinical facts (diagnoses, procedures, dates, provider details) from unstructured notes. • Real-Time Data Decisioning APS platforms enable real-time bill decisioning to reduce adjuster workload and improve processing quality. a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs). - Advanced Processing Solutions does not have direct experience working with Medicare Administrative Contractors (MACs) across multiple jurisdictions to support Medicare-compliant claims processing, prior authorization workflows, medical necessity validations, and appeals management. Although we do not have direct experience, our team is well-versed in the operational and regulatory frameworks MACs administer on behalf of the Centers for Medicare & Medicaid Services (CMS). APS systems have been designed to adapt to multiple worklows and integrations

	which include CMS. Key Functional Areas of MAC Engagement 1. Local Coverage Determinations (LCD) and NCD Compliance • APS systems can integrate LCD/NCD logic into claims validation and prior authorization decision engines. • We maintain jurisdiction-specific rules and ensure that diagnosis-to-procedure mappings comply with policies. • Pre-Claim Review and Prior Authorization (PA) o APS can support Medicare PA programs such as the Review Choice Demonstration (RCD) for home health and durable medical equipment (DME) through our 3rd party relationships. 3. EDI and Direct Data Interchange • Our systems are configured to submit and receive transactions via HIPAA-compliant EDI formats (837I/P, 835, 277CA, 999, and 276/277). • APS can build and maintain secure connectivity to MAC systems for batch claims submission and real-time eligibility and status updates. . – Advanced Processing Solutions maintains both a SOC 1 Type II and SOC 2 Type II certification. c.How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach. Advanced Processing Solutions (APS) takes a proactive, layered, and policy-driven approach to safeguarding protected health information (PHI) and ensuring full compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules. As a healthcare data processor and strategic partner to both payers and providers, APS treats compliance not only as a legal obligation but as a core operational imperative. Governance & Oversight • Chief Privacy & Security Officer (CPO/ CSO): APS designates a CPO and CSO responsible for oversight of all privacy and HIPAA-related activities, supported by a cross-functional Privacy & Security Governance Committee. • Formal HIPAA Compliance Program: Anchored by policies and procedures aligned to the HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), Security Rule (Subparts A and C), and Breach Notification Rule (Subpart D). • Ongoing Risk Assessments: Annual and ad hoc HIPAA Security Risk Assessments (SRAs) are conducted in accordance with NIST 800-30 and OCR guidance. Risks are scored, prioritized, and mitigated through a tracked remediation plan. Technical & Administrative Safeguards • Access Controls: Role-based access control (RBAC), multi-factor authentication (MFA), and least-privilege access are enforced across all systems handling PHI. • Audit Logs & Monitoring: Continuous monitoring and audit trails for all systems that access, store, or transmit PHI. Alerts are triggered for anomalous behavior, such as unauthorized access or data exfiltration. • Encryption Standards: PHI is encrypted in transit and at rest using industry-standard protocols such as AES-256 and TLS 1.2+. • Secure Software Development Lifecycle (SDLC): All products and solutions go through privacy and security review gates, including code scanning, vulnerability testing, and data minimization controls. Privacy Controls & Workforce Training • Workforce Training: All APS staff, contractors, and temporary workers receive annual and onboarding HIPAA training tailored to their job function. Training includes privacy incident reporting, minimum necessary standard, and safe handling of PHI. • Business Associate Agreements (BAAs): APS maintains and enforces BAAs with all covered entities and downstream vendors who may access PHI. • Data Use Governance: APS applies minimum necessary principles, restricts use/disclosure per client contracts, and uses de-identification techniques where applicable (per 45 CFR §164.514). Breach Notification and Incident Response • Formal Incident Response Plan (IRP): APS has a well-defined IRP that aligns with NIST SP 800-61 and HIPAA Breach Notification Rule requirements. Incidents are triaged, investigated, documented, and mitigated with legal review. • Breach Risk Assessment Tool: APS uses a standardized, four-factor risk assessment to evaluate potential breaches and determine notification obligations. • Regulatory and Client Notification: If a reportable breach occurs, APS will notify impacted covered entities within the required timeframes (typically within 60 days), in accordance with HIPAA and client-specific contractual obligations. 2c. ProPeer Resources is HITRUST certified and maintains a SOC 2 Type 2 certification APS maintains a SOC 1 Type 2 and SOC 2 Type 2 certification APS follows a Breach Notification Policy which outlines the steps that should be taken if a suspected data incident or breach occurs. The procedure involves the following steps: Discovery of the Breach Breach Investigation Risk Assessment Notification to Covered Entity (or upstream business associate) if necessary Log and Maintenance of Breach Information Workforce Training
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Reviews assigned to ProPeer are assigned to same specialty reviewers that undergo extensive training to ensure all MediCare Advantage patients receive the appropriate determination based on evidence-based guidelines. ProPeer clinical reviewers are well trained and have extensive experience in conducting peer-to-peer discussions. In an effort to obtain all pertinent clinical documentation and to gain further understanding of a patient's treatment plan, many times it is necessary to contact the ordering provider and have a one-on-one clinical discussion. It is the goal of the clinical reviewer to provide maximum opportunity for contact with the ordering provider. ProPeer clinical reviewers are trained in multiple processes that assist in ensuring the highest level of successful discussion. Through these discussions, the clinical reviewer may be able to obtain additional information from the ordering provider, enabling a more sound clinical judgement decision to ensure the best possible outcome for the patient. Our foundational standards regarding peer-to-peer discussion require a minimum of 2 phone call attempts over 2 business days within jurisdictional hours. ProPeer's clinical reviewers are trained to ensure any returned calls received from the ordering provider will be returned within 1 hour or less. ProPeer ensures these peer-to-peer discussions are compliant with UPMC and regulatory standards. When applicable, if a window of opportunity is provided upon assignment of the case, the clinical reviewer is trained to make every effort to ensure attempts are made during this timeframe. To ensure a strong staffing structure to access to dedicated qualified clinicians, ProPeer has both a dedicated recruitment team as well as a dedicated credentialling team. This ensure total focus from each team to strategize and market to the appropriate talented reviewers as well as ensuring only reviewers with the best qualification are onboarded to provide review services. ProPeer's in-house clinical reviewer recruitment team, in conjunction with our credentialling department, actively recruits and sources qualified clinical reviewer candidates. Through this process, our team preliminarily ensures that the potential clinical reviewer has experience in conducting medico-legal reviews and is adept at working in an electronic environment within stringent timeliness requirements. Once interviewed and necessary verifications are vetted, each candidate is placed before our internal credentialling committee led by our medical director and key clinical and operational team members to ensure each clinical reviewer meets and exceeds all accreditation requirements standards prior to being admitted to our exclusive panel. The minimum qualifications for clinical reviewers include: Clinical reviewers must hold current, unrestricted license to practice medicine (or their discipline) in a state in the United States. Have no history of disciplinary actions, loss of privileges or sanctions that have been taken or are pending that raise a substantial question as to the clinical reviewer's physical, mental, or professional competence or moral character. All Clinical reviewers must be Board Certified, where applicable. If an M.D., D.O., or D.P.M, has board certification by a medical specialty board accepted by a state or federal government entity of the U.S or one of its territories. Clinical reviewers must be actively participating in direct patient care (active practice). Clinical reviewers must have a minimum of five years full-time equivalent experience providing direct clinical care to patients. Clinical reviewers must reside in and perform all clinical reviews in the United States (or Territories). Clinical reviewers must be able to meet required time frames for completion of review for each assigned case. Clinical reviewers must attest that they will make themselves available for all depositions and/or request for testimony relevant to a reviewed case if necessary. Clinical reviewers must participate and successfully complete identity verification process. Clinical reviewers must agree to meet the terms of ProPeer's Independent Reviewer Agreement. ProPeer's Credentialing Program includes: Primary source verification of all state medical licenses (with expiration date(s)) declared on the reviewer application. Primary source verification for state licenses is obtained directly from the applicable state licensing board's web page, which includes history of sanctions and/or disciplinary actions. Where applicable primary source verification of Specialty Board Credentials (with expiration date(s). Primary source verification of Board Certification is obtained via subscription to the American Board of Medical Specialties (ABMS), CertiFACTS Online which indicates the original date of certification, all re-certification dates, expiration date of current certification, and Maintenance of Certification (MOC) dates, where applicable. Podiatry reviewer Board Certifications are verified via the applicable Board web page. Conduct National Practitioner Database check to obtain and verify any settlements, disciplinary actions and/or sanctions. Conduct verification check to ensure that potential clinical reviewer does not participate in government reimbursement programs via the OIG Exclusion Check and SAM Excluded Parties List. Verification of active practice requirement based on malpractice insurance level of coverage to meet practice standards and DEA validation if a prescribing clinician. Identity Verification process. The Independent Reviewer Application requires the reviewer to declare and attest to his or her professional experience, including complete work history and dates providing direct patient care. Once the clinical reviewer candidate submits all documents required and the credentialing department completes all required components, the clinical reviewer candidate is included in the next available Credentialing Committee meeting. The Credentialing Committee consists of our Medical Director, VP of Operations, Director of Credentialling, Director of Clinical

	Management, and Director of Operations. All aspects of the candidate's application are reviewed and considered, including clinical and administrative components, and their timeliness of task completion and communication via electronic mail. The Credentialing Committee must reach majority decision for a candidate to be admitted on to the panel. Our medical director maintains final decision authority within the committee. Once the Credentialing Committee has authorized entry on to the panel, ProPeer conducts a live video training with the clinical reviewer. The training includes ProPeer reviewer policies/expectations, conflict of interest training, prohibition of financial incentives training, URAC review standards, and portal orientation. Upon completion of their training, our medical director requires the clinical reviewer to conduct 5 mock cases to be completed for quality assessment review. Based on these 5 mock cases, our medical director will determine whether additional training is needed or if the clinical reviewer is ready to begin live case review. When a clinical reviewer begins live case review, our medical director will review the clinical reviewer's first 5 cases prior to submission to the client in an effort to ensure the highest level of quality. ProPeer chooses to exceed NCQA/URAC recredentialing requirements by conducting this effort on an annual basis for all clinical reviewers as opposed to the required 3-year recredentialing standard set forth through accreditations This effort is duplicative to the initial credentialing process to ensure all documents are re-verified, renewed, and obtained by our in-house credentialing team.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	While Advanced Processing Solutions (APS) has not yet established direct integrations with Electronic Health Record (EHR) platforms, we are fully prepared and technically equipped to do so in collaboration with clients and EHR vendors. Our team has extensive experience supporting EHR-enabled providers through adjacent systems and workflows, and our infrastructure is designed to be interoperable, standards-based, and scalable. EHR Integration Readiness APS has built our platform using modern, industry-standard technologies that support seamless integration with a wide range of EHRs via: • FHIR® and HL7® Standards APS's platform is FHIR-ready and capable of integrating with EHRs that expose APIs for patient data, clinical documentation, and order entry. • SMART on FHIR App Compatibility Our architecture supports SMART-on-FHIR applications that can embed APS functionality within EHR user interfaces, enabling clinicians to initiate and track PAs without leaving their workflow. • EDI, SFTP, and API-Based Data Exchange APS can ingest and return structured data files through secure, configurable pipelines—allowing us to support PA workflows even without direct embedded integration. a. Please also include a list of EHR platforms your application or suite is compatible with. While Advanced Processing Solutions (APS) has not yet established direct, embedded integrations with Electronic Health Record (EHR) platforms, our technology platform is fully designed and ready to integrate with a wide range of EHR systems through industry-standard protocols. Our experience working alongside EHR-enabled providers, combined with our interoperability-focused infrastructure, enables APS to effectively support prior authorization workflows within clinical environments. b.Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices. Advanced Processing Solutions (APS) is fully aligned with the intent and technical requirements of the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F). Our strategic roadmap includes both current capabilities and future enhancements that directly support improved data sharing, prior authorization (PA) transparency, and burden reduction for payers, providers, and patients.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met.	Advanced Processing Solutions has deep experience in developing and training Artificial Intelligence (AI) and Machine Learning (ML) models on complex healthcare datasets to support coverage determinations, prior authorization workflows, and clinical decision automation. Our approach centers on using AI to reduce administrative friction, improve compliance, and enable faster, more consistent determinations—directly aligning with the goals of WISeR. Experience Training AI/ML Models for Coverage Determinations APS has trained supervised and semi-supervised ML models using multi-modal healthcare datasets including: • Structured Claims and Eligibility Data: ICD-10, CPT, HCPCS, DRG, revenue codes, NPI-level data, utilization history, and payer rules. • Unstructured Clinical Data: progress notes, diagnostic imaging reports, operative summaries, and supporting documentation extracted using Natural Language Processing (NLP). a.Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. Advanced Processing Solutions is committed to delivering high-quality, compliant, and ethically sound technology solutions to support multiple functions. Our governance model incorporates multi-layered processes for verification, validation, security, and ethical use, ensuring the integrity and fairness of our workflows. 1. Our software development lifecycle (SDLC) includes robust quality controls to ensure that logic and workflows meet clinical and regulatory standards: • Clinical Policy Validation: All algorithms and workflows are cross-referenced with guidelines and policies to ensure accuracy. • User Acceptance Testing (UAT): end-users and compliance stakeholders test logic to verify accuracy, appropriateness, and usability before production deployment. • Ongoing Regression Testing: Regular testing is conducted to validate that updates, including new policy rules or coverage

b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	changes, do not introduce performance regressions or compliance issues. 2. APS is fully committed to HIPAA compliance and broader data privacy and cybersecurity requirements: • HIPAA Security Rule Compliance: Technical, administrative, and physical safeguards are implemented, including: o Role-based access control o Data encryption (in-transit and at-rest) o Audit logging and anomaly detection • Third-Party Risk Management: We assess and monitor any integrated or third-party services (e.g., EHRs, APIs) to ensure secure interoperability. • Vulnerability and Penetration Testing: Regular third-party security assessments and code reviews are conducted to prevent unauthorized access or data leakage. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI. At Advanced Processing Solutions , we recognize that while automation and artificial intelligence (AI) offer significant benefits in efficiency and consistency, they must be applied responsibly and transparently—especially in clinical and administrative decision-making. Our approach is designed to anticipate, monitor, and mitigate potential adverse effects of automation, ensuring that technology enhances rather than hinders equitable and ethical healthcare delivery. o Human-in-the-Loop Oversight – APS maintains a "human-in-the-loop" (HITL) framework for Automated-assisted decision-making. This ensures that: • Clinical decisions influenced by automation—are reviewed and approved by qualified users when necessary. • Users always have manual override capabilities in case of discrepancies or uncertainties flagged APS. • Automated decisions that may result in a denial of payments are reviewed for accuracy and compliance prior to final determination. This approach prevents overreliance on automation and upholds patient safety and fairness. o All Automated-driven tools are built with explainability and auditability in mind: • Every automated recommendation is accompanied by a clear rationale. • Users have access to explanatory notes, justification, and rule traces for each automated output.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	(b)(4)

Accreditations or Certifications Document

File Name	WISeR-00093_Accreditations_URAC IRO 2027
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7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Our compliance program is designed to promote a culture of accountability and transparency across all business functions. Quality standards are embedded in our clinical review protocols and operational workflows to support evidence-based decisions, ensure consistency in service delivery, and uphold the integrity of the review process. By fostering collaborative relationships with providers, payers, and clients, we strive to maintain the highest standards of care, compliance, and mutual accountability. Team Members are expected to act ethically, honestly, and with the highest standard of personal integrity always in the performance of their job responsibilities. Team Members must comply fully with federal, state, and local laws and regulations governing the Company's operations and must conduct their business affairs according to the highest legal and ethical standards. ProPeer maintains a code of ethical conduct that includes ethical principles, reporting mechanisms for unethical conduct and actions taken when unethical conduct is identified. Team Members are to report any actual or potential violations of applicable laws or regulations and any unethical, dishonest, or improper conduct. Violation of this policy may subject a Team Member to disciplinary action, up to and including termination. The Code of Conduct is reviewed and attested by Team Members at time of hire and annually thereafter. ProPeer also maintains consumer safety protocols to respond on an urgent basis to situations that pose an immediate threat to the health and safety of consumers. All ProPeer Team Members and Clinic Reviewers are instructed to notify their Supervisor immediately upon discovery of any situation that is or may pose a threat to the health and safety of a consumer. Management is then notified to then in turn notify the appropriate client representative. Possible consumer safety situations may include a provider of service practicing outside his/her scope of licensure, discovery of potential harmful prescribed drug interactions, undue delay of treatment, misdiagnosis by consumer's provider of service or potential consumer suicide. ProPeer's management conducts regular staff training on

	Consumer Safety and documents applicable situations and actions taken in the notes field of the database record. 7a.Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. ProPeer has an extensive Quality Assurance Program that effects all facets of the review process and our organization. This dedicated team ensures that ProPeer's reviews and practices reflect best-in-class quality. The Quality Assurance nurse team reviews 100% of all clinical reviews to ensure that all reviews are evidence based. The review ensures that all questions have been addressed and answered and that appropriate references have been cited for each recommendation or determination. ProPeer's Medical Director ensures that medical review and medical treatment guidelines are reviewed annually and are in compliance with the current appropriate jurisdictional requirements. ProPeer's Medical Director also conducts 10% review of all cases submitted and a full quality check on new reviewers on their first five cases. In order to ensure that ProPeer issues timely notices as required by each state jurisdiction, assigned clerical and professional staff maintains a regulatory log of notice requirements by jurisdiction and issue notices as prescribed by applicable regulations. All complaints and grievances or any disputes are monitored and tracked by the Director of Operations and Operations Manager. ProPeer will respond to any complaints within 5 days from the date the complaint was received, or a defined timeframe based on client requirements. If additional information is required to fully investigate the complaint, the 5-day clock starts on the day that all required information is received. ProPeer will inform the client of the final result either verbally or in writing. Avenues will be provided to seek further review if an additional complaint review process is available. 7b. Please provide any details related to approaches to ensure compliance with state and federal regulations. ProPeer manages a regulatory compliance program that tracks applicable jurisdictional laws and regulations, audits compliance with applicable jurisdictional laws and regulations, responds to detected risks, problems and incidents related to regulatory compliance and takes appropriate action to prevent future occurrences. ProPeer Compliance department staff regularly monitors state legislation and regulations to maintain compliance in all applicable states. This is accomplished in part by utilization of LexisNexis where the compliance staff receives and analyzes regular updates on all state and federal legislative activities affecting our review programs. Further, ProPeer's Compliance department utilizes its corporate membership benefits in national trade organizations, such National Association of Independent Review Organizations (NAIRO) and American Association of Payers Administrators and Networks (AAPAN), to supplement internal regulatory monitoring. These organizations offer collective knowledge of industry experts from around the country and employ a proactive approach in identifying and resolving regulatory compliance issues related to the provisions for independent review organization (IRO), independent dispute resolution (IDR), health utilization management (HUM), and workers compensation utilization management (WCUM) review services. The Compliance department then discusses with and disseminates relevant regulatory and legislative changes to and partners with other affected departments to ensure that any needed policy or process changes resulting from regulatory or legislative changes are implemented. ProPeer further ensures compliance with applicable state and federal laws and regulations by performing periodic audits. Audited areas include but are not limited to state industry licenses and state business registrations. When variances or non-conformities are identified through internal auditing and/or monitoring, the findings are promptly presented to senior leadership for review and recommendation for corrective action. Senior leadership will assign actions for management staff to carry out. ProPeer also maintains an Affirmative Action Plan (AAP) in accordance with federal regulations. The plan is reviewed and updated annually to support equal employment opportunity, ensure nondiscrimination in hiring and promotion practices, and identify actionable steps toward a diverse and inclusive workforce. As part of our HR compliance infrastructure, ProPeer regularly audits personnel practices, hiring records, and compensation data to ensure adherence to applicable federal and state employment laws, including those enforced by the EEOC, OFCCP, and Department of Labor. Compliance training is provided to all Team Members at the time of hire and on an annual basis, including specialized instruction for managers to ensure consistent application of employment policies, regulatory requirements, and ethical practices. Our approach emphasizes proactive communication between Compliance, HR, and operational teams to ensure timely response to evolving regulatory changes and workforce-related compliance risks.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Cost containment efforts such as utilization management and retrospective bill review have proven track records with respect to cost savings. Cost saving average from as low as 7% up to 44% based on the insurance vertical. We however expect to see between 9-17% cost savings with our program at a minimum. This range represents variances that exist across multiple jurisdictions and the variance also represents differences in the various healthcare specialty areas. Some programs are much more transparent and would reflect lower levels of savings while other more complex, less transparent areas would reveal higher levels of savings.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in	ProPeer stands ready to offer implementation efforts immediately. Technology integration may take up to 90 days or more depending on the MACs availability, technology staffing and willingness to move quickly for this program. ProPeer utilizes both internal and external resources to achieve rapid response while also maintaining high levels of quality and security. Cyber security, HIPAA and sensitive Medicare beneficiary information is of highest

accordance with HIPAA and other applicable privacy and security laws.	importance and we will work diligently to establish the secure means of digital health information transfers and will be compliant with ALL state and federal information security regulations.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Acrometis LLC
Certifying Individual: **Title:**	(b)(6)

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00115

Requested by (b)(6) on 07/28/2025 15:49

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Anterior, Inc.
b. Doing Business As (DBA) Name(s)	Anterior
c. Street Address	875 6th Ave STE 1202
d. City	New York
e. State	NY
f. Zip Code	10001
g. Tax Identification Number	981665266
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Anterior is a clinician-led healthcare technology company committed to reducing wasteful and low-value care through safe, policy-aligned artificial intelligence. Our platform, Florence, enables health plans to automate and accelerate prior authorization and medical necessity reviews, improving speed, accuracy, and transparency. Backed by Sequoia, NEA, and the CEO of Microsoft AI, Anterior has raised $65M to lead AI-enhanced utilization management. Florence interprets and applies Medicare coverage policy—including NCDs, LCDs, and the Medicare Benefits Policy Manual—in real time. It processes structured and unstructured clinical data, applies medical necessity criteria, and surfaces explainable reasoning with policy citations. This allows automation of the majority of affirmations while escalating complex cases to licensed clinicians. Florence in Action: 99.24% F1 accuracy on affirmations 74% time savings for clinician reviewers Real-time turnaround in 155 seconds (b)(4) (b)(4) (b)(4) All non-affirmed cases are escalated for clinician review in alignment with CMS's affirmation-only guidance. This hybrid model ensures clinical oversight, equity, and transparency. To strengthen our AI-powered approach, Anterior partners with HealthHelp, a URAC- and NCQA-accredited specialty benefits manager. HealthHelp brings 20+ years of experience in Medicare Advantage, Medicaid, and commercial plans, offering: Board-certified physicians and licensed nurses across WISeR service lines Peer-to-peer reviews, appeals, and CMS-aligned protocols QA systems with root cause analysis and performance tracking In a Medicare Advantage deployment for 550k members, Anterior and HealthHelp achieved 99.24% F1 accuracy, 100% precision, 98.44% recall, and 155-second average approvals. Non-affirmed cases were escalated to HealthHelp's clinicians for timely resolution, improving member and provider experience. Anterior has already deployed Florence for

	high-impact WISeR categories, including: Epidural Steroid Injections (L39015, L39242, L36920) Cervical Fusion (L39741, L39762, L39793) Each determination is documented, explainable, mapped to policy, and overturnable. We support full auditability, oversight, and appeals. Quality assurance teams monitor determinations for bias, safety, and consistency. Founded by clinicians, Anterior embeds licensed professionals across its teams and advises the URAC AI Healthcare Advisory Committee. We engage with AHIP and member plans to align with public policy goals and industry needs. We are preparing for FedRAMP Moderate and CMS-specific ATO certifications and are ready to support single-tenant GovCloud deployments to meet WISeR compliance needs. If selected, we are eager to collaborate with CMS and CMMI to meet WISeR's expectations for safe, scalable, accountable AI.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas

5. Provide street address, city and state for all locations.

Location Name	Headquarters
Street Address	875 6th Ave STE 1202
City	New York
State	New York
Zip Code	10001

Location Name	US Legal Correspondence
Street Address	169 Madison Ave #2408
City	New York
State	New York
Zip Code	10016

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00115_Ownership_Anterior Ownership Interests
Uploaded On	7/25/2025, 11:26 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary;Secondary
Email Address	(b)(6)
Name	

Title/Position	(b)(6)
Address	875 6th Ave STE 1202, New York, NY 10001
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	875 6th Ave STE 1202, New York, NY 10001
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00115_Licensure_Certificate of Incorporation (US)
Uploaded On	7/25/2025, 11:31 PM
File Name	WISeR-00115_Licensure_Anterior Name Amendment
Uploaded On	7/25/2025, 11:31 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Anterior currently has business associate agreements with the following Covered Entities: - (b)(4) (b)(4) is a regional health plan serving over 550,000 members across Pennsylvania. It offers a full spectrum of products, including Medicare Advantage, Medicaid, CHIP, and commercial

	plans. Through a delegated arrangement with HealthHelp, Anterior supports clinical review operations under a Business Associate Agreement (BAA) to enable AI-driven utilization management services. Anterior currently has business associate agreements with the following Business Associates of Covered Entities: (b)(4) (b)(4)

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Anterior has extensive experience working with Medicare Advantage (MA) plans and their delegated entities to support prior authorization workflows across outpatient, inpatient, post-acute, and rehabilitative services. Our AI platform, Florence, delivers timely, consistent, and policy-aligned determinations based on CMS coverage criteria, including National and Local Coverage Determinations (NCDs, LCDs). We support both full automation and clinician-in-the-loop workflows to improve speed, accuracy, and auditability — while reducing provider burden and delays to care. MA Customer 1: (b)(4) — Regional MA plan (deployed, current) Serving 550,000 members, this MA plan uses Florence embedded within the provider portal for outpatient UM reviews. Our platform accelerates determination timelines while ensuring full documentation and audit trails. Florence achieved 99.24% clinical accuracy, reduced manual review time by 74%, and shortened average approval time to 155 seconds. All escalated cases (those which cannot be affirmed by the AI technology) are reviewed by HealthHelp's URAC- and NCQA-accredited clinical team. (b)(4) (b)(4) (b)(4) MA Customer 4: Delegated utilization management entity, processing requests on behalf of multiple MA plans (deployed, ongoing and expanding (b)(4) is a delegated utilization management partner that performs prior authorization and case management reviews on behalf of several Medicare Advantage health plans. Anterior supports (b)(4) with AI-powered case summarization and clinical reasoning. Florence is embedded into (b)(4) internal workflows to accelerate clinical documentation review, assist with medical necessity assessments, and reduce operational burden. Florence currently powers AI-augmented reviews within (b)(4) case management system, achieving a 77% reduction in case review time across participating nurses. The platform operates in a clinician-in-the-loop model, where final determinations remain under nurse control, while Florence accelerates decision-making and produces structured, audit-ready outputs. A phased rollout is underway across both Utilization Review (UR) and Case Management

	(CM) functions, with support for Medicare Advantage policies, CMS-aligned documentation requirements, and full auditability.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Anterior has extensive experience working with health plans (including delegated entities, national payers, and Medicare Advantage plans) on prior authorization, pre-payment review, and coverage determination workflows. Our AI platform, Florence, is designed to align with CMS policy, payer-specific rules, and MAC-issued guidance to support accurate, scalable decision-making. Florence natively ingests and interprets CMS-issued documentation, including the Medicare Benefits Policy Manual, National Coverage Determinations (NCDs), and Local Coverage Determinations (LCDs). These are converted into structured (AI and LLM ready), FHIR-compliant, version-controlled decision tree logic used to guide automated and clinician-assisted determinations. Florence has been deployed across multiple national and regional plans for outpatient services closely aligned with the WISeR RFA Table 1. The platform is fully capable of reasoning over MAC-specific LCDs and adapting to jurisdictional variations in policy interpretation — for example, differing documentation requirements for imaging or musculoskeletal procedures under Noridian (JF) vs. Novitas (JL). In addition to digesting and reasoning over clinical records, Florence processes and extracts structured information from unstructured and semi-structured administrative documents (e.g., scanned faxes, PDFs, and EDI attachments). These include CPT, HCPCS, and ICD-10 codes, billed amounts, service dates, and rendering provider information. While we have not yet directly contracted with a MAC, we are prepared to do so under WISeR and have delivered MAC-aligned decision automation across our existing payer partners. Florence's flexible design supports both national and local policy logic, ensuring accurate alignment with MACs' jurisdictional interpretations. Security Authorizations and Readiness Anterior is currently in the process of being recertified for HITRUST e1, with SOC 2 Type II certification planned for later this year. All data is encrypted at rest (b)(4) and in transit (b)(4) (b)(4) Anterior offers secure single and multi-tenant virtual private cloud environments for our customers (b)(4) ensuring data isolation and data integrity for each customer. We maintain a structured incident response plan with tiered severity levels and (b)(4) Post-incident root cause analysis and corrective action plans are standard. Anterior has not yet completed FedRAMP authorization, but is actively preparing to meet all CMS and FedRAMP Moderate requirements by August of 2026 if supported by CMS. This includes standing up a GovCloud-hosted single-tenant per AWS account deployment and working with external firms to lead readiness and audit preparation. We are also prepared to pursue CMS-specific Authority to Operate (ATO) authorization in parallel.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Anterior combines a frontier AI research and application company with the operational depth of a clinical services organization. We bring substantial experience in performing medical necessity reviews, including initial coverage determinations, resubmissions, and peer-to-peer escalations. Our in-house clinicians include licensed UM nurses and physicians who have decades of experience performing medical reviews across a variety of service lines (including those listed in the WISeR RFA). These clinicians serve dual roles: they support implementations as Forward-Deployed Clinicians (FDCs), working alongside our engineering and customer success teams to tune Florence to client-specific policies and workflows – and they also lead ongoing Quality Assurance efforts to ensure clinical alignment and regulatory compliance for customers. This model has allowed us to meet both URAC and NCQA documentation standards and deliver auditable outputs at scale. While Anterior directly employs nurses and physicians, to meet the scale and delegated Utilization Management needs of WISeR, Anterior is partnered with HealthHelp, a URAC- and NCQA-accredited clinical services organization with deep experience managing Medicare,

	Medicaid, and commercial utilization management programs. HealthHelp's clinical teams routinely perform: - Coverage determinations across all outpatient service lines (aligned with WISeR Table 1) - Resubmission reviews and full peer-to-peer escalations with treating providers - Medical necessity evaluations against NCDs, LCDs, and local MAC guidance HealthHelp's staffing structure includes: - Licensed nurses who conduct initial clinical reviews - Board-certified specialist physicians (e.g., MSK, cardiology, oncology) for complex reviews and Peer to Peer (P2P) conversations - A national network of credentialed clinicians covering all WISeR-relevant specialties Their workflows span digital intake, automated criteria screening, nurse and physician review, peer to peer (P2P) outreach, and appeals. (b)(4) cases are submitted electronically, contributing to provider satisfaction (NPS >60). P2P reviews are conducted by domain-matched MDs to ensure clinical accuracy and provider collaboration. Real-World Performance on the Anterior / HealthHelp Partnership: - 99.24% accuracy (F1), including 100% precision and 98.44% recall - 155-second average determination time for outpatient cases in the provider portal - All non-affirmations are escalated to HealthHelp's clinical team for human review In addition to our integrated partnership with HealthHelp, Anterior maintains relationships with other nationally recognized delegated utilization management and independent review organizations, including (b)(4) Both examples are of URAC-accredited entities with deep experience supporting Medicare Advantage and Medicaid plans through medical necessity reviews, peer-to-peer consultations, resubmissions, and appeals. (b)(4) offers full-scope clinical UM services with strong compliance and turnaround time performance, while (b)(4) brings expansive specialty coverage and daily review capacity at national scale. These partners enhance Anterior's operational readiness and provide redundant clinical review infrastructure to ensure consistency, safety, and full lifecycle support under WISeR. These partnerships allow Anterior to deliver a hybrid model of technology and services that ensures operational resilience, clinical rigor, and full coverage of the WISeR model's requirements — including fallback support for resubmissions, peer-level review, disputes, and appeals. By combining our AI infrastructure with the capacity and credibility of multiple clinical review organizations, Anterior is uniquely positioned to meet the WISeR model's expectations for accuracy, auditability, scale, and beneficiary protection.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Anterior's Florence platform is purpose-built to support automated and AI-assisted prior authorization workflows across the outpatient services listed in Table 1 of the WISeR RFA. Florence is an API-first platform designed to integrate directly with provider EHRs, payer core systems (including care management systems), and CMS-required interfaces. Our architecture meets the interoperability and operational mandates set forth in CMS-0057-F and is capable of supporting near-term WISeR implementation and long-term CMS scalability. Florence supports full CMS-0057-F compliance and (b)(4) (b)(4) - FHIR-Native APIs and SMART on FHIR Applications: Florence supports HL7 FHIR R4 and is designed to be interoperable with all major EHR systems (e.g., Epic, Oracle Cerner, MEDITECH, athenahealth). Anterior's SMART apps integrate directly into provider workflows, auto-populating DTR questionnaires using CQL and structured clinical data. - Da Vinci CRD, DTR, and PAS API Support: Florence natively supports the Da Vinci Implementation Guides for Coverage Requirements Discovery (CRD), Documentation Templates and Rules (DTR), and Prior Authorization Support (PAS), enabling end-to-end digital prior authorization. - X12 / EDI 278 Compatibility: Florence supports traditional EDI transactions to ensure seamless connectivity with legacy MAC and payer systems, where applicable. - Policy Digitization and Clinical Reasoning: Florence ingests NCDs, LCDs, and MAC-specific coverage criteria and converts them into structured, FHIR-compliant decision trees and DTR forms. These are version-controlled, auditable, and editable to reflect policy updates or jurisdictional variation. - Structured Data from Unstructured Inputs: Florence extracts key administrative and clinical fields (e.g., CPTs, ICD-10s, service dates) from faxes, scanned documents, or free-text EHR entries, bridging the gap between manual intake and digital review. Alignment with CMS-0057-F Requirements Florence is architected to fully support the four required APIs and operational components of the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F). We are actively finalizing production-ready implementations of all four APIs, starting with the Prior Authorization API and expect to be able to support fully functional compliance by the end of the year for our partners. Our system is designed to meet both the technical and operational mandates of the rule, including auditability, structured data exchange, and transparency of determinations. - Prior Authorization API (CRD, DTR, PAS): We will enable real-time, fully electronic submission-to-determination workflows. Florence already ingests and applies clinical data in real time, generating audit-ready, criteria-level documentation. - Patient Access API: We will enable members to access structured prior authorization data, including status, expiration dates, and decision rationale. - Provider Access API: We will allow the sharing of prior authorization, claims, and USCDI data with attributed providers, including opt-out controls and attribution logic. - Payer-to-Payer API: We will support secure, consent-based exchange of prior authorization data, including clinical rationales and timing metadata. Florence also supports: - Auditability and Compliance Reporting: Every determination is logged with timestamps, rationale, and cited evidence from the medical record. Florence generates compliant non-affirmation letters and supports CMS-mandated data submission beginning in 2026. - TAT Acceleration: Florence reduces time-to-determination from days to seconds. In prior deployments, Florence achieved an average review time of 155 seconds for outpatient codes analogous to those in

	WISeR Table 1 (KLAS-validated) when embedded into a provider portal. Operational Readiness and Future Development - Go-Live Readiness by Q2 2026: Florence's CMS-0057-F-ready capabilities will be fully deployed and tested by Q2 2026, well ahead of the January 2027 federal mandate. - EHR-Specific Integration Development Underway: (b)(4) (b)(4) Flexibility for MAC Implementation and WISeR Oversight Florence can be deployed: - As a standalone portal or viewer for MAC staff - Integrated into MAC systems or workflows via secure API - Accessed by CMS for monitoring, audit, and regulatory compliance All determinations are traceable, transparent, and human-verifiable — supporting the goals of WISeR to improve patient access, reduce provider burden, and enhance CMS oversight of utilization management practices.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	Anterior has deep experience developing AI-driven systems for complex, high-volume utilization management across inpatient, outpatient, post-acute, and specialty services. Florence, our AI platform, is purpose-built to deliver safe, auditable, affirmation-only determinations aligned with Medicare policy. Florence supports the full prior authorization lifecycle, from real-time guideline interpretation to end-to-end audit traceability, and is ready to help CMS and its MAC partners deliver on WISeR's vision for timely, equitable, and patient-centered access to care. Experience in Coverage Determination AI Florence has been deployed in production across multiple lines of business, including Medicare Advantage, and has supported determinations across high-cost, medically complex benefit categories. Notably: - Post-Acute Care (PAC): --> (b)(4) (b)(4) (b)(4) - Outpatient Utilization Management: Florence is currently used by a 550,000-member regional payvider (integrated health system), across prior authorization reviews in categories similar to WISeR's Table 1 (e.g., MSK, neuro, wound care, etc.), including use on NCD / LCD guidelines. Florence has delivered: --> 99.24% F1 accuracy --> 74% time savings for clinician reviewers --> Real-time decision turnaround times of 155 seconds Florence has been validated in active production environments against real claims, medical records, and MAC-aligned criteria. AI Framework and Data Handling Florence orchestrates state-of-the-art large language models (LLMs), including models provided by OpenAI, Google, and Anthropic, within a proprietary clinical reasoning framework. (b)(4) (b)(4) (b)(4) That being said, the real impact in our approach is that driven by our multi-LLM (or constellation) approach. Anterior: - Uses structured decision trees derived from NCDs, LCDs, and MAC-specific policies. - Conducts extensive Quality Assurance using structured, unstructured, and synthetic datasets, including bias audits across protected groups. - Employs forward-deployed clinicians to benchmark and validate reasoning against clinical policy and QA standards. By leveraging our multi-LLM approach, which orchestrates the best model for each task within a clinical workflow, along with our unique clinical inference pipeline – Florence does not require PHI for model training or baseline deployment, supporting rapid time to value. Florence is uniquely suited to fulfill WISeR's objectives, with proven capabilities that align closely with CMS's stated priorities: - Accelerating and streamlining prior authorization: Florence enables real-time clinical approvals, (b)(4) and reducing turnaround times from days / weeks to ~155 seconds. - Supporting MAC-specific LCD/NCD alignment: Florence dynamically ingests and reasons over National and Local Coverage Determinations, including MAC-specific interpretations. These are transformed into editable, explainable, FHIR-compatible decision trees which are LLM-optimized and ready for AI reasoning. - Ensuring auditability and transparency: Each determination includes timestamped documentation, clinical rationale, and full traceability to the underlying medical record, supporting audits and appeals. - Detecting and mitigating bias: Florence undergoes regular disparity audits, with performance monitored across protected groups. Safety or fairness concerns trigger trapdoor safeguards to pause AI usage until resolved. - Maintaining human oversight: Florence only automates affirmations / approvals. Any case that cannot be confidently affirmed is escalated to licensed clinicians for full manual review, in line with CMS's AI Playbook and CMS-0057-F. - Scaling across clinical domains: While WISeR focuses on outpatient services, Florence is already in use across inpatient, post-acute, rehab, and other high-cost care settings — supporting future model expansion. Florence can be accessed via a secure dashboard or integrated via API with MAC case management tools. The platform is FHIR-compatible and supports CRD, DTR, and PAS APIs, ensuring straightforward compliance with CMS-0057-F interoperability standards. Verification, Validation, and Governance Florence is governed by a rigorous clinical QA and model validation process: - QA sampling includes specialty-based clinical reviewers and protected group audits - Metrics tracked include F1 score, false approval rate, false escalation rate, and correction rate - (b)(4) (b)(4) (b)(4) All decisions, whether AI-suggested or clinician-made

	— are explainable, traceable, and appeal-supportive. Managing Adverse Effects of AI: Anterior proactively manages adverse AI outcomes through rigorous clinician-led QA, continuous monitoring, and robust governance. (b)(4) (b)(4) Every AI decision includes a full chain of reasoning and cited evidence from the medical record. Responsible Communications and Public Trust: Anterior recognizes the public scrutiny surrounding prior authorization. We are committed to responsible, transparent deployment. Florence: - Never denies care. All non-affirmations are escalated to human reviewers. - Explains every decision. Clinical reasoning is visible, cited, and auditable. - Improves provider experience. Our deployments consistently reduce TAT, improve satisfaction, and reduce abrasion. Anterior's clinician-led culture, CMS-aligned safeguards, and proven real-world performance make us a uniquely qualified artificial intelligence partner to advance WISeR's mission of reducing inappropriate care while ensuring equitable, beneficiary-centered outcomes.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	Yes

Accreditations or Certifications Document

File Name	WISeR-00115_Accreditations_URAC Certificate EXP 8.2026- Philippines
Uploaded On	7/25/2025, 11:46 PM
File Name	WISeR-00115_Accreditations_Note on Earned Accreditations
Uploaded On	7/25/2025, 11:46 PM
File Name	WISeR-00115_Accreditations_NCQA Certificate_2022 EXP 12.29.2025
Uploaded On	7/25/2025, 11:46 PM
File Name	WISeR-00115_Accreditations_URAC Certificate EXP 8.2026 - Corporate
Uploaded On	7/25/2025, 11:46 PM

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Anterior's approach to ethics, compliance, and quality is anchored in a dual structure: (1) transparent, auditable AI governance through our Florence platform, and (2) rigorous clinical oversight through HealthHelp, our URAC-, NCQA-, and HITRUST-accredited delegated partner with over two decades of experience delivering compliant utilization management (UM) services across Medicare Advantage, Medicaid, and commercial lines of business. HealthHelp leads all clinical determinations within our delegated arrangements and maintains full alignment with URAC and NCQA standards. Their multidisciplinary team includes licensed nurses, board-certified physician reviewers across relevant specialties, and a Chief Medical Officer (CMO) who oversees clinical policy alignment, medical necessity determinations, peer-to-peer review processes, and quality performance tracking. HealthHelp's Quality Management Program (QM Program) governs all aspects of utilization management and performance monitoring. It is built on the Continuous Quality Improvement (CQI) methodology and promotes compliance with regulatory and accreditation requirements across all product lines. Oversight is delegated to the Quality Management Committee (QMC), which reports to the CMO and is responsible for auditing and monitoring all levels of the UM program. Key functions of the QM Program include: - Ensuring clinical reviewers are properly trained, credentialed, and assessed via inter-rater reliability (IRR) - Using only current, professionally developed medical necessity guidelines in all determinations - Monitoring metrics such as timeliness, appeal overturn rates, provider and member complaints, and customer satisfaction - Performing root cause analysis on grievances and overturned appeals to reduce error rates - Providing continuing education to UM staff based on performance trends and compliance findings - Ensuring HIPAA-compliant handling of all PHI HealthHelp processes all non-affirmations with detailed clinical rationale and manages appeals, grievances, and complaints according to CMS-required timelines and

	procedures. Complaint trends are tracked, escalated, and addressed through corrective actions as needed, with a focus on transparency, member protection, and provider trust. AI Governance and Transparency via Florence Anterior's AI platform, Florence, automates the interpretation and application of Medicare coverage criteria, including NCDs, LCDs, and the Medicare Benefits Policy Manual. Florence operates under a strict "affirmation-only" model: it can only approve requests that fully meet policy criteria and escalate all others to HealthHelp's licensed clinicians for manual review. This model ensures appropriate care access, aligns with CMS's AI Playbook, and avoids improper non-affirmations. All determinations — whether automated or clinician-rendered are: - Transparent and explainable, with criterion-level citations from source documentation - Fully auditable and appeal-ready - Supported by real-time dashboards and live Quality Assurance reports tracking metrics such as False Approval Rate and Correction Rate Anterior's internal Clinical Quality Assurance team, composed of physicians, experienced UM nurses, and AI engineers, continuously reviews decision performance. 100% of flagged cases undergo manual review, and random sampling is performed regularly. Regulatory Compliance and Interoperability Readiness Anterior and HealthHelp maintain strong compliance with applicable federal and state regulations. Florence is designed to support CMS-0057-F, including CRD, DTR, and PAS APIs. Its modular architecture allows state-specific logic and documentation workflows for jurisdictions such as California, Colorado, and New York. We are actively preparing for FedRAMP Moderate and CMS Authority to Operate (ATO) certifications and are committed to deploying within a single-tenant GovCloud instance to meet WISeR security and privacy requirements. Our VP of Clinical Operations, alongside HealthHelp's clinical leadership, ensures our integrated model remains fully aligned with state, federal, and accreditation body standards – supporting CMS's mission to deliver clinically appropriate, safe, and high-value care to beneficiaries.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	The services listed in Table 1 of the WISeR RFA are highly comparable to those Anterior supports today through existing payer and delegated utilization management deployments. Based on real-world Florence performance data and industry-standard cost assumptions, we model the below annual savings per MAC jurisdiction. We provide both conservative and optimistic estimates below, reflecting variability across core assumptions (e.g. in request volume and cost per service). (b)(4) (b)(4) (b)(4) These estimates reflect Florence's real-world performance in automating high-value, policy-aligned coverage determinations, reducing administrative burden, and flagging medically unnecessary or non-covered services for review. Actual savings will depend on adoption rate, claim mix, and historical overpayment trends — all of which we are eager to refine with CMS during pilot planning.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Anterior recognizes the sensitivity and regulatory obligations associated with interfacing with MACs and handling Medicare beneficiary data. Our implementation plan focuses on achieving full compliance with HIPAA, FISMA/NIST 800-53, and CMS-specific requirements (including obtaining a FedRAMP-Moderate ATO and CMS ATO) by August 2026. - Select FedRAMP/CMS 3PAO and support firm (Q3 2025) - Build FedRAMP-compliant, single-tenant GovCloud environment (Q4 2025-Q1 2026) - Complete required documentation (SSP, POA&M, etc.), internal testing, and risk assessment (Q2 2026) - Undergo 3PAO audit and submit for FedRAMP Moderate and CMS ATO (Q3 2026) - If needed, obtain CMS approval to operate under "FedRAMP in Process" status (Q3 2026) Anterior will assign an internal compliance lead and engage a FedRAMP-specialist consultant / company to manage the process end-to-end. We have prior experience adapting to similar frameworks (e.g., HITRUST) and our infrastructure is already designed for modular swap-out of non-compliant components. Our readiness plan is realistic, resourced, and responsive to the expectations of CMS, HIPAA, and state-level data protection requirements. We are committed to launching this work stream immediately upon award notification.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Anterior, Inc.
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00123

Requested by (b)(6) on 07/28/2025 15:50

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Tennr Incorporated
b. Doing Business As (DBA) Name(s)	
c. Street Address	275 Seventh Avenue, 21st Floor,
d. City	New York City
e. State	NY
f. Zip Code	10001
g. Tax Identification Number	871862494
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Function and Purpose Tennr is a healthcare technology company focused on solving one of the biggest challenges in the U.S. healthcare system: administrative waste. Delays, denials, and billing errors occur due to manual work and human error in processing. Tennr's mission is to reduce waste by automating those manual processes with high-accuracy solutions. We've built proprietary document-reading models, trained on millions of healthcare records. Our purpose-built healthcare models are the highest-performing for extracting and interpreting data from medical documents. These models power our automation platform, used daily by hundreds of providers and suppliers to process thousands of patients. The platform is modular and drives four capabilities that support faster, more accurate claims and authorization decisions. This makes Tennr well-suited to support CMS and MACs under WISeR. Document Wrangling: (b)(4) (b)(4) (b)(4) It doesn't rely on pre-set templates or need a human to sort or label documents. Intake: Our RaeLM model extracts patient demographics, CPT/HCPCS codes, ICD-10 codes, and insurance data with up to 98% accuracy. That structured data is then saved to the appropriate patient record. Qualification: Tennr's (b)(4) model, checks whether the submitted document supports coverage under CMS's LCDs and NCDs. It reviews clinical documentation, such as chart notes, labs, and orders, then flags missing or insufficient pieces. Affirmation decisions are always reviewed and validated by human operators. Missing Information Handling: Tennr flags what's missing and triggers automated follow-up messages to request the information. This helps avoid delays and speed approvals. Who We Serve Tennr is used across a range of healthcare organizations. We started in HME/DMEPOS, where we serve the largest portion of our customers. Since then, we've expanded to support: Infusion and Specialty Pharmacy Centers Respiratory Health Providers Digital

	Health Companies Imaging Centers Regional Health Insurers Customers rely on Tennr to automate document processing and align with Medicare and commercial coverage criteria. Tennr is ideally positioned to support CMS in pre-payment review under WISeR. Our Values Visibility Tennr is designed to ensure nothing is lost in the process. Our platform brings visibility and structure to documentation workflows, allowing providers and now CMS to track, review, and validate all steps of the authorization process. AI Transparency and Safety We don't rely on black-box models or offshore workforces. We built and trained our AI models to ensure transparent, auditable, and high-performing decision support. Every automated determination is paired with human oversight and annotated audit trails, enabling accurate pre-payment decisions aligned with CMS's quality, transparency, an
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JL Novitas

5. Provide street address, city and state for all locations.

Location Name	Headquarters
Street Address	275 Seventh Avenue
City	New York City
State	New York
Zip Code	10001

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00123_Ownership_Tennr Ownership Information
Uploaded On	7/24/2025, 4:09 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Contact Type	Secondary
Email Address	(b)(6)

Name	(b)(6)
Title/Position	
Address	
Business Phone Number	

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00123_Licensure_Tennr Incorporated -Restated Certificate of Incorporation (Filed 6.16.2025)
Uploaded On	7/24/2025, 8:27 AM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Tennr has active BAAs with the following HIPAA covered entities, which are active Tennr customers. These include HME/DMEPOS; infusion centers and specialty pharmacies; sleep, respiratory, and home health providers; digital health companies; and imaging centers. (b)(4)

	(b)(4)

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Tennr supports healthcare providers and suppliers in navigating prior authorization (PA) processes with Medicare Advantage (MA) plans and commercial payors. The core focus of Tennr has been to service provider organizations, by directly interfacing with payor policies and workflows. Integral to this is our Qualification Review Engine product which helps providers prepare documentation that aligns with CMS coverage guidelines (LCDs/NCDs) and payor-specific medical necessity criteria. In short, our technology takes a complete patient chart and any supplementary documentation and uses a language-model-first approach to clinically evaluate if an order will be successful in qualifying against LCD and NCD guidelines. Tennr has processed documentation involved in hundreds of thousands of PA reviews across MA plans such as (b)(4) ensuring that providers are equipped to submit complete, accurate, and verified documentation that meets requirements. We've also helped providers (and more recently as well, payors) catch thousands of 'would-be-denied' referrals with incomplete documentation. By working with providers to meet payor criteria before claim submission, Tennr reduces downstream denials and administrative waste for both payors and providers and delays patients' access to timely care.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Tennr has extensive experience with clinical and operational data used in coverage determination workflows. We started out of the Stanford AI lab with the foundational belief that generic-model approaches to clinical evaluations were likely to fail. As such, our Qualification engine supports pre-payment reviews by extracting ICD-10, CPT, and HCPCS codes from unstructured documentation (fax, email, PDFs), mapping them to clinical narratives, and verifying requirements against CMS LCDs/NCDs as well as payor specific criteria. Tennr's technology can also accurately detect where documentation is missing or failing to comply with given criteria and summarize medical necessity reviews for human validation. To ensure timely resolution of cases flagged as incomplete or non-affirmable, Tennr provides outbound phone outreach to providers via their SuperDial integration, requesting missing documentation or clarifying requirements. Foundational to Tennr's platform is a proprietary suite of machine learning (ML) models (b)(4) (b)(4) The models support real-time document classification (a key step for qualification review), code extraction, and coverage checks. Tennr performs tens of thousands of medical necessity reviews per day across DMEPOS and outpatient services, many tied to Medicare Advantage and CMS criteria. A) While Tennr does not have any direct relationships with MACs, our platform is designed to interface with MACs through HIPAA-compliant digital pathways (fax and secure file transfer, with backup support provided by phone). Our infrastructure aligns with MAC protocols for intake, processing, and adjudication consistent with Medicare coverage policy. Tennr is technically capable of submitting and receiving determinations via MAC channels under the WISeR model. B) Tennr is not FedRAMP certified. (b)(4) (b)(4) Tennr's infrastructure aligns with SOC 2, SOC 1, HIPAA, and CMS IS2P2 security protocols. Documentation to support SOC and HIPAA compliance is available upon request. C) HIPAA compliance and incident response: Tennr monitors and enforces compliance with the HIPAA Privacy, Security, and Breach Rules through a structured security and compliance program. Our HIPAA compliance program includes the implementation and enforcement of relevant policies and procedures, the appointment of a dedicated Privacy and Security Officer, HIPAA training on hire and annually thereafter for all employees, an annual HIPAA risk assessment, and the adoption and enforcement of Business Associate Agreements with all entities where PHI may be exchanged. Our security management process includes continuous monitoring of systems that contain electronic protected health information (ePHI) and periodic reviews of access and data use. All workforce members are required to report any suspected or known security or privacy incidents immediately, and Tennr's designated Privacy and Security Officer is responsible for investigating and documenting each event. Tennr also maintains comprehensive audit logs and implements automated monitoring tools to detect unauthorized access or suspicious activity across its infrastructure. In the event of a data incident or breach, we follow a defined Incident Response and Breach Determination Policy and HIPAA Breach Notification Policy that outlines steps from detection to resolution. Upon detection of a potential incident, we conduct a prompt and thorough investigation to determine if a breach occurred, whether any PHI or ePHI was involved, and if the event meets the criteria for a reportable breach under HIPAA. If applicable, we utilize a HIPAA breach risk assessment framework to evaluate the probability of compromise. Tennr also determines whether an exception under HIPAA rules applies to avoid unnecessary reporting. Tennr maintains a HIPAA incident log for all reported incidents, regardless of

	breach determination, and retains documentation for at least ten years. In confirmed breach cases, Tennr provides notice to affected parties in accordance with the notice requirements outlined in the parties' governing agreements and in accordance with the HIPAA Breach Notification Rule, including the nature of the breach, types of data involved, mitigation steps taken, and contact information for follow-up. Tennr's breach notification and response processes are coordinated by the Privacy and Security Officer, who also manages any required updates to safeguards and controls to prevent recurrence.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	We are first and foremost a technology provider that automates manual healthcare administrative tasks such as document intake, eligibility determination, payor guideline qualification, and provider communications. We employ clinicians to manage rulesets and update based on payor and policy changes. Tennr's document reasoning models will make a first pass determination of adherence to payor guidelines and our customers' users are typically the ultimate decision makers to agree/disagree with the automated affirmation/non-affirmation. We do however offer to take this work entirely off of our customers and have an operational team to do this when a customer requests it. For this program we would be following this 'augmented' approach where Tennr would employ users of Tennr's technology to review.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Our platform is architected to interoperate with the major EHR vendors and billing platforms in the healthcare industry. It is designed to connect with EHR systems via modern standards including REST APIs, HL7, and FHIR. Tennr performs bidirectional data exchange to both extract relevant clinical and administrative data and write back determination outcomes and related documentation into the EHR. a) In practice, Tennr actively integrates into leading EHR and EMR platforms such as Epic, Cerner, Brightree, NikoHealth, WeInfuse, AdvancedMD, Bonafide, CPR+, Caretend, TIMS, ZinniaX, Salesforce HealthCloud, Tebra, and TraumaSoft. Despite Tennr's system-agnostic architecture, integration limitations do exist due to restrictive vendor practices or legacy system architectures. Some EHR vendors either lack sufficient external API coverage or impose access restrictions, proprietary protocols, or high licensing fees that impede direct integrations. In such cases, Tennr adapts by leveraging alternative methods such as secure file transfer or providing API endpoints that our customers build custom integrations with. b) Tennr is committed to helping healthcare providers and payors work together more easily, following the CMS Interoperability and Prior Authorization Final Rule (CMS 0057-F). Our platform uses a modern, API-first design that meets all the required data standards (FHIR). Our goal is to reduce administrative burden by converting unstructured faxed documentation into structured data compatible with FHIR standards, accordant with CMS 0057-F. Incoming faxed authorizations and historical documentation can be processed using RaeLM, Tennr's industry-leading extraction model, to enable payers to comply with the Patient Access API, Provider Access API, and Payer-to-Payer API without any increase in administrative overhead. Additionally, we will reduce administrative burden by automating key steps in the prior authorization process, such as verifying whether a patient meets medical necessity criteria and preparing structured requests for submission to payors. Our key product in this regard, the Tennr Network, connects providers, payors, and technology systems. This allows for smooth sending of PA requests and real-time updates. We ensure everyone, from providers to patients, has clear and timely information about PA statuses through various channels like EHR integrations or patient portals, leading to better care coordination.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine	Tennr was started out of the Stanford AI lab with the singular purpose of building specialized machine learning models to solve the administrative problems in the US healthcare system. Over the first few years of the company we invested solely in novel techniques to build

Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	de-identified data sets of medical records to leverage as training data for our healthcare document extraction, classification, and reasoning models (b)(4) (b)(4) (b)(4) Because of Tennr's ability and experience in performing the qualification determination workflow at scale, delivering WISeR is a matter of adapting the existing models to CMS data rather than starting from scratch. This approach shortens time to value, reduces risk, and provides Medicare Administrative Contractors with consistent, auditable determinations that lighten provider burden and accelerate patient care. (b)(4) (b)(4)
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Tennr's approach to ethics, compliance, and quality standards is grounded in a commitment to protecting patient data, supporting healthcare partners, and maintaining the trust of providers and payors. These values are emphasized in Tennr's Code of Conduct, which all members of Tennr's workforce review and sign on hire. Tennr operates under a comprehensive compliance framework that includes adherence to HIPAA and other applicable healthcare regulations, as well as internal policies governing data protection, access control, and risk management. Tennr's workforce is trained upon hire and annually thereafter on HIPAA compliance and data security reinforcing a culture of accountability and integrity across all operations. Tennr enforces a strict data classification and handling policy to ensure that information is only accessed and shared by authorized individuals for legitimate business purposes. All workflows involving protected health information (PHI) are subject to role-based access controls, multi-factor authentication, encryption standards, and audit logging. Tennr's Software Development Life Cycle (SDLC) incorporates risk assessments, security reviews, and rigorous testing to ensure the quality and safety of technology solutions used in healthcare automation. Vendor partnerships are managed through a formal onboarding and monitoring process that includes security and compliance assessments, contractual protections such as Business Associate Agreements, and ongoing performance evaluations. Tennr has a documented Fraud, Waste, and Abuse (FWA) policy and conducts annual FWA training to ensure compliance with CMS regulations and promote ethical practices throughout the organization. Reporting mechanisms, including anonymous reporting, are in place to support transparency and allow any individual to report concerns confidentially and without fear of retaliation. Overall, Tennr's approach is designed to

	proactively manage risk, uphold ethical standards, and support safe, secure, and collaborative engagement with all stakeholders. a) For every qualification determination made by a machine learning model, a user (healthcare professional or clinician) reviews the result. Once the user makes the final decision on affirmation or non-affirmation, an automated output packet is generated containing the result, a summarized explanation as to why the guideline was satisfied or not, and highlighted annotations in the supplied documentation to support the determination. Tennr then stores this packet attached to the patient record containing the ordered services/products. This output packet is currently used by providers in their claims dispute workflows and we would use these output packets as part of the complaint, claims dispute workflows to support the MAC. b) Tennr ensures compliance with applicable state and federal regulations, including HIPAA, by maintaining a comprehensive security and compliance framework that incorporates regulatory requirements into company-wide policies, operational procedures, and technical controls. Tennr's Information Security Management Program is aligned with industry standards such as the Center for Internet Security (CIS) and incorporates regular risk assessments, policy reviews, and security audits. Risk assessments are conducted at least annually and quarterly where necessary, and results are documented in a risk register that is reviewed by a cross-functional Risk and Compliance Committee. Tennr enforces strict access controls, including role-based access and multi-factor authentication, to protect sensitive data. Data is classified according to a defined model to ensure appropriate handling and safeguards, particularly for PHI and ePHI. Tennr also employs encryption protocols, network security standards, and continuous monitoring tools to detect and respond to potential threats or policy violations. All employees undergo regular HIPAA training and security awareness programs to reinforce compliance expectations. Vendor and third-party relationships are subject to due diligence assessments and contractual obligations, including Business Associate Agreements where PHI is involved, to ensure that external partners also meet applicable legal and regulatory standards. Additionally, Tennr documents and retains compliance artifacts for audit readiness and performs internal reviews to verify adherence to both internal policies and external regulatory requirements. Any exceptions to policy must be approved by the Security Officer and fully documented with associated risk mitigation steps.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	(b)(4)
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	(b)(4)

	(b)(4) (b)(4) Conclusion By following this comprehensive implementation plan, Tennr will achieve a state of operational readiness by the WISeR model launch on January 1, 2026. All necessary safeguards and capabilities - from robust security architecture and HIPAA-compliant policies to trained clinical staff and tested MAC integrations - will be in place. Tennr's phased timeline ensures that each component is completed and verified in sequence, with continuous coordination with CMS and the MAC to align with federal requirements. Through diligent preparation and risk management, Tennr will enter the WISeR pilot fully equipped to handle sensitive Medicare data securely and efficiently, and to contribute to the model's goal of reducing wasteful services while protecting patients and the Medicare Trust Fund.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Tennr Incorporated
Certifying Individual: **Title:**	(b)(6)

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00134

Requested by (b)(6) on 07/28/2025 15:51

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Autonomize Inc.
b. Doing Business As (DBA) Name(s)	Autonomize AI
c. Street Address	9390 Research Blvd, Kaliedo 2, #310
d. City	Austin
e. State	TX
f. Zip Code	78759
g. Tax Identification Number	872597759
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Autonomize AI is a healthcare AI company that builds agentic software to reduce the administrative burden on healthcare knowledge workers. We develop domain-optimized AI agents—packaged as secure, configurable copilots—that organize, contextualize, and summarize unstructured data to accelerate clinical and operational decisions across health plans, providers, and life sciences companies. Mission: Our mission is to make knowledge-workflows more efficient by seamlessly combining data and context. We empower professionals by reducing administrative burdens and elevating the quality of their outcomes. Our vision is a world where AI is a catalyst and an extension of human cognition — enabling organizations and individuals to live up to their maximum potential. Values: Purpose-Driven Impact – Every product we build aims to make a measurable difference in patient outcomes and healthcare delivery. Human-AI Collaboration – We design AI to augment, not replace healthcare professionals—elevating knowledge workers, not displacing them. Trust & Transparency – We prioritize explainability, data provenance, and ethical AI practices to build trust with users and institutions. Speed with Purpose – We move fast, but always in service of meaningful, patient-centered innovation. Mission First – We are relentlessly focused on improving access, quality, and efficiency in healthcare. Customers: Top 10 health plans, Regional and Medical Advantage Plans, Integrated Provider Networks, Provider Groups/Organization, and healthcare technology organizations. Products & Services: AI enabled workflows for Prior Authorization, Care Management, Claims Adjudication, Appeals, Clinical Quality etc. A flexible and configurable AI orchestration engine to automate and augment complex healthcare workflows. Optimized and built from the ground up for healthcare complex and regulated environments. Focused on enabling seamless human-in-the-loop workflows for healthcare organizations and stakeholders. Clinical and technology services to enable the workflows and run it effectively for our clients.

4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS

5. Provide street address, city and state for all locations.

Location Name	Autonomize, Inc.
Street Address	9390 Research Blvd, Suite 310
City	Austin
State	Texas
Zip Code	78759

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00134_Ownership_Autonomize Inc Ownership Interest
Uploaded On	7/25/2025, 9:10 PM
File Name	WISeR-00134_Ownership_Disclosure control interest
Uploaded On	7/25/2025, 9:11 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address Name Title/Position Address Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address Name Title/Position Address Business Phone Number	(b)(6)

Contact Type	Tertiary

Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00134_Licensure_Autonomize, Inc. - Certificate of Incorporation
Uploaded On	7/25/2025, 9:11 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Two (b)(4) Health Plans with PBMs A national managed care organization focused on delivering Medicaid and Medicare services to underserved / senior populations across multiple states. A nonprofit Medicare Advantage plan dedicated to serving older adults with a focus on equity, independence, and coordinated care. A physician-led healthcare services company supporting independent providers with tools for value-based care and practice management. A value-based care enablement company helping health systems and providers improve outcomes and lower costs through technology and risk-sharing support.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Autonomize AI has partnered with leading Medicare Advantage, national payers, and regional health plans to modernize, streamline, and automate prior authorization processes and workflows through AI-powered agents and copilots that integrate directly with clinical and administrative systems, accelerate decisions, reduce errors and improve regulatory compliance, improve alignment with clinical policy and regulatory compliance, and free up clinical staff to focus on proactive member engagement to improve outcomes. Our experience spans national and regional payers that serve Medicare, Medicaid and Commercial business across the US (b)(4)

	(b)(4) This foundation—across real-world deployments with regulated health plans—has equipped Autonomize to meet CMS's expectations for the WISeR model with confidence, speed, and a strong track record of responsible innovation.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	We have implemented a comprehensive Privacy and Security Program designed to ensure ongoing compliance and protection of sensitive data. We have a designated CISO who oversee compliance and incidents response effort We conduct audit and risk assessments at least once a year and as needed. We have policies and procedures that covers data access, data usage, data retention, and data sharing Our employees are required to perform annual HIPPA training and quarterly security awareness training Access control, audit logs, data encryption and endpoint protection are in place to ensure systems are secure and compliant Attached Security Incident Response Policy document outlines our response plan to handle security events related to data breach.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	Yes

Authorizations or Certifications Document

File Name	WISeR-00134_Authorizations_Autonomize HIPAA - Self Attestation Report
Uploaded On	7/25/2025, 8:03 PM
File Name	WISeR-00134_Authorizations_SOC 2 Type 2 Report (1)
Uploaded On	7/25/2025, 8:03 PM

3. Describe your clinical experience in	Autonomize AI brings a deep understanding of CMS's expectations around medical

medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	necessity review, coverage determination integrity, and clinician-led oversight for prior authorization. (b)(4) (b)(4) (b)(4) Our experience is that this model yields the best results. If this model is unacceptable, we have partnerships with qualified clinical business process outsourcers who can perform medical necessity reviews on our behalf.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	(b)(4)
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	(b)(4)
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))?	No

If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.	

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Ethics and Governance Philosophy Ethical decision-making is embedded into every clinical and operational process we manage, including utilization management (UM). We ensure this through a formal Compliance and Ethics Committee, overseen by our Chief Compliance Officer, with direct reporting to the executive team and Board. This governance structure promotes accountability across all departments. We also operate under the guidance of a Clinical Advisory Committee, led by a physician executive with deep expertise in Medicare policy, prior authorization protocols, and technology-driven utilization management. This committee provides strategic oversight on clinical policy alignment, documentation standards, and care appropriateness frameworks that guide both our AI-driven and manual workflows, ensuring all decisions reflect current clinical evidence and regulatory intent. We are committed to transparency, fairness, and non-bias—including in AI-assisted decision-making. All decisions are subject to clinical review, with escalation pathways to licensed physicians for complex cases. In cases of non-affirmation or denial, we ensure proactive support to providers and beneficiaries in understanding the rationale and navigating next steps such as peer-to-peer reviews, appeals, or education on coverage criteria. Quality Assurance and Grievance Handling Approach We maintain a robust Quality Assurance (QA) program that includes inter-rater reliability assessments, policy and procedure audits, and performance tracking against decision timeliness benchmarks in accordance with CMS standards. All provider and beneficiary complaints and grievances are logged, categorized, and tracked in a centralized system. Each case is reviewed by compliance and clinical teams, with resolution processes governed by defined service-level agreements (SLAs). We conduct root cause analyses on trends to drive process improvements and prevent recurrence. We are equipped to support claims appeals and dispute resolution workflows, whether initiated by MACs, providers, or beneficiaries. Our team is trained on CMS escalation protocols and maintains clear documentation to support prompt, evidence-based responses . Compliance Infrastructure We operate in full alignment with federal standards including HIPAA, CMS IS2P2, HHS ARS, FISMA, and FedRAMP. For any systems not yet fully FedRAMP authorized, we have defined timelines and third-party validation processes in place to achieve full compliance. We strictly adhere to state-specific Local Coverage Determinations (LCDs) and billing codes, and our systems are updated regularly to reflect the latest CMS coding guidance. Our compliance is validated through both internal audit programs and independent third-party certifications. These audits include IT security reviews, operational process audits, and CMS readiness assessments, ensuring continuous alignment with Medicare regulatory requirements and data privacy standards.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Our current book of business for prior authorization processing with national and regional health plans measures (b)(4) (b)(4) Below is a summary of our results: (b)(4) (b)(4) (b)(4) We welcome the opportunity to innovate with CMS and move to a pricing model based on shared savings. We expect to collaborate with the assigned jurisdiction to further identify realistic savings targets.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Autonomize AI is fully prepared to meet all technical, regulatory, and operational requirements to securely interface with Medicare Administrative Contractors (MACs) and access sensitive Medicare beneficiary data under the WISeR model. Our team has a proven track record of integrating with payer systems, working as a HIPAA-compliant business associate, and operating secure, scalable AI infrastructure in high-stakes healthcare environments (b)(4) (b)(4)

	(b)(4)
	(b)(4) Conclusion Our implementation plan is designed to ensure seamless, secure integration with CMS and MAC systems, while minimizing risk and accelerating time-to-value for the WISeR program. Autonomize AI brings not only the technical capability to meet these requirements — but also the operational discipline, compliance maturity, and healthcare experience necessary to serve as a trusted partner to CMS from day one.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Autonomize Inc.
Certifying Individual: **Title:**	(b)(6)

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00024

Requested by (b)(6) on 07/28/2025 12:30

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	ClarityCare AI Inc
b. Doing Business As (DBA) Name(s)	ClarityCare AI
c. Street Address	1111B S Governors Ave, Suite 21607
d. City	Dover
e. State	DE
f. Zip Code	19904
g. Tax Identification Number	990892123
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Company Overview: Partnership between Novitas Solutions and ClarityCare AI ClarityCare AI and Novitas Solutions have partnered to transform utilization management (UM) and prior authorization (PA), combining deep expertise with advanced AI to improve efficiency, transparency, and patient outcomes for Medicare and major health programs. ClarityCare AI is an AI-native healthcare technology company with a mission to ensure patients receive the right care, at the right time, in the right setting. We streamline PA workflows, reduce provider burden, and accelerate access to medically necessary care, while upholding the highest standards of compliance, security, and clinical integrity. Our values—transparency, reliability, partnership, and ethical AI—guide us in building privacy-first solutions that promote equitable access. We envision real-time, point-of-care PA determinations and see the WISeR model as a step toward this vision. Novitas Solutions, a subsidiary of GuideWell Source, is a national leader in Medicare administration. For 58+ years, Novitas has partnered with CMS to administer Medicare Part A and B across 12 states, D.C., Puerto Rico, and the U.S. Virgin Islands, serving 10.4 million beneficiaries and 829,000 providers. Novitas' 2,500+ employees process 360+ million claims and $129 billion in benefits annually. Novitas focuses on sustainability, operational excellence, and integrity, with a culture built on partnership and performance. Services: ClarityCare AI's flagship platform automates and optimizes PA and UM, with: - Automated intake of PA requests from any channel (mail, EHR, portal, phone, fax) - Structuring of clinical and insurance data, having processed (b)(4) of clinical records - AI-driven recommendations for UM clinicians, improving speed and consistency Integration with payer and provider systems, including Medicare Administrative Contractors (MACs) - Audit and analytics tools supporting compliance and continuous improvement Novitas delivers at national scale: - Processing 360+ million Medicare claims annually, totaling $129 billion in payments - Managing 500,000+

	provider enrollment transactions and 4 million provider inquiries per year - Conducting 7+ million medical reviews, appeals, and outreach events annually - Overseeing financial management for $238 billion in annual government health payments - Delivering $57+ million in annual savings through PA and program integrity initiatives Clientele: ClarityCare AI serves health plans, third-party administrators (TPAs), UM vendors, and cost containment organizations in the commercial healthcare sector. Novitas' clients are Medicare beneficiaries, providers, and the federal government, administering the world's largest health insurance program.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; JL Novitas

5. Provide street address, city and state for all locations.

Location Name	CA office
Street Address	435 Brannan St, Suite 201
City	San Francisco
State	California
Zip Code	94107

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00024_Ownership_(b)(4)Consent
Uploaded On	7/2/2025, 6:44 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Contact Type	Primary
Email Address Name Title/Position	(b)(6)

Address	(b)(6)
Business Phone Number	

Contact Type	Secondary
Email Address Name Title/Position Address Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address Name Title/Position Address Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00024_Licensure_ClarityCareAIInc - Approved Certificate of Incorporation (Articles of Incorporation)
Uploaded On	7/2/2025, 6:46 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Novitas Solutions has a Business Associate Agreement with CMS consistent with its A/B MAC JH and JL contracts, and its National Provider Enrollment Eastern Region DMEPOS Task Order. ClarityCare AI has established Business Associate Agreements (BAAs) with the following HIPAA-covered entities: - Regional Health Plans: We have executed BAAs with regional health plans to support their utilization management and prior authorization operations, ensuring secure handling of PHI throughout automated intake, review, and reporting workflows. - Third-Party Administrators (TPAs): ClarityCare AI works with TPAs providing administrative services to self-insured employers, under formal BAAs that govern all data exchange, processing, and compliance requirements. - UM Vendors Seeking Advanced Automation: We maintain BAAs with utilization management vendors who leverage our technology to enhance the efficiency and consistency of their review processes while meeting all HIPAA privacy and security standards. - Cost Containment Organizations Providing Medical Reviews: ClarityCare AI partners with cost containment firms conducting medical necessity reviews, operating under BAAs that ensure the protection and privacy of all patient data handled. Note: Due to client confidentiality and contractual obligations, we do not disclose the names of specific organizations that ClarityCare AI works with publicly, additional details can be provided to CMS upon request and agreement from the specific organizations.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Together Novitas and ClarityCare AI cover a broad range of experience working with payers on prior authorizations. Novitas is currently the Medicare Administrative Contractor (MAC) responsible for administering the CMS-mandated prior authorization programs for both Jurisdiction H and Jurisdiction L. Our affiliated sister company, First Coast Service Options, is the MAC that administers the prior authorization program for JN. As a result, we have extensive experience, knowledge, and expertise with expanding the prior authorization models/demonstrations and will ensure a seamless transition to this new model. ClarityCare AI partners with payers, utilization management vendors, and third-party administrators to modernize and streamline the prior authorization process across fully insured and self-insured populations. Functional Scope of Services & Capabilities: ClatityCare AI technology platform automates two critical aspects of prior authorization and enables full client reporting on any of the components below to enable quality and performance measurement: 1. Data Validation: Upon ingesting data from any source (whether from the provider or from a partner such as a MAC, and from a variety of formats including mail, phone, fax, EHR, web portals, etc.), automates member eligibility checks, benefit verification, and provider network confirmation to ensure every request is accurate and complete before moving to clinical review. Supports ability to resubmit requests for authorization (with audit trail) if initial request is not affirmed, and also supports ability to gold-card providers who have been deemed compliant based on surpassing a pre-defined affirmation threshold. 2. Comprehensive Clinical Review Support: ClarityCare AI leverages advanced AI to provide robust, clinically meaningful support throughout the review process: - Clinical Summarization: Automatically generates clear, structured summaries of the patient's presentation, including relevant history and key test results—with identification of trends over time where applicable (e.g., lab values, imaging results, or vital signs). - Coverage Determination Matching: Matches payer-specific coverage criteria to key evidence extracted directly from the medical record, ensuring transparency and auditability for each decision. - AI-Generated Clinical Rationale: Produces a detailed clinical rationale that specifies why a case meets (i.e., "affirmations")—or does not meet (i.e., "non-affirmations")—coverage determination criteria. The rationale is fully editable by clinicians and tailored to highlight any missing or non-compliant elements. The solution is designed so that affirmations can be automatically generated at a client's request, whereas non-affirmations require clinician involvement and can then facilitate navigation toward higher value services/clinical pathways as well as a peer-to-peer clinical review. - Customizable Letter Generation: Enables creation of prior authorization and denial letters directly from customer-approved templates, streamlining communication with providers and patients (and enabling discussion of potentially higher value clinical pathways) while ensuring compliance with payer requirements and avoiding a perception from providers or beneficiaries that any non-affirmation is an arbitrary limitation on care access. - Enhanced Medical Record Access: Makes the entire medical record—including handwritten notes and low-quality scanned images—searchable, readable, and easily navigable for reviewers, reducing manual effort and minimizing the risk of overlooked information. Experience Across the Care Continuum: ClarityCare AI has processed (b)(4) of prior authorization requests for outpatient procedures (imaging, elective surgeries, therapies), inpatient admissions, specialty and high-cost drugs, and durable medical equipment (DME). Our solutions are deployed by leading regional health plans, TPAs, UM vendors, and cost containment organizations, consistently driving measurable gains in administrative efficiency, turnaround time, accuracy, and compliance. Novitas is currently administering the Medicare Fee-For-Service prior authorization program and has reviewed and processed tens of thousands of prior authorization requests for blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, vein ablation, cervical fusion with disc removal, implanted spinal neurostimulators, and facet join interventions. We also recently implemented a new prior authorization demonstration in Pennsylvania for Inpatient Rehabilitation services. As

	such, we are extremely familiar with the CMS requirements for this program which include provider education, meeting and exceeding timeliness requirements, appropriate interpretation and application of formally documented guidelines (i.e., LCDs, NCDs, etc.) and the importance of reducing fraud, waste and abuse in the Medicare Program. Additionally, Novitas supports the Centers for Medicare and Medicaid Services in administering the world's largest health insurance programs–more than $1 trillion annually: - Medicare Administration: GuideWell Source subsidiaries, Novitas Solutions, Inc. and First Coast Service Options, Inc., possess a portfolio represents over 33% of total Part A/B Medicare program with a $2.3 billion potential contract ceiling spread across three contracts in 15 states/territories serving 10.4 million government beneficiaries and 829,000 healthcare providers. Includes the following services: - Enrollment & Eligibility - Annually process more than 500,000 provider enrollment transactions - Claims Processing - Annually process more than 360 million claims representing over $129 billion in benefit payments - Customer Service - Run a large omnichannel call center that annually process nearly 4 million provider inquiries, over 58.8 million portal transactions, and almost 40,000 beneficiary inquiries - Education & Outreach - Annually deliver about 500 in-person and virtual events reaching over 80,000 participants while maintaining customer satisfaction scores of 4.9 out of 5 - Medical Review/Medical Policy - Using comprehensive data analytics to target reviews, annually process over 7 million automated, routine manual, and complex reviews and conduct outreach efforts to ensure billing and documentation compliance; Develop Medical Policies to help providers understand what services are medically reasonable and necessary, and how to bill/code those services based on data analysis and clinical evidence review - Prior Authorization - Helped CMS stand up and expand the Prior Authorization program, which has contributed over $57 million in projected annual savings, based on the current CMS-approved codes - Appeals - Annually process more than 7 million appeals - Financial Management and Audit Services - Perform financial management, financial reporting, and reconciliations for over $238 billion in government payments and debt management activities for more than $18.2 billion in receivables annually; Annually process more than 12,000 cost reports and perform more than 50,000 audits/reviews annually - Document Management - Annually control, index, and distribute over 14 million incoming hard copy & electronic documents or over 25 million pages using image capture technology & OCR - Healthcare Exchange: Novitas is the national contractor for Exchange Financial Services Support performing financial services in all 50 states and reconciling over $90 billion in payments and collecting over $11 billion in accounts receivables - Program Integrity: Novitas Solutions is one of 14 companies on CMS' multiple award $2 billion IDIQ to provide enrollment and screening support to detect and prevent fraud, abuse, and waste in Medicare and Medicaid programs; Won the CMS East Region Durable Medical Equipment (DME) Provider Enrollment task order valued at over $40 million Novitas has the people (2,500+, including clinicians), innovation (bold ideas and thought leadership), relationships (sought after partners), performance (high CPAR ratings) and program management to support both large- and small-scale transitions, execute on high visibility and complex challenges and help transform and sustain our nation's healthcare ecosystem.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Our organizations bring extensive expertise in healthcare-specific data management and coverage determination implementation. As an established, experienced MAC, Novitas has extensive knowledge of the Medicare Program. We use data to quickly identify Program risks using a variety of data analysis tools to implement corrective activities like prepayment targeted probe and educate reviews and policy development. Novitas relies heavily on National Coverage Determinations (NCDs) and LCDs to reduce improper payments by utilizing these policies in their prepayment and prior authorization reviews. In addition, Novitas works closely with their partners (Unified Program Integrity Contractors, Recovery Auditors, Supplemental Medical Review Contractors, other MACs, etc.) to ensure their LCDs are clear, concise and are evidence based, supported by published literature as they understand the benefit of strong policy in conducting medical reviews and provider education. Novitas monitors the data specific to their LCDs to ensure the LCD is effective and operationalized correctly to reduce appeals and safeguard the Trust Fund by reducing improper payments. The ClarityCare AI model was purpose-built and rigorously trained on comprehensive CMS coverage determination frameworks, including both National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), in addition to other standard UM criteria sets in use by Commercial and Medicaid payers. Since deployment, we have successfully processed (b)(4) pages of medical records across (b)(4) (b)(4) of prior authorization requests across several payer systems, demonstrating proven proficiency with diverse criteria sets from major national carriers, leading third-party criteria developers, and industry standards organizations. ClarityCare AI has developed a deep understanding of Medicare Administrative Contractors (MACs), informed by our proactive engagement and commitment to partner with Novitas for this WISeR RFA response. We recognize that working with a MAC shares many similarities with collaborating with a TPA—both require rigorous compliance, seamless data exchange, and a strong operational partnership to deliver results at scale for downstream customers. Having successfully implemented solutions with TPAs to date, we are adept at meeting the high standards and complex integration needs required by organizations overseeing large and regulated populations. While (b)(4) Novitas, we have proactively established a close working relationship to ensure the WISeR pilot's success. We initiated and led in-depth roadmap discussions with Novitas to clarify milestones, address technical and operational requirements, and assign the right resources

	for each step of the process. This advanced planning has allowed us to map out the full implementation journey, identify key success factors, and ensure all stakeholders are aligned from the outset. We are confident that our strategic partnership will align our service model for CMS and facilitate a smooth implementation for your downstream stakeholders. By leveraging our experience with TPAs and our proactive partnership-building with Novitas, we are well-positioned to deliver a robust, compliant, and fully integrated solution by 1/1/2026—making WISeR a model for successful collaboration and innovation in Medicare prior authorization. Novitas is a FISMA High System with an active Authority-to-Operate (ATO) with CMS, which is based upon its compliance with federal requirements such as the Business Partner Systems Security Manual (BPSSM) and Acceptable Risk Safeguards (ARS) for the High baseline and High Value Asset (HVA) overlay requirements. ClarityCare AI maintains enterprise-grade security certifications and is actively pursuing federal authorization to serve government agencies at the highest security standards. Current Federal Compliance Status: We have achieved substantial progress toward FedRAMP Ready status, having implemented (b)(4) of the required FedRAMP (b)(4) security controls. Our comprehensive security framework positions us to complete full FedRAMP authorization efficiently upon client requirements. Verified Security Certifications: SOC 2 Type 2 Certified - Independently audited annual compliance with stringent security, availability, and confidentiality controls HIPAA Compliant - Full adherence to healthcare data protection standards with documented safeguards for protected health information Documentation & Transparency: All certifications, security assessments, and compliance documentation are available through our dedicated Trust Center, providing complete visibility into our security posture and ongoing compliance efforts. ClarityCare AI actively addresses privacy risk and governance requirements by conducting yearly third-party penetration testing and quarterly disaster recovery mitigation planning. All access logs to personal data are stored in an immutable read-only mode. We have alerts in place when anomalies are detected via (b)(4) If we receive an alert, we investigate to ensure there is no security breach. We also have quarterly meetings in place to review each customer's logs. Our incident response plan includes immediate containment, investigation, notification, and remediation of any problem found. ClarityCare AI is committed to a culture, processes, and technologies that ensure comprehensive privacy protection.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	(b)(4)

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Novitas has been performing medical reviews since the inception of the Medicare Program. We employ credentialed clinical staff, including certified professional coders, that provide clinical experience in performing medical record reviews using formally documented guidelines (e.g., NCDs, LCDs, etc.) to ensure that claims billed to the Medicare Program are medically reasonable and necessary and in compliance with all Medicare rules and regulations. We conduct clinical as well as peer-to-peer reviews and provide documentation checklists, self-service tools, and one-on-one provider education to ensure that we produce and the provider understands our sound coverage determination decisions. Novitas helped CMS set up the Prior Authorization program and we focus on reducing provider burden and appeals by providing thorough education and comprehensive medical reviews. Thanks to ClarityCare AI's footprint within the utilization management world, we have access to organizations with networks of hundreds of clinicians, physicians and specialists who have extensive experience with utilization review and peer-to-peer reviews.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations.	ClarityCare AI enables seamless prior authorization submissions directly within provider EHR workflows. We have implemented (b)(4) allowing providers to initiate and manage prior authorization requests without leaving their native EHR environment. Our solution supports the Da Vinci Prior Authorization Support (PAS) Implementation Guide, facilitating automated, standards-based exchanges with payer

a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	systems. When additional clinical documentation is required, ClarityCare AI is able to identify such cases in a few seconds to flag it to the provider. - Currently Supported: (b)(4) (b)(4) - Planned Support: (b)(4) ClarityCare AI is fully aligned with the CMS Interoperability and Prior Authorization Final Rule. Our technology is built on API-driven architecture and meets HHS-adopted data standards to maximize data sharing, reduce administrative burden, and improve the efficiency and transparency of the prior authorization process for payers, providers, and patients alike. Currently Supported Da Vinci Implementation Guides: - Prior Authorization Support (PAS) Version 2.0.1 - Documentation Templates and Rules (DTR) Version 2.0.0 - Coverage Requirements Discovery (CRD) Version 2.0.1 - Payer Data Exchange (PDex) Version 2.0.0 On Our Roadmap: - CARIN for Blue Button Implementation Guide Supported Specifications and Standards: - OpenID Connect Core 1 - USCDI (United States Core Data for Interoperability) v3.1.1 - HL7 FHIR Release 4.0.1 - HL7 SMART App Launch 2.0.0 - HL7 FHIR US Core 4.0.0 - FHIR 4.0.1 ClarityCare AI remains committed to advancing interoperability by rapidly adopting new industry standards and Implementation Guides as they are published. Our ongoing roadmap is focused on expanding EHR compatibility, enhancing payer integration, and leveraging emerging data exchange frameworks to further streamline prior authorization, reduce friction, and support regulatory compliance for all stakeholders.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	ClarityCare AI leverages a multi-model, best-in-class approach to artificial intelligence, purpose-built for the complexities of utilization management and prior authorization. We integrate and adapt leading AI models from (b)(4) —ensuring rapid innovation, reliability, and world-class security. - Guideline-Driven Model Adaptation: Our adaptation process focuses exclusively on encoding and aligning with publicly available coverage policies and medical necessity guidelines (e.g., Medicare NCDs and LCDs as well as commercial payer criteria). No patient data is ever used for model training; model updates are strictly to ensure the AI follows current clinical policy and coverage rules. - Enriched Clinical Context with Verified Data: In applying these guidelines to individual cases, ClarityCare AI draws on clinically-verified external data sources—including published, peer-reviewed medical literature—to enhance the context and strengthen the clinical evidence for each decision. This ensures every determination is both guideline-compliant and rooted in the latest scientific research. - Customer Data Handling: All customer data is used solely to perform contracted services, such as case review and documentation generation, and never for broader model development or training. - AI Algorithms and Frameworks: Our platform orchestrates (b)(4) (b)(4) architectures using secure cloud infrastructure. Outputs are always traceable, auditable, and fully compliant with CMS and HIPAA requirements. Real-Time, Straight-Through Processing for WISeR: ClarityCare AI's solution is engineered to deliver real-time, straight-through processing for prior authorization affirmations —directly aligned with WISeR RFA objectives: - Real-Time Processing: Our system analyzes thousands of pages of medical records in seconds, providing fully automated, auditable affirmations in real time when coverage criteria are clearly met. - Accurate Results: We are confident in the accuracy and replicability of our results and have demonstrated this through controlled client studies that demonstrate near (b)(4) consistency with client's manual process, with approximately of the remaining (b)(4) (equivalent to (b)(4) cases) suggesting an inappropriate approval of care. We believe this suggests significant opportunity for both enhanced quality and medical cost savings by avoiding medically unnecessary or non-covered services. - Provider-Facing Real-Time Experience: We believe providers should receive real-time authorization decisions at the point of care. Our technology supports immediate determinations for submitted authorizations, drastically reducing administrative burden and patient delays, and enabling resubmissions as providers wish. In our experience, provider satisfaction is directly related to our ability to deliver immediate processing of accurate authorization decisions (based on data submitted) at the point of care. - Automatic Escalation for Non-Affirmation or Ambiguity: In cases where documentation is unclear or clinical nuance is required, our AI proactively escalates to a human reviewer. Based on experience deploying the solution approximately (b)(4) cases are flagged as requiring human review (beyond non-affirmations) —primarily for complex scenarios—ensuring safety and clinical rigor. - End-to-End Traceability: Every decision is linked to supporting evidence in the original medical record, with a clear, editable clinical rationale generated for each case. - Rapid Turnaround: Automated, straight-through approvals are issued in real time (within minutes), while escalated cases are resolved by clinicians within (b)(4) ClarityCare regularly conducts verification checks in order to maintain accuracy and address any emerging risks. ClarityCare does not make clinical decisions, it follows the coverage determinations and looks for evidence to support each of them. It's a tool used by clinicians to streamline their review process. For cases that go through our algorithm, we run statistical tests on key variables every quarter (e.g. service lines). This ensures that there is no statistically significant difference in case outcomes for comparable cases across service categories. Furthermore, we have a panel of clinicians who we meet with on a regular basis to evaluate the model's performance in production and the new models under development. Finally, all protected health information is managed in strict accordance with HIPAA and CMS requirements, with comprehensive access controls and data governance to safeguard privacy at every step. Our robust human-in-the-loop escalation protocol is foundational to our approach. The AI is specifically trained to recognize its own uncertainty and escalate cases it cannot confidently approve—maintaining

	patient safety and clinical standards while enabling true real-time, straight-through processing for the majority of authorizations. This creates a continuous improvement loop, with escalated cases providing critical learning to further advance safe automation and move toward a future where (b)(4) of prior authorizations can be processed immediately, with human oversight reserved for the most complex or ambiguous cases (and to preserve human decision making for any non-affirmation decision). By combining advanced AI, real-time automation, careful escalation, continuous validation, and strict guideline adherence, ClarityCare AI is uniquely positioned to help WISeR set a new standard for efficient, accountable, and patient-centered prior authorization. Suggestion: Given our system's real-time capabilities, we recommend that the WISeR pilot explicitly offer participating providers real-time(<1 min) processing of authorizations affirmations they submit. This will maximize value for providers, reduce delays for patients, and fully demonstrate the transformative potential of straight-through, technology-enabled prior authorization.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	(b)(4)

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	At ClarityCare AI, security, ethics, and quality are foundational to every aspect of our technology and operations. Our approach is built on three pillars: patient safety, transparent decision-making, and collaborative partnership with providers and payers. - Human-Centered, Evidence-Based Ethics: Our system is grounded in evidence-based medicine and established clinical guidelines. We ensure that every decision is anchored to objective, peer-reviewed criteria—never arbitrary or opaque algorithms. While our technology enables advanced automation, we have deliberately engineered the system to escalate any ambiguous or uncertain cases to expert clinicians for review. This "human-in-the-loop" design safeguards against inappropriate automation and ensures that complex clinical decisions remain in the hands of qualified professionals. - Transparency and Auditability: ClarityCare AI provides full traceability for every recommendation, clearly indicating the specific source in the original medical record and the clinical rationale for each determination. Clinicians retain the ability to override, edit, or supplement any AI-generated suggestion, maintaining accountability and trust at every step. - Continuous Quality Assurance: We conduct regular verification checks and continuous statistical testing on key variables across all service categories. This ensures consistency, fairness, and the absence of unintended bias in outcomes. Our panel of practicing clinicians performs ongoing retrospective reviews to evaluate model performance and quality in production, and to validate any system updates before deployment. - Rigorous Compliance and Data Security: ClarityCare AI adheres strictly to all HIPAA, CMS, and industry regulations for the handling of protected health information (PHI). Our infrastructure is built with robust security controls, proactive monitoring, and comprehensive access management. We maintain a proactive approach to risk management and rapid incident response. - Deep Partnership for Pilot Success: For this WISeR RFA, we have established a direct partnership with Novitas, recognizing that close collaboration with the MAC is essential for pilot success. By working hand-in-hand with Novitas—who oversees the necessary infrastructure—we ensure seamless technical integration, alignment on regulatory requirements, and rapid issue resolution. This relationship, already in place, is crucial for meeting the targeted 1/1 launch date and achieving the ambitious goals of the WISeR initiative. - Commitment to Ongoing Collaboration: We view our relationships with patients, providers, and payers as true partnerships. By prioritizing safety, ethics, and transparency, we create an environment of mutual trust—supporting collaborative problem-solving and ongoing system improvement. We make it very easy for providers and payers to contact our support and have dedicated on-call engineers. Through these standards, ClarityCare AI delivers a solution that advances the safety, ethics, and partnership support for all stakeholders—ensuring that technology enhances, rather than replaces, the vital human judgment at the heart of healthcare. The Novitas MR QA Program evaluates the prior authorization review decision, identifies any quality trends, determines opportunities for improvement and develops training activities that foster continuous improvement. The key quality elements include monthly quality assessments, quarterly Inter-Rater Reliability (IRR) reviews and a robust training program.

	Documented processes, encouragement of continuous improvement and monthly monitoring reports ensure the program's success. After a claim denial, a provider has 120 days to submit a redetermination request for additional review of the claim denial. This is sent with medical documentation to review the service or if there is a clerical error, i.e., UTN not on claim, that caused the claim denial the provider will send in the redetermination request what needs to be corrected on the claim and any documentation to support this. The MAC has 60 days to review the redetermination and send a decision letter of the review to the requestor of the redetermination (Provider or Beneficiary). If no records are received the Appeals team will send an additional documentation request (ADR) letter requesting medical documentation. When reviewed the clinical reviewer is looking to see if the additional documentation submitted meets the established coverage requirements. ClarityCare AI maintains comprehensive compliance with federal regulations through multiple layers of oversight and certification, including full HIPAA compliance with robust data privacy protections and SOC-2 Type 2 certification that undergoes annual auditing processes. The system is designed to support CMS 0057-F compliance requirements, providing new prior authorization API endpoints with proper documentation, faster turnaround times, transparent decision-making trails, and comprehensive metrics reporting. At the state level, we are actively addressing varying state laws that limit AI involvement in medical benefit decisions, specifically acknowledging and ensuring compliance with SB1120 in California, SB24205 in Colorado, HB2472 in Illinois, and the pending A9149 legislation in New York. We have a commitment to full compliance, so if there are any specific regulations that you would like to validate in the ClarityCare AI solution, please let us know and we will provide that detail. Novitas is currently a Medicare Administrative Contractor (MAC) who is very familiar with CMS contractual requirements/regulations. We have multiple layers of oversight including an enterprise-wide compliance program which has been awarded the Health Ethics Trust (HET) certification since 2015 which is the only compliance program certification-accreditation in the healthcare industry. We received an HET Best Practice recognition for seven consecutive years and care deeply about doing the right things the right way. Our proven track record of exemplary performance demonstrated by the outcomes of CMS audits (i.e., Quality Assurance Surveillance Program) demonstrates our commitment to ensuring compliance with all Medicare regulations.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	ClarityCare's experience in deploying our AI-driven utilization management platform within health plan UM departments has demonstrated initial medical cost savings in the range of (b)(4) This figure reflects outcomes observed when our solution is implemented across all procedures within a health plan, rather than targeting a specific subset of services. These savings primarily arise from the reduction of inappropriate, unnecessary, or non-medically necessary care immediately following implementation. It is important to note that this (b)(4) savings range is based on a comprehensive deployment and may vary depending on the specific services, volume, locations and specialties ultimately selected for the WISeR program in each MAC jurisdiction. Savings in WISeR may be higher or lower depending on baseline utilization, local practice patterns, and the targeted scope of the program. Short-Term Impact: - Immediate cost avoidance through the elimination of improper payments and reduction in unnecessary care. - Pronounced impact in the early phases, as provider behavior adjusts to the new review protocols and oversight. Long-Term Impact: - Ongoing reductions in improper payment rates, fraud, waste, and abuse. - Reduced provider and administrative burden, especially regarding appeals and post-payment audits. - Enhanced protection for Medicare beneficiaries—both medically and financially—by reducing exposure to unnecessary interventions. Additional Notes: Actual realized savings are directly tied to the types and volume of services selected for inclusion in WISeR. Projections are informed by ClarityCare's historical data and our operational track record, as well as industry benchmarks and publicly available data. We are eager to refine these estimates in partnership with Novitas, as more granular information on service selection and jurisdictional needs becomes available.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Implementation Timeline & Plan for MAC Interface and Medicare Data Access Drawing on our successful deployments in payer environments—including direct collaboration with Novitas—we have developed a structured timeline and set of internal actions to ensure readiness for interfacing with MACs and handling Medicare beneficiary data in compliance with HIPAA and all applicable privacy and security laws. Target Go-Live: 1/1/2026 4 Months Prior: Contracting & Legal Readiness - Execute all necessary agreements between CMS and the model participant, detailing roles, responsibilities, and payment terms - Complete Business Associate Agreement (BAA) and Master Services Agreement (MSA) - Legal review and revisions to ensure all contracts align with HIPAA, Medicare, and state-level requirements - Deadline: 09/30/2025 3 Months Prior: Implementation Planning - Coordinate handoff between MAC and model participant - Joint planning sessions to define implementation steps and responsibilities - MAC-led provider training for portal usage - Establish and integrate national and local coverage determination policies for the jurisdiction - Set up secure technical connectivity for UTN generation and medical review workflows - Deadline: 10/31/2025 2 Months Prior: Initial Testing & Validation - Conduct retrospective testing using the previous 6 months of adjudicated prior authorizations for the 13 designated services - Run ClarityCare AI review alongside human review to compare outcomes Measures: - Concordance rates between AI and human decisions (inter-rater reliability of affirmations and non-affirmations) - Projected medical cost savings - Review cycle times - Use findings to identify improvement areas and refine models/processes - Pilot live

	submission of authorizations with select provider partners - Deadline: 11/30/2025 1 Month Prior: Final Testing & Launch Prep - Complete final round of integrated testing and process validation - Address any outstanding technical or operational issues - Deadline: 12/31/2025

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	ClarityCare AI Inc
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00035

Requested by (b)(6) on 07/28/2025 12:31

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Connect Health Information Network Corporation
b. Doing Business As (DBA) Name(s)	ConnectHIN
c. Street Address	960 Wheeler Road #5218
d. City	HAUPPAUGE
e. State	NY
f. Zip Code	11788
g. Tax Identification Number	990836395
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	ConnectHIN offers direct healthcare services through our national network of licensed providers. Our platform connects patients with ConnectHIN qualified physicians, nurse practitioners, and specialists for a wide range of clinical services. These services can be delivered virtually or in person, depending on the program and location. By leveraging our integrated technology and care coordination tools, ConnectHIN ensures efficient, compliant, and patient-centered care across all touchpoints. ConnectHIN empowers providers to maintain their independence while gaining access to the full infrastructure required to deliver reimbursable, high-impact care at scale. Whether you're an individual practitioner, part of a medical group, or expanding your services through remote or pharmacy-based care, ConnectHIN offers a streamlined path to success. By joining ConnectHIN, providers receive the freedom to focus on clinical care while we handle the operational, billing, pre-authorization and compliance complexities. From Medicare Part B billing to commercial payer programs, our platform enables you to offer services like telehealth, Remote Monitoring (RPM/RTM),Chronic Care Management (CCM), Continuous Glucose Monitoring (CGM), and incident-to procedures, all with confidence and support. We provide a state-of-the-art technology platform for documentation, eligibility verification, care planning, and analytics—ensuring you remain audit-ready and aligned with payer expectations. Our team takes care of credentialing, benefit reassignment, and claims management so you can expand your practice without expanding your overhead. Perhaps most importantly, ConnectHIN helps providers bridge gaps in care and succeed in value-based programs by connecting them to patients at critical points—such as pharmacies or underserved communities where access to care is limited but engagement is high. You gain more than just billing capability; you gain a care delivery model that improves outcomes and positions your practice for long-term sustainability. ConnectHIN is a National Billing Provider • Approved

	by CMS to bill Medicare Part B nationwide • Serves as a centralized billing entity for incident-to, telehealth, and pharmacy-based services • Expanding to bill commercial payers, Medicaid, and value-based care programs ConnectHIN offers Turnkey Reimbursement Infrastructure • Manages all billing operations: claims, eligibility checks, clearinghouse submission, payment tracking • Handles reassignment of benefits, payer link letters, and provider enrollment • Offers direct billing for Medicare, commercial insurance plans, and managed care organizations ConnectHIN offers Multi-Program Enablement • Telehealth visits • Chronic Care Management (CCM) • Remote Physiologic Monitoring (RPM) • Remote Therapeutic Monitoring (RTM) • Continuous Glucose Monitoring (CGM) • Medical procedures and incident-to services • Preventive services, screenings, behavioral health, and weight loss management
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	J15 CGS

5. Provide street address, city and state for all locations.

Location Name	ConnectHIN IPPN Service Location
Street Address	(b)(6)
City	Scottsdale
State	Arizona
Zip Code	85254

Location Name	ConnectHIN Principle
Street Address	31 Lindbergh Circle
City	Huntington
State	New York
Zip Code	11743

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00035_Ownership_ConnectHIN Ownership Interest 7.5.25
Uploaded On	7/5/2025, 11:07 AM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	

Title/Position	(b)(6)
Address	31 Lindbergh Circle, Huntington, NY 11743
Business Phone Number	631-403-0062

Contact Type	Secondary
Email Address Name Title/Position	(b)(6)
Address	960 Wheeler Road #5128, HAUPPAUGE, NY 11788
Business Phone Number	631-403-0062

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00035_Licensure_ConnectHIN NYS Filing Certified Copy
Uploaded On	7/5/2025, 11:10 AM
File Name	WISeR-00035_Licensure_NYS ConnectHIN Filing Receipt (2)
Uploaded On	7/5/2025, 11:11 AM
File Name	WISeR-00035_Licensure_Connect HIN Certificate of Status - Short
Uploaded On	7/5/2025, 11:12 AM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business	Independent Pharmacy Provider Network - 150 independent Pharmacies Collaborating with Providers using Incident to Billing with Providers Nationwide (b)(4) (b)(4)

associate agreement.	(b)(4)

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	ConnectHIN is a healthcare technology and services company built on two decades of health IT and operations experience through Helix Data Services (HelixDS). Founded and led by experts in EHR integration, provider enablement, and value-based care, the ConnectHIN team has developed scalable tools to support care delivery and administrative efficiency across Medicare Advantage, commercial, and Medicaid payers. With over 20 years of experience through HelixDS, our leadership has supported provider groups, pharmacies, FQHCs, and large payer-aligned entities through the development of platforms that reduce administrative burden, accelerate reimbursement, and enhance clinical documentation and compliance. Experience with Medicare Advantage Plans and Other Payers ConnectHIN and HelixDS have provided services aligned with the operational requirements of major Medicare Advantage (MA) and commercial plans, including: • (b)(4) (b)(4) Functions and Services Performed for These Plans: 1. Automated Prior Authorization (PA) Technology Our team developed a comprehensive PA engine that supports electronic submission, tracking, and decision support across multiple specialties. This includes: (b)(4) (b)(4) (b)(4) 2. Staffed and Hybrid PA Operations We offer a staffed prior authorization support service that works in tandem with the technology. Staff members: (b)(4) (b)(4) (b)(4) 3. Pharmacy-Integrated Clinical Services With the IPPN model and ConnectHIN's supervisory framework, prior authorization has been embedded into the workflow for: (b)(4) (b)(4) (b)(4) 4. Primary Care Enablement and Compliance Our prior authorization system is integrated directly into encounter workflows for ConnectHIN-affiliated providers, ensuring: (b)(4) (b)(4) (b)(4) Provider Gold Star Program – Now Embedded in ConnectHIN As part of our innovation at HelixDS, we developed a Provider Gold Star Program, which (b)(4) (b)(4) (b)(4) All ConnectHIN Network Providers now have the opportunity to participate in this model. Through consistent and accurate documentation and billing practices, providers can gain accelerated access to services and reduce administrative burdens associated with prior authorization. Demonstrated Outcomes • (b)(4) reduction in PA turnaround times • (b)(4) approval rate on first submission for Gold Star Providers • Improved provider satisfaction and reduced manual data entry • Better alignment with payer audit and compliance standards
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	A. Healthcare-Specific Data Experience, Prior Authorizations, Pre-Payment Reviews, and Coverage Determinations ConnectHIN is a healthcare technology and services company whose leadership has spent more than 20 years building, deploying, and supporting data-driven solutions for providers, pharmacies, and health plans nationwide. Our cloud platform and operational teams handle every stage of the utilization-management life cycle: Functional Area What ConnectHIN Delivers (b)(4) (b)(4)

	(b)(4) (b)(4) . b. Federal Security Certifications and Authorizations Area Status Notes (b)(4) (b)(4) (b)(4) . c. HIPAA & Data-Privacy Compliance Framework (b)(4) (b)(4) _____ Summary ConnectHIN combines two decades of healthcare data expertise with a modern, security-first platform. We automate prior authorizations, embed LCD/NCD guidance, replicate MAC audit logic through our own Ai enabled (b)(4) and maintain rigorous HIPAA and federal security controls—delivering faster approvals, fewer denials, and continuous compliance for our network providers and payer partners.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	ConnectHIN maintains a clinical infrastructure that supports real-time and retrospective medical reviews to ensure documentation and coverage determinations meet payer and CMS standards. Our clinical team has extensive experience conducting: • Medical necessity reviews aligned with LCDs/NCDs, CMS manuals, and payer-specific coverage criteria. • Resubmissions and appeals with enhanced documentation following initial denials. • Peer-to-peer (P2P) consultations, engaging directly with medical directors at Medicare Advantage plans and commercial payers to support approval of clinically justified services. Our experience spans multiple high-priority service categories, including: • (b)(4) (b)(4) (b)(4) Staffing and Clinical Oversight Structure ConnectHIN's coverage determination and review process is supported by a multi-tiered clinical staffing model designed to ensure all reviews are handled by appropriately credentialed professionals: (b)(4) (b)(4)

	(b)(4) _____ Summary ConnectHIN has a robust clinical review and medical necessity infrastructure that combines (b)(4) (b)(4) Our structured, scalable staffing model allows us to conduct accurate, policy-aligned medical reviews, handle appeals and peer-to-peer resubmissions, and support our providers in delivering care that is both clinically appropriate and reimbursable.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	EHR Integration for Prior Authorization Deployment ConnectHIN has developed a modular prior authorization engine that can integrate with Electronic Health Record (EHR) systems using a combination of: HL7v2 and HL7 FHIR® standards SMART on FHIR application layers Direct APIs and flat-file integration (for legacy systems) Custom webhook and queue-based interfaces (for specialty use cases) Our platform enables prior authorization (PA) initiation, documentation verification, status tracking, and closure — all triggered directly from within the EHR workflow or via our standalone portal. Functional Capabilities within EHRs: (b)(4) (b)(4)
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the	Artificial Intelligence (AI) and Machine Learning (ML) Experience in Coverage Determination ConnectHIN has developed and deployed a proprietary artificial intelligence framework known as (b)(4) (b)(4)

MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	(b)(4)
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality	ConnectHIN's Commitment to Ethics, Compliance, and Quality ConnectHIN is built upon a foundation of ethical healthcare delivery, technology transparency, and regulatory compliance. Our operations are guided by principles that prioritize: Patient safety and access Provider autonomy and documentation integrity Payer alignment and regulatory consistency Equity, transparency, and trust across all interactions Our leadership team

standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	brings over 20 years of experience implementing compliance-driven systems and provider-focused solutions in both public and private healthcare settings. a. Quality Assurance in Utilization Management, Grievances, and Claims Utilization Management (UM) Quality Controls All UM decisions are made based on evidence-based criteria, including CMS coverage guidelines (LCD/NCD), payer-specific policies, and clinical judgment from licensed medical professionals. (b)(4) (b)(4)
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	ConnectHIN has a robust clinical review and medical necessity infrastructure that combines licensed providers, trained nurse reviewers, and a dedicated medical director. Our structured, scalable staffing model allows us to conduct accurate, policy-aligned medical reviews, handle appeals and peer-to-peer resubmissions, and support our providers in delivering care that is both clinically appropriate and reimbursable. ConnectHIN projects meaningful cost savings and operational efficiency gains from its participation in the WISeR initiative, driven by automation, reduced administrative burden, improved documentation accuracy, and faster decision-making. Estimated Savings by Category: Area of Impact Estimated Annual Savings per MAC Jurisdiction Basis of Estimate Prior Authorization Processing Costs (b)(4) Automating (b)(4) of prior auth volume for high-use services, reducing manual review time by (b)(4) Denied Claims and Appeals (b)(4) Reducing initial denial rate from (b)(4) through better documentation and AI-driven pre-check Administrative Labor (Provider and Payer) (b)(4) Decreased call-center and admin time for staff at both provider and MAC levels Turnaround Time & Avoided Delays (b)(4) Improved patient access and throughput by reducing PA delay by (b)(4) on average Appeals and Peer-to-Peer Reviews (b)(4) in peer reviews and appeal volume due to AI-based alignment with (b)(4) at the point of care These jurisdictions include large Medicare Advantage and high-volume FFS Medicare populations, giving the initiative immediate savings potential at scale. Total Estimated Savings: (b)(4) per MAC jurisdiction annually, with national scalability potential exceeding (b)(4) per year as ConnectHIN and (b)(4) are deployed across more regions and services.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in	ConnectHIN has a proven, scalable infrastructure and compliance framework that enables rapid deployment and secure data exchange with MACs, including National Government Services (NGS) under Jurisdiction 6. We are fully prepared to meet WISeR timelines for technical integration, operational readiness, and regulatory compliance. Implementation Timeline and Milestones Phase Timeframe Key Actions & Deliverables (b)(4)

accordance with HIPAA and other applicable privacy and security laws.	(b)(4) (b)(4) • HIPAA-Compliant Environment: All systems used to store or process beneficiary data meet HIPAA Privacy, Security, and Breach Notification Rule requirements. (b)(4) (b)(4) (b)(4) Business Associate Agreements (BAAs): BAAs are in place with any third-party vendors or hosting providers involved in claims or data transmission. • Data Incident Response Plan: (b)(4) (b)(4) Medical Review Protocols: (b)(4) (b)(4) Summary ConnectHIN is fully prepared to meet WISeR timelines and compliance requirements. Our technology platform, internal processes, and experienced team are ready to interface with NGS (J6 MAC) to manage Medicare beneficiary data responsibly and securely—while delivering prior authorization automation that meets the program's goals.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Connect Health Information Network Corporation
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00084

Requested by (b)(6) on 07/28/2025 15:45

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Belcan Government Solutions, Inc.
b. Doing Business As (DBA) Name(s)	Belcan Government Solutions, Inc.
c. Street Address	21345 Ridgetop Cir, Ste 300
d. City	Sterling
e. State	VA
f. Zip Code	20166
g. Tax Identification Number	522119134
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Belcan Government Solutions (Belcan), a Cognizant Company, is a prominent global supplier of design, manufacturing, supply chain, information technology, product engineering, and software and digital engineering services to the aerospace, government services, automotive, industrial, and defense markets. Bolstered by Cognizant, Belcan brings deep experience and proven high performance delivering across a federal portfolio over the past two decades. Founded in 1958 and based in Cincinnati, Ohio with 10,000+ employees spread across 60+ worldwide locations in 30+ countries, Belcan has established itself as a leader in providing mission-critical solutions through our network of more than 6,500 skilled engineers and technical consultants, and more than 1,200 supply chain experts supporting over 600 customers. We consistently earn customer trust by taking a performance-driven, partnering approach to provide value-added solutions with speed and scalability. Cognizant's recent strategic acquisition of Belcan integrates our deep engineering capabilities and domain expertise across aerospace, maritime, defense, and the federal government with Cognizant's scale and multidecade digital engineering experience, providing our clients with access to advanced AI, cloud, and data technologies. Belcan is now Cognizant's federal sector delivery arm for its family of companies under its ownership. This positions us to provide innovative, high-quality solutions tailored to meet complex government and military needs with proven delivery assurance. As a Cognizant company, Belcan has the breadth of a large company's capabilities, resources, and experience to manage programs of large scope and scale while retaining the agility and responsiveness of a smaller company. Our unique industry-based, consultative approach helps many of the best-known organizations in every industry and geography envision, build, and run more innovative and efficient businesses. Belcan and Cognizant together form a powerhouse firm that will meet the vast majority of requirements for this initiative. Our services and solutions serve

	over 220 million lives in the United States. We are clearly an unrivaled “one-stop-shop” organization as your partner.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas

5. Provide street address, city and state for all locations.

Location Name	Belcan Government Solutions, Inc.
Street Address	21345 Ridgetop Cir, Ste 300
City	Sterling
State	Virginia
Zip Code	20166

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00084_Ownership_Belcan_Ownership Interest Document
Uploaded On	7/25/2025, 2:51 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	21345 Ridgetop Cir, Ste 300, Sterling, VA 20166
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00084_Licensure_Belcan Government Solutions, Inc.-VA-Incorporation
Uploaded On	7/25/2025, 2:55 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.	
N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Our parent company, Cognizant, regularly processes PHI and ePHI as a Business Associate for all our clients. Due to our disclosure policies and client agreements, we will not be providing the names of our clients, but this can be discussed further in the process if desired.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	We have deep and broad experience working with Medicare Advantage (MA) plans and other health insurers to modernize and optimize prior authorization (PA) processes. Our engagements span both technology and operations, with a focus on automation, regulatory alignment, and member/provider experience. We currently support prior authorization for several major Medicare Advantage organizations, including: • Largest National Insurer • Blues plans • Regional Health Plans Across these engagements, we deliver a mix of technology solutions and business process services designed to support clinical appropriateness, cost management, and compliance with CMS and state requirements. Functions Delivered for Medicare Advantage Plans 1. Technology Enablement: Through our TriZetto® suite, we provide technology solutions that automate prior authorization workflows, apply real-time medical necessity logic, and improve transparency between payers, providers, and members. Capabilities include: • Automated intake and routing of PA requests • Real-time benefit and cost estimation (including for items/services covered under CMS transparency rules) • Configurable clinical criteria engines aligned with NCD/LCD guidelines • Integrated authorization tracking, reporting, and audit trails 2. Clinical and Operational Support Services: We also deliver full-service utilization management (UM) and PA operations for MA plans, including: • Clinical staff (RNs, MDs, LPNs) for medical necessity review • Non-clinical staff for intake, routing, provider communication, and data entry • Appeals support and peer-to-peer review coordination • Delegated reporting and CMS compliance monitoring 3. Compliance and CMS Readiness: Our solutions and services are built to align with CMS guidelines for prior authorization, including: • Timeliness standards for decision-making • Medical policy management tied to NCDs/LCDs • Audit preparation and documentation • Integration with CMS initiatives, including the CMS Interoperability and Prior Authorization proposed rule and WISeR-specific transparency and reporting expectations In addition to providing prior authorization support to Medicare

	Advantage program, we leverage more than 20 years of experience in providing technology-enabled services to the government market exclusively. We are the #1 core system vendor in Managed Medicare and Medicaid. Our Government Programs practice proudly supports all of the top 10 Medicare Advantage leaders. Our expansive payer client base includes over 100 Medicare Advantage plans covering12 million Medicare Advantage lives demonstrating our deep expertise and trusted presence in the managed care landscape. We partner with over 400 payer organizations and support over 360,000 care providers across our healthcare business.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	We offer comprehensive Business Process Outsourcing (BPO) support that extends across both non-clinical and clinical components of Utilization Management. Our teams include experienced clinicians—such as registered nurses—who conduct clinical reviews for prior authorizations and perform medical necessity assessments. Meanwhile, physician advisors lend expert guidance and oversight to ensure clinical integrity through Cognizant's Clinical Circle of Excellence. With 6+ global delivery centers and over 15 years of experience, we've built a strong foundation in medical determination. With our established Clinical Circle of Excellence, we possess the flexibility to adapt to and adhere to a wide range of policies and guidelines including the application of NCDs, LCDs, InterQual, and MCG guidelines. This capability allows us to tailor our services to meet the specific goals and requirements of each client. For instance, our experience with guideline application is demonstrated by our achievement of a first pass Inter-rater Reliability (IRR) accuracy rate exceeding 96%, reflecting consistent adherence to medical necessity review standards for a large Midwest payer. Our UM services include intake, medical prior authorization, concurrent and retrospective reviews, appeals and disputes, behavioral health and pharmacy authorization, and peer review support. As a leader in the healthcare industry, we leverage Cognizant's significant experience integrating with a variety of different applications including claims processors. Today, we support and maintain foundational relationships with a handful of clients that work with MACs within multiple jurisdictions. We use Health Information Trust Alliance (HITRUST) guidelines for guidance for healthcare business services. We achieved HITRUST certification for one of our healthcare business units and are in the process of obtaining HITRUST certification for an additional three healthcare business units. We regularly process PHI and ePHI for healthcare clients as a Business Associate. In some of these cases, we've achieved HITRUST certification for specific client engagements according to contractual requirements. Cognizant is ISO/IEC 27001:2022 certified which is valid for the Security of information and information processing facilities owned and operated by Cognizant. Cognizant also has an ISO 22301:2019 certification for Business Continuity Management Systems (BCMS). This achievement reflects our commitment to client focus, operational resilience, and regulatory alignment. The security management of our solutions must adhere to local and global security standards including ISO 27001, NIST (National Institute of Standards and Technology) and HIPAA (Health Insurance Portability and Accountability). Our solutions are built to and operated under a set of security controls mandated by Cognizant that are based on ISO 27001, NIST and meet HIPAA requirements. Various TriZetto Solutions have achieved SOC 2 and HITRUST Certifications. While our solution within the current hosted infrastructure is not a FedRAMP government cloud, we are prepared to deploy our TriZetto product solution for this engagement into a government cloud environment, such as the CMS AWS GovCloud. As our setup would likely constitute a new Cloud Service Offering (CSO), we understand we would need to obtain a separate FedRAMP authorization through preparation, third-party testing, and agency review. We would leverage the government cloud provider's compliant controls (e.g., physical security, access management) to reduce the assessment burden via control inheritance, documented in our System Security Plan and seek an interim Authority to Operate as we proceed to obtain FedRAMP authority for the CSO. Additionally, we have experience supporting clients in achieving FedRAMP Moderate authorization for their government cloud environments hosting our solutions, ensuring seamless compliance with federal requirements. We also hold the CMMC Maturity Level 2 (NIST 800-171) Certification as well as the ISO 27001:2022 certification. We have implemented applicable HIPAA controls where required, such as for accounts that are a part of our healthcare line of business, or for client engagements where such controls have been mutually agreed upon. We take our obligations under applicable privacy laws very seriously and have implemented extensive measures to protect against data breaches. We have policies and procedures in place to respond to potential data incidents and ensure compliance with applicable laws and our contractual obligations. Additionally, compliance with NCQA, CMS, and other regulatory standards is achieved through a multi-layered governance and operational framework when services are utilized and agreed upon: 1. URAC Accreditation: Cognizant is URAC-accredited provider for Utilization Management services, with full accreditation for HUM 8.1 and WCUM 8.2 valid until March 1, 2028. 2. Dedicated Compliance Department: As part of our Business Process Outsourcing (BPO) team, we maintain a specialized compliance team responsible for monitoring regulatory changes, ensuring timely filing of US state licensure requirements, and managing mandatory reporting. 3. Security and Infrastructure Controls: o (b)(4) (b)(4) (b)(4) (b)(4) 4. Training and Certification: o Our internal training platform supports NCLEX licensure for nurses, ensuring clinical staff meet US standards. o Ongoing reinforcement through refresher sessions, process knowledge tests, and

	performance improvement plans. o Quality assurance frameworks including RCA, CAPA, and calibration sessions to maintain compliance and performance 5. Incident Response Plan: We have a documented process for reporting and responding to privacy complaints and security incidents involving client information. (b)(4) (b)(4) (b)(4) Additionally, we will follow incident reporting procedures set forth in an applicable client services agreement.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	Yes

Authorizations or Certifications Document

File Name	WISeR-00084_Authorizations_BGS CMMC Certificate
Uploaded On	7/25/2025, 3:05 PM
File Name	WISeR-00084_Authorizations_2024 Cognizant TPS SOC 2 vF
Uploaded On	7/25/2025, 3:07 PM
File Name	WISeR-00084_Authorizations_2024 TCHS SOC 2 _vfinal
Uploaded On	7/25/2025, 3:06 PM
File Name	WISeR-00084_Authorizations_2024 TPS HITRUST r2 Certification Ltr wScope
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3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Clinical Experience We are proud of the scale and impact of our Clinical Services Practice. We currently support over 40 million lives through our platform, work with 30+ clients (a large portion of which have Medicare Advantage plans), and have a team of more than 4,000 associates, including 1650+ registered nurses. Utilization Management, including prior authorization intake and review continues to reflect a large portion of our health plan engagement. Our teams are proficient in a variety of clinical areas, including and most especially: • Utilization Management: Evaluating the necessity, efficiency, and appropriateness of healthcare services. • Prior Authorization Reviews: Ensuring that medical services are approved before they are provided. • Concurrent Reviews: Monitoring patient care during hospital stays to ensure appropriate treatment and resource use. • Appeals Reviews: Handling appeals for denied claims or services to ensure fair and accurate decisions. Staffing Structure We maintain rigorous standards for the qualifications, licensure, and training of our staff involved in Utilization Management (UM) and Care Management (CM) activities. Our clinical teams consist of credentialed professionals, including registered nurses (RNs), physician advisors, and other licensed healthcare practitioners, each holding active and unrestricted licenses in their respective jurisdictions. For clinical roles, we require relevant educational backgrounds—such as nursing degrees or medical qualifications—along with valid licensure that is regularly verified and kept current. Staff assigned to U.S.-based health plans or providers often hold U.S. state licenses, ensuring compliance with client and regulatory requirements. We also support ongoing professional development, encouraging advanced certifications in case management (such as CCM, ACM, or URAC certifications), utilization review, and related healthcare domains. All UM staff undergo comprehensive onboarding and periodic training programs covering clinical protocols, regulatory requirements (including HIPAA, NCQA, CMS, and URAC standards), data security, and best practices for quality assurance. Training is updated regularly to

	reflect the latest industry developments, compliance standards, and digital toolsets used in our service delivery. In addition, we foster a culture of continuous learning through ongoing education, case reviews, peer discussions, and access to subject matter experts. This ensures our teams remain well-versed in evolving clinical guidelines, regulatory expectations, and innovative care management strategies—delivering the highest levels of service quality, compliance, and patient-centered outcomes for our clients.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	We enable the exchange of prior authorizations today as part of our clearing house business through TriZetto Provider Solutions—the third largest clearing house exchanging over 3 billion transactions a year, nearly 11,000 payer connections, 500+ EHR systems, and 900,000 provider relationships. Building on our existing network and platform architecture, we support EHR integrations to also exchange FHIR based prior authorization transactions. TriZetto has existing working relationships with ~500 EHR platforms across the country exchanging X12 EDI transactions including the X12 278. This list includes EPIC, Cerner, eClinicalWorks, Azalea, Kareo, Maverick, Waiting Room Solutions, and more. A larger list of connected EHRs can be provided at the next stage of this process. The Prior Authorization Solution is built in alignment with the Da Vinci Implementation Guides enabling standards-based integrations making our solution compatible with all EHR applications that also support the standards. In section b of question 1.6.4, we discuss our various integration methods and options to support EMR integration beyond the standards. Our parent company, Cognizant has been supporting clients with various interoperability and regulatory solutions for 15 years and is ready to support clients with the CMS-0057-F regulation. Leveraging Cognizant, we offer a commercially available Prior Authorization Solution that adheres to CMS-0057-F regulations and the Da Vinci implementation guides. This solution enables payers to meet Prior Authorization API requirements by providing FHIR compliant API endpoints and supporting electronic prior authorization (ePA) functionality, including routing, clinical guideline development and integration, and response orchestration. While the regulation is mandated for payers, we recognize the importance of provider adoption including technical readiness and education. On the provider side, real-time FHIR requests and responses will be facilitated through the TriZetto Provider Solution's FHIR intermediary. As the third largest clearing house processing over 3 billion transactions a year, TriZetto Provider Solutions has the foundation and expertise in prior authorization transaction exchange. The TriZetto Integration Platform supports both FHIR and X12 clearinghouse capabilities, ensuring seamless process continuity and robust support for provider workflows during the transition from X12 to FHIR standards. To further encourage provider adoption, TriZetto offers multiple integration methods, including direct EMR integration, SMART on FHIR capabilities, partnerships with other clearinghouses and intermediaries, as well as non-FHIR compatible translators. We participate in industry recognized testing initiatives, such as the Da Vinci Trebuchet Initiative, proof-of-concept testing with various EMRs, and pilot testing. These efforts strengthen relationships within the industry and demonstrate our ongoing commitment to interoperability and innovation.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	We support (b)(4) models today and arelooking to support (b)(4) (b)(4) models in upcoming releases. We leverage a robust suite of automation and AI tools to enhance efficiency, accuracy, and scalability across clinical and operational workflows. These capabilities are deployed across key areas such as prior authorization, clinical review, and care management. Examples of these solutions and processes are below. • TriZetto Assistant: The TriZetto Assistant within Clinical CareAdvance (CCA) (b)(4) The data can be pulled from various areas within CCA and other sources including claims processing applications. For example, the end user can see (b)(4) (b)(4) (b)(4) • Medical Policy Digitization: (b)(4) (b)(4) (b)(4) We are actively exploring other use cases where the policy digitization tool can be leveraged, including Case Management Assessments. • AI Fax Solution: (b)(4) (b)(4) (b)(4) Our approach to verifying, validating, securing, and regulating our enhanced technology software to ensure ethical and high-quality utilization management metrics are met involves several key strategies: • Verification and Validation: We conduct regular reviews of our solution functionality and content against industry standards, regulatory agencies, and accreditation

	organizations. This includes input from current clients to ensure our solutions meet evolving requirements. • Security: (b)(4) (b)(4) Regulation: Our Healthcare Regulatory Center of Excellence is committed to identifying and following regulatory activity to ensure that our products, people, and services are informed and up to date with the latest expectations. We incorporate new regulatory requirements into our standard product development planning cycle, resulting in regular enhancements. We also retain third-party industry experts to ensure our solutions stay current with changing regulatory and accreditation requirements. • Audit and Compliance: Our solution provides multiple mechanisms for reporting on utilization management and care management events. (b)(4) (b)(4) Leveraging the above strategies, we have achieved (b)(4) (b)(4) (b)(4) Overall, our commitment to continuous improvement and alignment with regulatory standards ensures that our clients can achieve their compliance and care excellence goals effectively. We apply a rigorous, enterprise-grade approach to ensure our enhanced technology solutions meet the highest standards of accuracy, security, ethics, and regulatory compliance (b)(4) Our methodology integrates technical best practices with deep healthcare domain expertise—anchored by our dedicated Regulatory Center of Excellence (CoE)—to ensure compliance with CMS guidelines while promoting fair, clinically appropriate, and timely decision-making. 1. Verification and Validation with Clinical and Regulatory Oversight We follow a robust Software Development Life Cycle (SDLC) framework with multiple checkpoints for functional and clinical assurance. Our Regulatory CoE plays a critical role in reviewing system updates, rule sets, and coverage logic to ensure: • Verification – Confirming the software functions as intended and meets all performance, workflow, and documentation requirements. • Validation – Ensuring the solution aligns with CMS rules, NCDs/LCDs, plan-specific policies, and evidence-based medical guidelines. The Regulatory CoE collaborates closely with product and clinical teams to evaluate prior authorization rules for transparency, consistency, and equity—mitigating clinical bias and promoting defensible determinations. 2. Built-in Ethical Guardrails and Responsible Use of Technology Our solutions are designed to reinforce ethical decision-making and member protections through: • Human-in-the-loop design – Ensuring licensed clinicians retain final decision authority on all determinations involving medical necessity. • Bias mitigation – Conducted through the CoE's oversight of business rules, logic models, and audit feedback loops. • (b)(4) (b)(4) This ethical framework is central to our (b)(4) and is continually refined through lessons learned from payer partnerships and federal engagements. 3. Security and Privacy-First Architecture We uphold the highest standards for security and data protection in line with HIPAA, FISMA Moderate, and CMS IS2P2 policies: • (b)(4) (b)(4) 4. Continuous Quality Management and Regulatory Alignment The Regulatory CoE provides a formal governance structure that keeps our technology and operations tightly aligned with federal guidelines. (b)(4) (b)(4) (b)(4) • Quarterly compliance reviews – Internal audits of business rules, clinical decisions, and documentation standards. • Client and agency reporting – Standardized reporting packages aligned to CMS audit and oversight needs. (b)(4) (b)(4) (b)(4) —supporting the goals of the WISeR model while protecting access and ensuring beneficiary-centered care.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	Yes

Accreditations or Certifications Document

File Name	WISeR-00084_Accreditations_MediCall dba Cognizant Technology Solutions MM - Health Utilization Management Accreditation 8.2- Clinical Review Criteria, Pre-
Uploaded On	7/25/2025, 3:14 PM
File Name	WISeR-00084_Accreditations_MediCall dba Cognizant Technology Solutions CC - Health Utilization Management Accreditation 8.2- Clinical Review Criteria, Pre-
Uploaded On	7/25/2025, 3:14 PM
File Name	WISeR-00084_Accreditations_MediCall dba Cognizant Technology Solutions AZ - Health Utilization Management Accreditation 8.2- Clinical Review Criteria, Pre-
Uploaded On	7/25/2025, 3:15 PM
File Name	WISeR-00084_Accreditations_MediCall dba Cognizant Technology Solutions M - Health Utilization Management Accreditation 8.2- Clinical Review Criteria, Pre-R
Uploaded On	7/25/2025, 3:14 PM
File Name	WISeR-00084_Accreditations_MediCall dba Cognizant Technology Solutions - Workers' Compensation Utilization Management 8.1
Uploaded On	7/25/2025, 3:15 PM

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Our Ethics & Compliance (E&C) Program is structured around the elements of an effective compliance program as defined by the U.S. Federal Sentencing Guidelines. It is led by the Chief Ethics & Compliance Officer (CECO), who reports to both the General Counsel and the Audit Committee of the Board of Directors. 1. Program Structure • Governance: The CECO is supported by a global team and the Global Ethics & Compliance Committee (GECC), which includes executive leadership and key stakeholders. • Policies: A comprehensive suite of policies governs ethical conduct, including the Code of Ethics, Anti-Corruption Policy, Whistleblower Policy, and Data Privacy Policy. These are reviewed regularly and updated as needed. • Training & Communication: Mandatory annual training for all associates, with additional targeted training based on role, geography, and client requirements. Communication is reinforced through multiple internal channels. 2. Auditing and Monitoring Controls • Internal Audits: Regular audits assess compliance with policies and procedures. Findings are reported to the Board and Audit Committee. • Investigations: A global, standardized investigation process is in place, supported by trained personnel and documented in the Compliance and Ethics Issues Response Handbook. • Monitoring: Ongoing monitoring of global regulatory changes ensures proactive compliance updates. 3. Experience with Regulatory Audits • Our E&C team is experienced in managing high-sensitivity regulatory audits and investigations and aligning corrective actions with external enforcement expectations. • The program includes mechanisms for self-reporting to authorities when necessary and is benchmarked against industry best practices to remain current and effective. 4. Risk Management • Annual enterprise-wide risk assessments are conducted in collaboration with the Enterprise Risk Management team and other stakeholders. • Operational risk assessments address regulatory, contractual, and transactional risks. Additionally, our Healthcare practice implements strict HIPAA-compliant protocols to safeguard Protected Health Information (PHI), including data encryption, access controls, and regular audits. (b)(4) (b)(4) (b)(4) This comprehensive compliance framework allows us to deliver high-quality, secure, and legally sound clinical services. (b)(4) (b)(4)

	(b)(4) (b)(4) We ensure compliance with federal, state and local laws applicable to our organization through the Office of the General Counsel. Our Office of the General Counsel has a team of lawyers and compliance professionals that, with the assistance of outside advisors, monitors such laws and regulations, including employment laws for all countries where we have employees, and monitors compliance. In addition, as a publicly traded U.S. organization (Nasdaq: CTSH), Cognizant's Audit Committee currently develops and recommends to the Board of Director's corporate governance guidelines applicable to the company. The Audit Committee also, from time to time as it deems appropriate, reviews and reassesses the adequacy of such corporate governance guidelines and recommends any proposed changes to the Board for approval. In order to ensure continued compliance, we continuously adopt and implement various internal controls, policies and procedures. Furthermore, if our services impact our Clients from a regulatory compliance perspective, we work with our Clients to develop such controls and procedures as may be necessary to ensure our Client's compliance. In addition, our legal teams around the world constantly monitor legislative and regulatory changes that affect the our business operations and those of our Clients, as well as changes in the application of standards and enforcement policies and security measures undertaken by governmental entities around the world and take proactive steps to ensure that we have the ability to seamlessly implement any necessary changes to the services we provide. (b)(4) (b)(4)
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	We anticipate meaningful reductions in spending within the selected jurisdictions (JH, JL, JF, J15) through the application of our automation-enabled, clinically governed prior authorization platform and services. Based on publicly available CMS data and internal actuarial modeling, we estimate potential savings of (b)(4) on the targeted items and services across the WISeR Model's performance period, depending on service category and regional utilization trends. Our projection is grounded in the following assumptions and benchmarks: • Historical CMS PA impact: CMS reports a 31% reduction in OPD services like blepharoplasty and rhinoplasty from 2019–2023 due to prior authorization. • AI and Automation driven efficiency: Automation can reduce administrative waste and increase non-affirmation accuracy. For example, AI reduced PA cycle time by up to 88% in pilot programs (e.g., BCBS of MA) and increased affirmation decision speed. While our preferred jurisdiction is (b)(4) supporting the states participating in this program (b)(4) (b)(4) (b)(4) subject to final CMS service selection and claim volumes. The projected reductions are based on: • Avoidance of medically unnecessary or non-covered services • Real-time clinical decisioning aligned with NCDs/LCDs • Technology-assisted education redirecting care to higher-value alternatives

	We are confident in our ability to achieve these savings while improving provider experience, accelerating processing time, and upholding beneficiary access to medically necessary care.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Implementation Approach We are well-positioned to support CMS and its Medicare Administrative Contractors (MACs) through the successful implementation of the WISeR model. As a trusted partner to government and commercial healthcare organizations, we bring deep domain expertise, proven delivery models, and scalable technology to drive secure, compliant, and outcomes-based implementations. Our approach simplifies execution and accountability by delivering end-to-end support through a single vendor—eliminating handoffs, reducing integration complexity, and accelerating speed to value. Implementation Framework We apply the TriZetto Accelerated Framework (TZAF)—a five-phase implementation methodology that has been successfully used across more than 900 healthcare transformation projects. This structured, repeatable model ensures disciplined execution, from project planning through post-deployment optimization. Phase 1: Align • (b)(4) implementation timeline, including technology configuration, operational readiness, and staff enablement. Key milestones include: • (b)(4) (b)(4) For Business Process Operations, resource ramp-up follows this sequence: • (b)(4) (b)(4) This approach offers several advantages: • (b)(4) (b)(4) Our integrated model ensures that every phase of the project is connected, measurable, and aligned to CMS's vision for reducing wasteful and inappropriate Medicare services—while protecting beneficiary access and data integrity.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Belcan Government Solutions, Inc.
Certifying Individual:	(b)(4)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00112

Requested by (b)(6) on 07/28/2025 15:49

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Sanger Shia, LLC
b. Doing Business As (DBA) Name(s)	CarePilot
c. Street Address	2334 Caminito Cala
d. City	Del Mar
e. State	CA
f. Zip Code	92014
g. Tax Identification Number	202359914
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	CarePilot is a healthcare technology startup founded in 2024 to address Medicare fraud, waste, and abuse in skin and tissue substitutes. Our mission is to transform compliance from a burden into a competitive advantage for ethical providers while protecting Medicare beneficiaries and taxpayers. We specialize in prior authorization technology for amniotic wound grafts, combining automated rule-based systems with clinical expertise to ensure appropriate care delivery. Our platform validates Medicare coverage requirements in real-time, helping providers understand documentation needs while preventing inappropriate utilization. Led by founder Justin McIntosh and Medical Director Dr. Douglas Hampers, MD, MBA, our team brings direct Medicare compliance experience and clinical leadership. We serve wound care providers, Medicare Administrative Contractors, and ultimately Medicare beneficiaries by streamlining prior authorization processes while maintaining rigorous clinical oversight. Our focus on education and real-time feedback helps providers improve compliance rates and patient outcomes.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JL Novitas; JF Noridian
5. Provide street address, city and state for all locations.	

Location Name	(b)(6)
Street Address	
City	
State	
Zip Code	

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00112_Ownership_Untitled document
Uploaded On	7/25/2025, 9:40 AM
File Name	WISeR-00112_Ownership_Operating Agreement
Uploaded On	7/25/2025, 9:41 AM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	2334 Caminito Cala, Del Mar, CA 92014
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00112_Licensure_IRS Tax ID Number

Uploaded On	7/25/2025, 9:23 AM
File Name	WISeR-00112_Licensure_LLC Articles OR Certificate of Organization
Uploaded On	7/25/2025, 9:23 AM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.	
N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	CarePilot brings foundational experience working with Medicare through our founder's direct operational experience. Justin McIntosh, our Founder and CEO, has hands-on experience through Sanger Consultants (Feb 2024-Present) where he: - Created processes and workflows to facilitate provider submissions of insurance verifications, orders, and patient tracking - Worked directly with manufacturers to understand pain points with grafts and ensure compliance - Ensured CMS regulations were consistently met across all operations - Maintained HIPAA standards compliance throughout all processes Our Medical Director, Dr. Douglas Hampers, MD, MBA, brings over 20 years of clinical and healthcare executive experience, including: - Board certification in Orthopedic Surgery with deep understanding of Medicare reimbursement - MBA from Dartmouth's Tuck School with healthcare business expertise - Over a decade as President & CEO of National Bioskills Laboratories - Board service on CardiacAssist (now LivaNova) with medical device regulatory experience While CarePilot was specifically designed for Medicare Fee-for-Service, our leadership team has worked extensively within Medicare's regulatory framework and understands the nuances of coverage determinations, documentation requirements, and provider workflows that will be essential for WISeR success.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Prior Authorization and Coverage Determinations Experience: CarePilot was conceived specifically to address Medicare's coverage criteria and prior authorization requirements. Our platform incorporates: - Deep understanding of Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) - Real-time rules engine encoding relevant Medicare coverage criteria (LCD L36690, L35041 for skin substitutes) - Automated validation of compliance with Medicare documentation requirements - Experience with pre-payment review processes and coverage determination workflows Medicare Administrative Contractor (MAC) Interface Experience: We have designed our technical architecture to interface with MAC systems through: - RESTful API integration and HL7 FHIR-compliant data exchange - Real-time status updates and tracking for every request - Seamless routing of decisions back through MACs or directly to providers - Full audit trail capabilities for all transactions b. Federal Data Security Authorizations: CarePilot is committed to the highest levels of federal data security compliance: FedRAMP Strategy: We will deploy our platform on Google Cloud's Assured Workloads for Government, a FedRAMP High-authorized environment, ensuring immediate infrastructure compliance with federal security requirements. While this provides a secure foundation, we acknowledge that achieving our own FedRAMP Moderate certification typically requires 12-18 months. We are prepared to operate under MAC sponsorship if needed while pursuing independent

	certification. All security controls and processes are designed from day one to meet or exceed FedRAMP Moderate baseline controls. c. HIPAA Compliance and Privacy Framework: CarePilot adheres to strict HIPAA standards for Protected Health Information (PHI): Data Protection Measures: - All data encrypted at rest and in transit (AES-256) - Role-based access controls with full audit logging - SOC 2 Type II compliant hosting environment planned - Business Associate Agreements with all required entities Privacy and Security Monitoring: - Continuous monitoring of all system and user actions - Regular security assessments and penetration testing planned - Staff training on HIPAA requirements and data handling - Quarterly compliance audits by external security firms once operational Incident Response Plan: - Immediate reporting to CMS Service Desk (1-800-562-1963) within one hour of incident awareness - Dedicated incident response team structure planned - Breach remediation procedures documented - Coordination with CMS Risk Management Handbook Chapter 8 requirements - Regular testing of incident response procedures through tabletop exercises
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Medical Leadership: Dr. Douglas Hampers, MD, MBA serves as our Medical Director, bringing board-certified orthopedic surgery expertise and healthcare executive experience. Dr. Hampers earned his MBA at Dartmouth (Tuck) and has 20+ years in medical leadership, including over a decade as President & CEO of National Bioskills Laboratories. Advisory Board Development: We are assembling a distinguished advisory board to strengthen our clinical and regulatory expertise: - Former CMS/OIG officials with direct Medicare fraud prevention experience - Wound care clinical experts from leading academic medical centers - Healthcare technology leaders with successful federal contracting experience - Medicare Advantage medical directors familiar with skin substitute utilization patterns This advisory structure follows the successful model of healthcare startups like Pearl Health, which secured CMS ACO REACH participation within three years of founding by demonstrating strategic partnerships and clear alignment with CMS priorities. Clinical Review Team Expansion Plan: Upon WISeR award, we will begin recruiting wound care specialist clinicians with a target of having three specialists operational by launch, expanding to five within the first six months: Targeted Recruitment: - Clinicians with MAC and Medicare Advantage medical director experience - Specialists in dermatology, plastic surgery, and wound care - Board-certified physicians with expertise in chronic wound management - Experience with Medicare policy and coverage determinations Staffing Structure: - Initial coverage through business hours with on-call after-hours support - Geographic alignment with WISeR MAC jurisdictions where possible - Expansion to 24/7 coverage as volume justifies - Peer-review process for complex determinations Quality Assurance Framework: - Monthly clinical case review meetings led by Dr. Hampers - Quarterly training updates on Medicare policy changes - Evidence-based protocols embedded in platform for consistency - Real-time consultation network among specialists Clinical Decision Support: - Standardized decision trees based on evidence-based guidelines - Built-in protocols for appropriateness decisions - Real-time access to relevant clinical guidelines and CMS coverage criteria - Peer consultation capabilities for cases outside individual specialty areas Evidence-Based Clinical Protocols: - Wound Progression Algorithm: Standardized measurement of healing trajectory required for continued graft approval - Alternative Treatment Pathways: Built-in decision trees for when grafts are non-affirmed (compression therapy, surgical debridement, etc.) - Contraindication Checking: Automated flags for patients with conditions making grafts inappropriate - Episode of Care Tracking: Monitor total treatment duration and outcomes across multiple providers Clinical Quality Indicators: - Healing rate benchmarks by wound type and location - Infection rate monitoring post-graft application - Hospital admission rates for wound complications - Patient-reported outcome measures integration

4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	a. EHR Platform Compatibility: CarePilot recognizes the critical importance of EHR integration for seamless workflow adoption. While our initial platform will launch with a secure web portal and multiple submission methods (phone, fax, email), we have designed our architecture to support future EHR integrations. We are actively engaging with Epic, Cerner, and Athenahealth to develop integration pathways and plan to begin pilot integrations within 12-18 months of model launch. Our RESTful API architecture and FHIR-compliant design ensure we can rapidly deploy integrations as partnerships develop. Alternative Access Methods: For providers without EHR integration, CarePilot provides: - Standalone web portal that is mobile-responsive - Tablet-friendly interface for point-of-care use - Phone, fax, and email submission options as backup - Multiple data submission formats to accommodate various workflows b. CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) Support: Current Compliance Measures: - RESTful API technology meeting technical requirements - HL7 FHIR-compliant data exchange capabilities - HHS-adopted data standards implementation - Real-time prior authorization status updates - Standardized reason codes for determinations Ongoing Development Plans: - Enhanced API functionality for bidirectional data exchange - Automated prior authorization workflows to reduce administrative burden - Improved transparency through real-time status tracking - Standardized documentation requirements communication - Provider portal enhancements for clearer submission guidance Timeline for Full Compliance: Phase 1 (Launch): Basic API compliance and FHIR standards Phase 2 (6 months): Enhanced automation and workflow integration Phase 3 (12 months): Full rule compliance with advanced features Ongoing: Continuous improvement based on CMS guidance and industry feedback Electronic Prior Authorization Impact: Industry data demonstrates that electronic PA can save $449 million annually in healthcare spending while cutting clinician time by 10 minutes per transaction. With physicians currently spending 14 hours weekly on prior authorization tasks, our streamlined approach directly addresses this burden. Medicare Advantage plans processed nearly 50 million PA determinations in 2023, with CMS estimating $15 billion in savings over 10 years from new interoperability requirements—validating the massive opportunity for technology-enabled solutions like CarePilot.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	AI/ML Training Experience: CarePilot employs a phased approach to technology implementation: Phase 1 - Rule-Based Foundation (Launch-Ready): - Deterministic rules engine encoding Medicare LCD requirements - Binary compliance checks for documentation requirements - Mathematical validation of dates, episode limits, measurements - 90%+ accuracy target for straightforward cases without AI - Immediate deployment capability with proven reliability Phase 2 - Document Intelligence (6-12 months): - Integration with established AI services for document parsing - Basic optical character recognition for structured data extraction - Wound photo compliance checking (ruler presence, image quality) - Gradual implementation with human validation Future Development Considerations: - Pattern recognition for utilization anomalies - Predictive modeling based on historical approval patterns - Fraud detection capabilities pending sufficient data collection - All advanced features subject to rigorous testing and validation Technical Architecture Details: - Rules Engine: Built on open-source Drools business rules management system - Document Processing: Integration with Google Document AI for structured data extraction - Image Analysis: OpenCV implementation for wound measurement validation - Database Architecture: PostgreSQL with partitioning for scalability, Redis for sub-second cache responses - API Design: GraphQL for efficient data fetching, REST for MAC compatibility Phased Development Framework: -Phase 1 (0-6 months): Core fraud detection with immediate ROI - rules-based validation, documentation checking, episode tracking - Phase 2 (6-18 months): Enhanced capabilities - advanced pattern recognition, provider profiling, predictive analytics - Phase 3 (18+ months): Transformational features - real-time intervention, network analysis, generative AI assistance This approach demonstrates continuous value delivery while managing development risk, positioning capabilities as "AI-enabled" rather than "AI-dependent" to emphasize human oversight throughout. Validation Methodology: - Shadow Mode Testing: Run AI predictions parallel to human decisions for 3 months before activation - Confidence Scoring: Every automated decision includes confidence percentage - Audit Sampling: Random 10% audit of all decisions weekly - Feedback Loop: Provider appeals automatically trigger model retraining queue Unique WISeR Implementation: Our technology uniquely meets WISeR goals through: - Hybrid Intelligence: Combining automated rules (fast, reliable) with future AI enhancement (nuanced analysis) and clinical oversight (complex cases) - Amniotic Graft Specialization: Deep focus on highest-risk, highest-value segment with specialized validation - Provider Education: Real-time coaching and feedback transforming compliance burden into competitive advantage - Medicare-Specific Design: Built specifically for Medicare workflows rather than retrofitted from private payer systems Proven Industry Impact: Similar focused approaches have demonstrated transformational results. MultiCare and Regence's collaboration reduced patient wait times from 15 days to near real-time approvals. Electronic PA implementations save $449 million annually while cutting clinician time by 10 minutes per transaction. With Medicare Advantage plans processing nearly 50 million PA determinations in 2023, and CMS estimating $15 billion in savings from new interoperability requirements, CarePilot's specialized solution addresses a critical market need. a. Verification, Validation, and Security Framework: Technology Validation: - Continuous testing against known Medicare outcomes - A/B testing of recommendations vs. clinical decisions - Regular model performance monitoring - Bias

	detection and mitigation protocols - Transparent audit trails for all decisions Ethical AI Implementation: - Human oversight required for all non-affirmative decisions - Clear explainability of recommendations to clinicians - Regular ethical review of decision patterns - Compliance with emerging AI regulation and best practices - Patient safety prioritization in all automated decisions Quality Metrics: - Target <5% appeal overturn rate on non-affirmations - 95%+ accuracy in automated document processing - Sub-30 second initial validation response time - Continuous improvement tracking of performance b. Managing Adverse Effects of Automation: Safeguards Against Over-Automation: - Mandatory human clinical review for all non-affirmations - Fallback to manual processes if confidence drops below thresholds - Regular auditing of automated decisions for quality and bias - Provider feedback integration to identify automation issues Maintaining Clinical Judgment: - Technology serves as decision support, not replacement for clinical expertise - Board-certified specialists retain final authority on complex cases - Peer-to-peer review availability for all contested decisions - Continuous training of clinical staff on tool limitations Patient Safety Protections: - Expedited review processes for urgent clinical situations - Override capabilities for emergency situations - Regular monitoring of patient outcomes following decisions - Integration with adverse event reporting systems
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Organizational Ethics Framework: CarePilot's approach to ethics centers on our core mission: transforming the burden of compliance into a competitive advantage for ethical providers while aggressively preventing fraud, waste, and abuse. a. Utilization Management Quality Assurance: Decision-Making Standards: - Evidence-based protocols embedded in all clinical decisions - Board-certified specialist review for all non-affirmations - Peer-review process for complex determinations - Regular case review meetings analyzing decisions for quality and consistency Complaints and Grievances Process: - Dedicated help desk with 5-minute response guarantee - Escalation procedures for unresolved provider concerns - Regular feedback integration into process improvements - Quarterly stakeholder satisfaction surveys Claims Billing and Dispute Resolution: - Transparent explanation of all non-affirmative decisions - Clear guidance for resubmission and appeals processes - Peer-to-peer consultation availability for contested decisions - Appeals automation to reduce provider administrative burden Quality Metrics Monitoring: - Target <5% appeal overturn rate demonstrating decision accuracy - 95%+ processing within 4-hour commitment timeframe - Net Promoter Score target >4.5 for provider satisfaction - Continuous monitoring of clinical outcomes and patient safety b. State and Federal Regulatory Compliance: - Medicare Compliance Framework: - Strict adherence to all LCD and NCD requirements - Regular updates reflecting Medicare policy changes - MAC coordination ensuring seamless workflow integration - CMS reporting requirements fulfillment Privacy and Security Compliance: - HIPAA Privacy, Security, and Breach Notification Rules adherence - FedRAMP security standards implementation - State privacy law compliance (where applicable) - Regular compliance audits and certifications maintenance Professional Licensing and Standards: - All clinical staff maintain appropriate board certifications - Regular continuing education ensuring current standards knowledge - Professional liability insurance coverage for all clinical decisions - Compliance with state medical board requirements Ethics in AI and Technology: - Transparent AI decision-making with audit trails - Human oversight for all non-affirmative determinations - Regular bias testing and mitigation in automated systems - Ethical review board for AI implementation decisions Provider Success Program: - Onboarding Specialist Assignment: Each new provider gets dedicated support for first 30 days - Documentation Templates: Pre-built templates for common wound types ensuring compliance - Monthly Webinars: Live training on documentation requirements and policy updates - Success Metrics Tracking: - Average provider affirmation rate improvement over time - Time to gold card status achievement - Provider satisfaction scores by region Compliance Monitoring Dashboard: - Real-time visualization of key metrics for CMS - Automated anomaly detection for unusual patterns - Predictive analytics for resource allocation - Transparent reporting accessible to all stakeholders Gold Card Provider Advancement Program: Following successful models from UnitedHealthcare and Highmark

	Health, CarePilot will implement a gold card pathway for high-performing providers: - Providers achieving 92% or higher approval rates become eligible for expedited review - Reduces administrative burden by up to 85% for compliant providers - Real-time tracking of provider progress toward gold card eligibility - Active coaching program to help providers improve documentation and achieve exemption - Continuous monitoring to ensure sustained compliance This approach addresses the critical market need where 88% of physicians report high PA burden, spending 14 hours weekly on authorization tasks. By offering a clear path to reduced requirements, we transform compliance from burden to competitive advantage.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Based on conservative analysis of 2023 Medicare data and the documented fraud crisis in skin substitutes, CarePilot projects significant and achievable cost savings. The $10 Billion Challenge: Medicare spending on skin substitutes has exploded from $256 million in 2019 to over $10 billion in 2024—a 4,000% increase. The Office of Inspector General identified that 30 of 68 skin substitute products represent a "disproportionate share of Part B spending" due to non-compliance, with products ranging from $100 to over $1,000 per square centimeter. Most concerning, CMS found that "the efficacy of many of these products has not been studied." Geographic Savings Projections: Texas (JH/Novitas): - Current annual (b)(4) (b)(4) reduction) - Target inappropriate utilization patterns causing waste Arizona (JF/Noridian): - Estimated annual spending (b)(4) (Note: Arizona companies received $600M in fraudulent Medicare payments in just 16 months) - Conservative projected saving (b)(4) reduction) - Emphasis on provider education and compliance improvement Total First Year Impact: - Combined Savings: (b)(4) across two states - CarePilot Cost: $5-8 million - Conservative ROI for Medicare: 4:1 to 6:1 Methodology and Conservative Estimates: Our projections are based on: - Historical Medicare spending data for skin and tissue substitutes - Known patterns of inappropriate amniotic graft utilization - Comparison with Medicare Advantage utilization management results - Conservative (b)(4) reduction rate (industry benchmarks suggest higher potential) - Accounts for cases that would be caught by existing MAC reviews Service-Specific Savings Potential: - Skin and Tissue Substitutes: Highest impact due to cost and fraud prevalence - Stimulator Services: Moderate savings through appropriate candidate selection - Pain Management Procedures: Savings through evidence-based approval criteria - Surgical Procedures: Focus on medical necessity and alternative treatments ROI Calculation Transparency: - Average amniotic graft claim: $1,500-3,000 - Estimated inappropriate utilization (b)(4) based on audit data - Our reduction target: (b)(4) (conservative) - Cost per review: $25-50 - Net savings per prevented inappropriate claim: $1,450-2,950 Scaling Potential: - Year 2: Additional states could yield proportional savings - Multi-year impact: Compound savings as provider education improves compliance - Industry transformation: Model success could influence broader Medicare policy Quality-Adjusted Savings: Beyond direct cost reductions, CarePilot will generate value through: - Improved patient outcomes by ensuring appropriate care delivery - Reduced provider administrative burden through streamlined processes - Enhanced Medicare program integrity and beneficiary trust - Prevention of harm from inappropriate procedures Direct Savings Breakdown: - Prevented Inappropriate Applications: (b)(4) (primary savings) - Reduced Appeals Processing: (b)(4) (administrative savings) - Fraud Prevention: (b)(4) (based on OIG estimates) - Provider Education Impact: (b)(4) (improved first-time compliance) Indirect Benefits: - Reduced Beneficiary Harm: Fewer unnecessary procedures - Provider Time Savings: 50% reduction in documentation rework - MAC Efficiency: 30% reduction in manual review burden - Industry Transformation: Precedent for other high-cost services Risk-Adjusted Projections: - Best Case (b)(4) savings, (b)(4) - Conservative Case (b)(4) The explosive growth in skin substitute fraud creates an unprecedented opportunity. The Department of Justice's recent takedown revealed schemes where providers collected $330 million in illegal kickbacks from graft distributors, frequently targeting vulnerable populations including elderly patients in hospice care. With 30 of 68 skin substitute products representing a "disproportionate share of Part B spending" according to OIG, and many products lacking efficacy studies, CarePilot's specialized focus addresses Medicare's most urgent fraud crisis. Competitive Advantage: While broad prior authorization platforms exist, none focus specifically on the unique fraud patterns in skin substitutes. Our specialized approach aligns with federal procurement trends favoring deep domain expertise over comprehensive platforms, positioning CarePilot as the precise solution for this $10 billion challenge.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Pre-Launch Preparation (August 2025 - December 2025) Months 1-2 (August-September 2025) - MVP Completion & Early Team Building: August 2025: Continue MVP development and core platform features Begin recruitment process for Clinical Director and Lead Developer Initiate discussions with potential MAC partners Develop initial technical specifications for MAC integration September 2025: Complete MVP by end of month Finalize hiring of Clinical Director and Lead Developer Begin recruitment for 3 clinical reviewers targeting wound care expertise Conduct initial MVP demonstrations to potential partners Start developing comprehensive training materials framework Months 3-4 (October-November 2025) - Accelerated Development & Team Mobilization: October 2025: Complete integration testing with assigned MAC systems Customize CarePilot platform to MAC jurisdiction specifications Onboard 2 wound care nurse reviewers Deploy platform on

Google Cloud's Assured Workloads (FedRAMP High) Begin provider outreach and establish operational procedures Initiate strategic pilot programs with Medicare Advantage plans November 2025: Complete security controls implementation and documentation Pursue FedRAMP Ready designation through Third Party Assessment Organization Add third clinical reviewer and QA specialist Implement HITRUST CSF framework as interim certification pathway Continue end-to-end MAC workflow testing Hire provider support specialists (2) Refine rules engine using available historical data Months 5-6 (December 2025) - Final Testing & Launch Preparation: First Half of December: Conduct limited pilot with select high-volume wound care clinics Process test prior authorization requests in controlled environment Add data analyst and compliance officer to team Validate system performance and optimize user interface Perform full-scale load testing and infrastructure failover drills Second Half of December: Finalize staffing schedules and complete all staff training Convert 2-3 Medicare Advantage pilot programs to full implementations Complete disaster recovery site setup in separate GCP region Execute all Business Associate Agreements Final system validation and go-live preparation Adjusted Technology Milestones: September: MVP completion with core rules engine October Week 1-2: MAC integration specifications and sandbox testing October Week 3-4: Provider portal UI/UX development November Week 1-2: Security hardening and penetration testing November Week 3-4: Load testing and performance optimization December Week 1-2: Pilot program execution December Week 3-4: Final iterations and launch preparation Critical Path Adjustments: Given the compressed timeline post-MVP, we'll implement parallel workstreams: Technical Track: MAC integration and security certification Clinical Track: Reviewer recruitment and training Business Track: Provider engagement and pilot programs Compliance Track: FedRAMP and HITRUST documentation Strategic Partnerships Following successful models like Pearl Health's rapid CMS contract acquisition, we are developing partnerships with: Medicare Advantage plans experiencing high skin substitute costs for pilot programs Wound care specialty societies for clinical validation and provider engagement Healthcare systems seeking to reduce inappropriate graft utilization Technology partners with complementary fraud detection capabilities Launch Readiness (January 1, 2026) Day One Operational Capabilities: Google Cloud Assured Workloads environment provisioned and tested 3 clinical reviewers trained and operational MAC integration APIs documented, tested, and operational Provider portal launched with training videos Business hours help desk staffed with Medicare-certified coders Disaster recovery site operational in separate GCP region MAC Interface Readiness: RESTful API integration with real-time data exchange capability HL7 FHIR-compliant data standards implementation Unique Tracking Number (UTN) generation and management Seamless routing of requests and determinations Full audit trail capabilities for all transactions Sensitive Medicare Data Access: Business Associate Agreements executed with CMS and relevant MACs HIPAA Security Rule compliance fully implemented Role-based access controls with comprehensive audit logging Encrypted data transmission and storage (AES-256) Incident response procedures tested and documented Performance Commitments: 95% of prior authorization requests decided within 24 hours initially Progress to 4-hour turnaround within 90 days <5% appeal overturn rate on non-affirmations Sub-30 second initial validation response time 99% availability during business hours, expanding to 24/7 Post-Launch Performance Monitoring Daily operational dashboard reviews tracking volume and turnaround times Weekly clinical quality meetings reviewing adverse determinations Monthly progress reports to CMS and MACs with key metrics Quarterly performance review sessions with CMS stakeholders Continuous improvement actions based on real-world feedback Contingency Planning FedRAMP Delays: Deploy within MAC's FedRAMP-authorized environment AI System Issues: Automatic fallback to manual clinical review processes Volume Surges: Auto-scaling infrastructure with additional clinical staff on-call Technical Problems: 5-minute response guarantee for all support requests Provider Partnership Approach CarePilot views providers as partners, not adversaries. Our platform includes: Real-time coaching that explains exactly why documentation may be insufficient Educational feedback on every non-affirmation to prevent future issues Templates and examples of compliant documentation Direct line to clinical specialists for peer-to-peer consultation Success tracking to help providers achieve gold card exemption status Operational Service Standards Initial response to providers: Under 30 seconds for rules-based validation Complete determination: 4 hours for 95% of requests Provider support response: 5-minute callback guarantee Appeals processing: 24-hour turnaround for peer-to-peer reviews System availability: 99.9% uptime commitment Success Metrics and Continuous Improvement Track predictions vs. actual Medicare decisions for model refinement Monitor provider satisfaction through regular NPS surveys Measure clinical quality outcomes and patient safety indicators Implement rapid iteration cycles based on CMS, MAC, and provider feedback This comprehensive implementation plan ensures CarePilot is fully prepared to launch on January 1, 2026, with all necessary infrastructure, personnel, and compliance measures in place to serve Medicare beneficiaries, providers, and the program's integrity goals effectively from day one. Detailed Staffing Plan September: Hire Clinical Director and Lead Developer October: Recruit 2 wound care nurse reviewers November: Add third clinical reviewer and QA specialist, hire provider support specialists (2) December: Add data analyst and compliance officer, full team operational with backup coverage Provider Engagement Timeline Pre-Launch: Identify top 50 wound care providers in each state October: Begin educational webinar series November: Individual outreach to high-volume providers December: Soft launch with 10 pilot providers January 1: Full availability with dedicated support Enhanced Risk Mitigation Strategies Technical Risks: Dual data centers

	for redundancy Automated failover systems 24/7 monitoring with 15-minute response SLA Staffing Risks: Partnership with locum agencies for surge capacity Cross-training all team members Retention bonuses for critical staff Adoption Risks: Provider incentive program for early adopters Simplified submission process for small practices Multi-language support (English and Spanish initially) Strategic Alignment with CMS Priorities Federal procurement increasingly favors specialized expertise over comprehensive platforms, creating ideal conditions for CarePilot's focused approach. The WISeR Model represents the first Innovation Center program where technology companies serve as primary participants, demonstrating CMS's commitment to partnering with innovative, technology-first organizations. Our specialized focus on the $10 billion skin substitute fraud crisis positions CarePilot as the precise solution Medicare needs. By demonstrating: Deep understanding of specific fraud patterns in amniotic grafts Immediate ROI through targeted fraud prevention Provider-friendly features like gold card pathways Commitment to reducing the 14 hours weekly physicians spend on prior authorization CarePilot embodies CMS's vision for the WISeR Model: leveraging advanced technology to protect beneficiaries, reduce waste, and transform administrative burden into value for the healthcare system. Why CarePilot Will Succeed The convergence of three critical factors creates an ideal environment for our success: The $10 Billion Crisis: Medicare's skin substitute spending explosion demands immediate, specialized intervention CMS Innovation Readiness: The WISeR Model's technology-first approach aligns perfectly with our AI-enabled platform Proven Startup Success Path: Companies like Pearl Health demonstrate that focused, innovative startups can rapidly win CMS contracts By combining deep Medicare expertise, proven technology approaches achieving 72-80% efficiency gains, and unwavering focus on the skin substitute fraud crisis, CarePilot is uniquely positioned to deliver transformational impact for the WISeR Model. We don't just detect fraud—we transform the entire prior authorization experience into a pathway for provider success and beneficiary protection. The Unprecedented Opportunity The WISeR Model launches at a critical inflection point: Skin substitute spending has reached crisis levels ($10B annually, 4000% growth) DOJ enforcement actions validate the fraud epidemic ($1.1B in recent cases) CMS is actively seeking technology-first partners for innovation

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Sanger Shia, LLC
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00135

Requested by (b)(6) on 07/28/2025 15:51

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Covasant Data Sciences Inc.
b. Doing Business As (DBA) Name(s)	Covasant Data Sciences Inc.
c. Street Address	2601 Little Elm Pkwy Suite 701
d. City	Little Elm
e. State	TX
f. Zip Code	75068
g. Tax Identification Number	33-388784
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	At Covasant, we go beyond automation, enabling our clients to build, scale, and innovate with intelligence. We deliver AI-led Services-as-Software powered by our AI Fabric, a low-code, enterprise-grade platform that integrates Agentic AI, predictive analytics, intelligent automation, and seamless data orchestration into our clients' operations. Engineered for speed, security, and scalability, the AI Fabric allows us to develop applications 10x faster, make real-time decisions with confidence, and drive continuous innovation, ensuring our clients' business stays agile, resilient, and ready for what's next. Covasant has partnered with Integrity Advantage (https://www.integrityadvantage.com/) in this endeavor. Integrity Advantage provides healthcare program integrity and fraud, waste, and abuse (FWA) professional services and expertise for health plans of all sizes and lines of business. Leveraging more than four decades of consultative, investigative, clinical and program development expertise from experience across commercial, Medicare and Medicaid payers as well as healthcare payment integrity vendors, our team has all the credentials needed to support your FWA program. Not only have we performed FWA investigations, medical reviews and built successful Special Investigations Units, but we have also helped conceptualize models that detect FWA for some of the leading analytic solutions in the market today. Using our knowledge of fraud trends and data mining techniques, we identify risks, new cases, perform investigations and medical reviews, recover overpayments and support prepayment prevention of improper payments. Payers have relied on the expertise of our team to expand their capabilities and support their changing FWA programs as they mature. Representative list of clients we work with, at various capacities 1. GEHA (Government Employees Health Association) 2. IEHP (Inland Empire Health Plan) 3. Lumeris 4. Blue Cross Blue Shield Association 5. MVP Healthcare 6. CalOptima Health 7. Sentara 8. Texas Independence Health Plan 9. SummaCare 10. MassAdvantage 11. Sandford

	Health Plan 12. Aspire Health Plan 13. Zing Health Plan 14. Provider Partners 15. Lucet Health
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	Integrity Advantage Solutions, LLC
Street Address	516 Adamsway Ct
City	Toms River
State	New Jersey
Zip Code	08753

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00135_Ownership_Covasant Ownership
Uploaded On	7/25/2025, 8:56 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address Name Title/Position	(b)(6)
Address	2601 Little Elm PkwySuite 701, Little Elm, TX 75068
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address Name Title/Position Address Business Phone Number	(b)(6)

Contact Type	Tertiary
Email Address	(b)(6)

Name	(b)(6)
Title/Position	
Address	
Business Phone Number	

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00135_Licensure_Covasant Data Sciences Inc - Cert of Incorporation
Uploaded On	7/25/2025, 8:57 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	The following are the entities we have a BAA with 1 (b)(4) (b)(4)

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	We partner with Medicare Advantage Plans around the country to provide a variety of statistical, analytical, and professional program integrity services with the primary objective of identifying inappropriate payments and assessing potential vulnerabilities due to FWA. Through our work with health plans and prior professional experiences in government, managed care, and technology vendor sectors, we have identified potential risks within payer prior authorization programs and assisted in the mitigation of those risks, resulting in significant savings. At an individual level, prominent members of our team have experience implementing FWA analytics solutions with Medicare Advantage plans as well as with state Medicaid Managed Care Organizations (MCO). The solutions offered a suite of analytics and dashboards designed to identify potential FWA within the MCO claims data. The head of Special Investigations Unit has successfully led teams that identified numerous instances of fraud, waste and abuse by Medicare providers across 34 states.

2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	We have deep experience with healthcare data and performing prepayment and post payment reviews across all lines of business. We also have experience with handling appeals leveraging the expertise on our team. Our knowledge of LCDs, NCDs and specific plan policies is applied as required by client agreements. When analyzing client data, we clean, validate, and perform quality assessment checks, applying rigorous analytical methodologies to uncover high risk providers, beneficiaries, and schemes. We do not currently have any interface with MACs. We do not currently have a FedRAMP certification. The Covasant + Integrity Advantage partnership is building robust safeguards to protect data. We have a tested incident response plan in place. In the recent past, our leadership had experience as a Zone Program Integrity Contractor (ZPIC) working with various MACs across multiple jurisdictions. It included developing Joint Operating Agreements (JOAs), prepayment review, appeals process, payment suspensions and revocations. Also, the experience includes the 'appears process' with the MAC's, QIC and ALJ. The specific prior experiences with MAC's include - First Coast Service Options, CGS, Novartis, Noridian, Palmetto GBA, and WPS.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	We pride ourselves on investing in our staff to maintain and earn essential credentials that add value to this industry and our clients. Efficiency, expertise, and integrity are the ways we differentiate ourselves. Our team has many decades of experience and an array of credentials including Accredited Healthcare Fraud Investigators (AHFI), Certified Medical Audit Specialist (CMAS), Certified Case Manager (CCM) Certified Professional Coders (CPC), Certified in Healthcare Compliance (CHC), Certified Fraud Examiners (CFE), Certified Inpatient Coder (CIC), Certified Occupational Therapy Assistant (COTA/L), Certified Outpatient Coder (COC), Registered Nurses (RN). Our approach to staffing is based on ensuring appropriate staffing is available to clients based on the quantity of reviews or authorizations required. As such, we would require some estimates of authorizations and coverage determinations monthly/annually to formulate an appropriate staffing structure.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior	Covasant is an AI-native technology products, platforms and services organization that has decades of cumulative experience in developing processes, tools and accelerators in integrating IT applications, systems and platforms. For instance, our product KonaAI, is an FWA Anomaly Detection platform for financial transactions, where integrations with ERPs (like SAP and Oracle Fusion) are a minimum requirement for operating. Also, the AI Fabric we've developed has pre-built modules for enterprise integrations. Simplified, low-code EHR integrations are actively being developed under Covasant's AI Fabric accelerators. Covasant acknowledges the importance of the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) in advancing healthcare data exchange, improving prior authorization workflows, and reducing administrative burden across stakeholders. While we have not yet initiated formal activities in support of this rule, we are actively monitoring regulatory developments and industry responses to better understand the implications and opportunities. As we continue to evolve our capabilities and define our strategic direction, we recognize that alignment with CMS-0057-F will be essential for supporting payer and provider interoperability in the future. Our forward-looking considerations include: • Exploring API-Driven Interoperability: We intend to evaluate the use of HL7® FHIR®-based APIs, including those for Prior Authorization, Provider Access, and Payer-to-Payer data exchange, in line with the technical requirements and HHS-adopted standards specified in the rule. • Understanding Data Exchange Standards: We are committed to building foundational

authorization practices and data exchange practices.	knowledge around the Da Vinci Implementation Guides and other relevant standards to inform future development efforts. • Composable, API-Driven Platform Vision Covasant's architecture is being designed with modularity and interoperability in mind, enabling future support for CMS-aligned data exchange, consent-aware workflows, and real-time authorization orchestration. • AI-Augmented Automation Potential While not yet implemented, our long-term vision includes leveraging our AI engineering capabilities to reduce prior authorization friction through intelligent document extraction, decision support, and workflow agents. • Reducing Stakeholder Burden: As part of our long-term vision, we aim to contribute to solutions that simplify prior authorization processes and enhance data transparency for payers, providers, and patients. • Commitment to Compliance and Trust As we scale, we intend to embed policy-as-code, auditability, and explainability into our platform to support evolving CMS, ONC, and HIPAA compliance requirements. We view CMS-0057-F not just as a regulatory requirement, but as a catalyst for innovation in payer-provider collaboration. While we are early in our journey, Covasant is committed to building the technical and strategic foundation necessary to support this transformation in the near future.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	Covasant is a technology firm focused on building intelligent, composable, and AI-native platforms for enterprise transformation. While we have not yet trained AI/ML models specifically for coverage determinations or prior authorization workflows, our internal investments in AI governance, observability, and agent lifecycle management position us to support initiatives like WISeR in the near future. AI/ML Experience and Future Plans We have not trained AI models on prior authorization or CMS-specific datasets to date. However, Covasant has built an in-house Covasant Agent Management Suite. It is a modular, enterprise-grade system designed to build, orchestrate, govern, and monitor AI agents across diverse business functions. It enables organizations to deploy intelligent agents with confidence ensuring safety, compliance, and performance at scale. It has three major components, Agent Builder, Agent Registry and Control Tower. 1. Covasant AI Agent Control Tower (CAACT) The Control Tower is the governance and observability layer of the platform. It ensures that all AI agents operate within defined ethical, regulatory, and operational boundaries. Key capabilities include: • Real-Time Monitoring • Explainability & Auditability • Policy Enforcement • Safety Guardrails • Unified Governance 2. Agent Registry The Agent Registry acts as a centralized catalog of all deployed agents—whether developed in-house or by third parties. It enables: • Agent Discovery & Metadata Management • Peer Agent Authentication • Lifecycle Management 3. Agent Management Suite This suite includes tools for: • Agent Development: Low-code/no-code builders, test benches, and packaging tools. • Workflow Orchestration: Agent routers, LLM routers, and API gateways for multi-agent coordination. • Observability & ROI Tracking: Dashboards for usage, cost, and performance metrics across agents and environments. Why It Matters for WISeR: Together with Agent Management Suite, Covasant can help with: • Agentic AI orchestration for automating complex workflows such as documentation intake, eligibility checks, and rule-based decision support. • Designing Retrieval-Augmented Generation (RAG) pipelines for context-aware decision support using LLMs, vector databases (e.g., Pinecone, Weaviate), and LangChain. • Integration with LLMs and RAG pipelines for context-aware reasoning and document summarization. • Policy-driven agent governance to ensure safe, explainable, and compliant AI behavior across healthcare use cases. As we expand into payer and CMS-aligned domains, we plan to leverage these capabilities to support: • Coverage determination logic orchestration using rule-based agents and future fine-tuned models. • Explainable decision support through embedded traceability and audit trails. • Secure API-based integration with MACs and payer systems. a. Verification, Validation, Security & Ethical Assurance Our AI Agent Management Platform provides foundational capabilities to ensure safe and ethical AI operations: • Explainability & Auditability: Every agent action is logged with decision trace graphs and rationale metadata. • Compliance Gateways: Agent behavior is validated against pre-approved policy logic, with support for HIPAA, GDPR, and SOC2-aligned controls. • Role-Based Access Control (RBAC) and agent-level scopes ensure that only authorized users or systems can trigger sensitive actions. • Drift Monitoring & Feedback Loops: Agents are continuously monitored for performance degradation, hallucination, or bias, with human feedback loops for retraining. b. Managing Adverse Effects of Automation and AI We proactively address AI risks through: • Human-in-the-Loop (HITL) Safeguards: Agents can be configured to defer to human reviewers for high-risk or ambiguous decisions. • Guardrails & Safety Filters: Built-in detection for PII/PHI exposure, toxicity, and jailbreak attempts. • Reward Modeling for Compliance: Agents are penalized for violating policy logic or producing non-compliant outputs. • Observability & Alerts: Real-time monitoring of agent behavior, latency, token usage, and anomaly detection to prevent unintended consequences.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))?	No

If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.	

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	We are dedicated to upholding the highest standards of ethics, compliance, and quality in all operations. Our core mission is to safeguard patients, support providers, and partner with payers through robust, transparent, and accountable program integrity services focused on preventing fraud, waste, and abuse (FWA). Ethics are prioritized throughout our organization to ensure trust, safety, and partnership excellence. Utilization decisions are grounded in national and local coverage determinations (NCDs/LCDs), medical necessity, and evidence-based clinical guidelines, drawing from years of direct industry experience. Every issue—be it about utilization decisions, provider disputes, or claim denials—is investigated promptly, documented thoroughly, and evaluated for root causes and systemic remediation. Systematic auditing of claims, resolutions, and process compliance ensures continuous improvement in claims management services.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	For the WISeR model services and jurisdictions, a conservative preliminary estimate would be a savings range of 5%–10% of baseline targeted expenditures for selected items/services in each jurisdiction during the demonstration period, assuming best practices in analytics and compliance oversight. Actual realized savings will depend on a variety of factors including baseline service utilization, provider adoption of PA workflows, and maintaining high accuracy and low improper denial rates as required for shared savings.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Day 1 through Day 30: • Project Manager and Contract Manager Assignment: Covasant will assign a Project Manager (PM) and Contract Manager to the project. The Project Manager will oversee the daily implementation process and Contract Manager will be the liaison between the Covasant team and CMS. • Initial Kick-off Meeting: The PM will schedule an initial kick-off meeting within seven days with CMS, MACs, subcontractors, and other required stakeholders to review the project, establish a charter, identify key stakeholders, assign roles and responsibilities, establish a status meeting cadence, and provide a draft schedule of deliverables. • Daily Standup Meetings: The Covasant team will have daily standup meetings led by the PM to ensure the project is on schedule and to address, resolve, or escalate issues. • BAA Flow Down: Share BAA flow down with subcontractor(s) for review and acceptance. • BAA Signing: Review and sign the BAA for data exchange. • Draft Joint Operating Agreements (JOA): Develop Draft Joint Operating Agreements (JOA) with the MAC for review. • Training: Attend or complete any required security or other training as designated by CMS. • Data Field/Mapping Review: Review data fields with the MAC to ensure proper mapping. • Azure Environment Creation: Covasant will create an Azure environment for the data project in accordance with CMS and HIPAA requirements. • System Security Plan (SSP): If required, Covasant will create a System Security Plan (SSP). • Data Transfer Setup: Establish SFTP or API for the transfer of data and conduct file tests. Day 31 through Day 45: • Draft Joint Operating Agreements (JOA): Signed JOA between all required parties. • System Access Forms: If direct system access to VMS, FISS, or MCS is required, submit the necessary forms for access to the MAC. • Initial Test Data Ingestion: Covasant will ingest the initial test data from the MAC and review it for completeness. • Data Issue Resolution: If the data is incomplete or other data irregularities are identified, the Covasant PM will review with the MAC PM to address the data issues and resubmit an updated file. • Data Loading: Once a complete file is validated, the initial data required for the project will be loaded to the Azure environment to begin analysis. • Updated Data Loading: The updated data will be loaded in accordance with the project timelines. • Policy and Procedure Review: Covasant's team will review the applicable Medicare policies and procedures, LCDs, and NCDs related to the claim types for the initial modeling. • Staff Training: Training of Covasant staff assigned to the project will be performed in preparation for the start of the project. Day 46 through Day 75: • Initial Model Creation and Testing: Covasant will create and test the initial models for the specific services outlined in year one. • Maintenance and Operational Phase: Once the models have been tested and approved, the project will move to the maintenance and operational phase day 75. Maintenance and Operational Phase The Covasant team will perform the functions outline in the statement of work (SOW) for the project for the duration of the period of performance. Covasant will submit all reports in accordance with the SOW requirements and ad hoc reports if requested by CMS.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Covasant Data Sciences Inc.
Certifying Individual: **Title:**	(b)(6)

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00142

Requested by (b)(6) on 07/28/2025 15:52

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Concert Genetics, Inc.
b. Doing Business As (DBA) Name(s)	Concert
c. Street Address	333 Commerce Street, Suite 1400
d. City	Nashville
e. State	TN
f. Zip Code	37201
g. Tax Identification Number	273979447
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Concert's purpose is to provide reliable digital infrastructure for managing diagnostic testing and precision medicine. The company is about half technologists and half clinical. The Concert Diagnostic Benefit Program today serves (b)(4) clients encompassing more than 30 million covered lives, and delivers $15-25 PMPY savings across outpatient laboratory. An additional (b)(4) ives edit on Concert's reimbursement policy only. Concert holds a patent for automating coverage and payment accuracy for diagnostic tests, including genetic tests (US10,896,405B1) and for tracking and standardizing molecular and diagnostic testing products and services (US10,223,501B1). Key supporting capabilities from Concert include the following: -- Clinical Policies: Concert maintains a comprehensive set of medical policies for outpatient laboratory testing. These policies are machine-readable, transparent, and updated twice a year. Health plans review and adopt Concert policy as their own to provide a transparent means to determine what is medically necessary for the patient. -- Real-Time Claim Edits: Concert provides a cloud-based, machine-learning-powered claim editing platform that can identify complex multi-code claims and return line-level edits in real-time. These claim edits are aligned with clinical guidelines and reimbursement policies, translating the coverage and payment guidelines into the language of coding (ICD and CPT). -- Test Identifier and Standard Coding: Concert offers a rules-based coding engine that identifies when laboratories bill with codes inconsistent with AMA, CPT, and NCCI guidelines. Powering this coding engine is a test registry that tracks over 175,000 high-cost tests with the Concert Genetic Test Unit (GTU). Laboratories verify their tests are coded correctly in the Concert catalog and Concert identifies claims billed incorrectly or inconsistently. -- Prior Auth Enablement: The Concert policies are written as a data asset, are designed for use in real-time prior authorization workflows. Companies like Evolent, EviCore, Availity, and Optum (InterQual) offer various Concert

	policies in their workflow. While customers take different approaches to implementing Concert, all health plans benefit from consistent application across policy, authorization, and editing. Mission/Values: -- Concert aims to promote health by offering reliable and efficient management of diagnostic testing, today focusing in outpatient laboratory testing. -- The company believes that waste harms patients and creates programs that benefit patients, providers, and payers by reducing healthcare costs from waste and fraud, and lowering member cost-sharing for overbilled claims. -- The company's guiding principles include acting courageously and admitting mistakes, recognizing that systematic change requires boldness, adaptability, and openness to feedback in a trusting and collaborative team environment.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian
5. Provide street address, city and state for all locations.	

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00142_Ownership_WISeR-00142_Ownership_Concert Genetics Inc Ownership 25July2025
Uploaded On	7/25/2025, 2:57 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	333 Commerce St., Suite 1400, Nashville, TN 37201
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	333 Commerce Street, Suite 1400, Nashville, TN 37201
Business Phone Number	(b)(6)

Contact Type	Tertiary

Email Address Name Title/Position	(b)(6)
Address	333 Commerce Street, Suite 1400, Nashville, TN 37201
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00142_Licensure_Concert Genetics Inc Certificate of Existence 25July2025
Uploaded On	7/25/2025, 3:01 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Concert has business associate agreements with all healthcare providers and health plans that use our products and services where protected data is involved. This would include a considerable number of customers and partners. We ensure protection of all protected data used in our products and services. Additional information can be provided as needed in the context of forming a formal business relationship.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Concert has experience working with Medicare Advantage (MA) plans and other payers to streamline coverage determination and prior authorization by providing tools and machine-readable policies. For Medicare Advantage plans, Concert's historical approach has involved: -- Concert criteria meeting or exceeding corresponding Coverage Determinations, which Concert already ensures for Biomarker Law states. -- Applying Concert machine-readable medical policies (and criteria within the payer's Utilization Management (UM) Platform) to streamline self-service authorizations and claim editing enforcement. -- Machine Learning powered analytics to identify and deny claims that are coded incorrectly or are for medically unnecessary services. -- Clinical criteria being searchable by test GTU within the UM Platform. -- Claim edits available directly from the Concert API or via partners. -- Improved analytics and real-time claim review/editing has

	been used to dramatically reduce waste and the scope of prior authorization required Overall, Concert's functions for these plans include: 1. Translating Medicare National Coverage Determinations (NCDs), LCDs, and Billing & Coding (B&C) policies into computable elements. Developing policies and machine readable criteria where there are guidelines but no NCDs or LCDs. 2. Providing clear reimbursement and clinical policies to address inconsistency in genetic testing billing, unbundling, and code stacking. 3. Developing and maintaining coverage algorithms, claim edits, and references to support policy and criteria. 4. Maintaining the only comprehensive registry of genetic tests organized by type, the Concert GTU, which complements a plan's prior authorization process and reduces what needs prior authorization. This is linked to coverage criteria, billing and coding policies, and integrated into Concert's claim edits where applicable. 5. Reducing prior authorization volume and manual reviews where possible (as much as 50%). Concert has worked with a variety of Medicare Advantage plans including Centene, BCBS MN, Health Partners (MN), et al. Concert tools are used to eliminate coding irregularities and to streamline determination of coverage. These are guidelines-based, reviewed constantly throughout the year, updated semi-annually, and should work not only for MACs, but for CMS as well. Lastly, it should be noted that OIG Report A-09-22-03010 suggests that despite CMS oversight, over $850 million in improper payments for one type of molecular pathology test occurred. Concert could provide vital infrastructure for the stewardship of U.S. tax dollars and reduction of inappropriate healthcare spending in diagnostic testing, including these high-cost genetic tests. Similarly, Müskens et al (2022) found substantial and highly varied overuse of diagnostic testing, including laboratory testing.(1) Another study by Mafi et al (2017) demonstrated that low-cost, high-volume health services contribute the most to unnecessary spending.(2) Traditional approaches to prior authorization have not been a good fit for low-cost, high-volume laboratory tests, given the high administrative costs of management and the need to maintain a low turnaround time. However, Concert's approaches to management, leveraging technology and connectivity, are showing significant value in decreasing waste and promoting medically necessary testing. Footnotes: (1) Müskens, J. L. J. M., Kool, R. B., van Dulmen, S. A., & Westert, G. P. (2022). Overuse of diagnostic testing in healthcare: a systematic review. BMJ quality & safety, 31(1), 54–63. https://doi.org/10.1136/bmjqs-2020-012576 (2) Mafi, J. N., Russell, K., Bortz, B. A., Dachary, M., Hazel, W. A., Jr, & Fendrick, A. M. (2017). Low-Cost, High-Volume Health Services Contribute The Most To Unnecessary Health Spending. Health affairs (Project Hope), 36(10), 1701–1704. https://doi.org/10.1377/hlthaff.2017.0385
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Concert has significant experience with healthcare-specific data, particularly in the context of genetic testing and general laboratory services. This experience includes: Prior Authorizations and Pre-Payment Reviews: - Concert offers patented, AI-powered pre-pay claim edits in real-time and post-pay analytics to identify anomalies. Concert's platform supports prior authorization determination via health plan policy and helps manage the health plan authorization workflow. - Concert provides alerts for category-specific health plan policies, which can inform prior authorization processes. - Concert also engineers its policy in JSON decision trees, for easy incorporation into authorization workflows like Evolent, InterQual, Availity, etc. - Concert's experience with health plan authorizations indicates that genetic tests represent 15-20% of authorization requests but less than 1% of claims costs for many plans. Furthermore, complex reviews, peer-to-peers, and appeals are frequent, yet inappropriate utilization for many tests is low. For example, see the following: --High-volume prenatal tests such as carrier screening panels, single gene tests (CFTR, SMA, SMN1/2), and non-invasive prenatal tests are approved in 85-90%+ of prior authorization cases.(1) --Hereditary cancer testing for cancer patients is also used appropriately in the vast majority of cases. --Single gene rare disease testing is infrequent and reviews are long and burdensome, despite almost always resulting in 90%+ approvals. The same is true for many rare disease panels. Implementing Coverage Determinations (LCDs/NCDs): - For Medicare Advantage (MA) plans, Concert streamlines the lookup for LCDs, and for cases without an LCD, utilizing Concert's own evidence-based criteria for the translation of guidelines into machine readable policy and real-time edits. These criteria are reviewed by internal clinical experts as well as an external clinical advisory board that includes Drs Beth Harris (former Medicare Advantage medical director), Girish Putcha (former MAC Medical Director), Michele Schoonmaker (former FDA staff member), Thomas Holland (a leading infectious disease specialist), and Lalan Wilfong (a leading oncologist). - Concert's approach for MA plans ensures that Concert medical policies (and criteria within the payer's Utilization Management (UM) Platform) meet or exceed corresponding Coverage Determinations, while simultaneously enforcing NCCI and AMA CPT® coding standards for appropriate coding. Administrative Claims Data from CMS or other Payers/Plans: - Concert's savings analyses are conducted on historical claims data provided by payers. This data includes "Current Spend on Claims" and "Volume of Claims Processed." - Concert requests details on the "Complexity of Claims (e.g., DRG, CPT coding)" and "Error Rate in Claims," along with "Types of Errors (coding, eligibility, duplicate billing, etc.)," indicating familiarity with the structure and content of administrative claims data. - Concert edits claims for health plans and TPAs covering more than 40 million lives, demonstrating extensive experience processing claims data from multiple payers. - Concert has in the past conducted Medicare claims analysis on CMS public use files. Footnotes: (1) Bajguz, D., Danylchuk, N. R., Czarniecki, M., Selig, J. P., Sutphen, R., & Kaylor, J. (2022). Utilization of genetic testing: Analysis of 4,499 prior authorization requests for molecular genetic tests at four US regional health plans. Journal of Genetic Counseling, 31, 771–780. https://doi.org/10.1002/jgc4.1543

b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	By developing policies that are consistent with evidence-based medicine and guidelines, and integrated with real-time technology systems, prior authorization can be dramatically reduced or eliminated altogether. The Concert solution is unparalleled in terms of coverage, savings, and technological advancement. Medical directors who interact with Concert benefit from this. It is Concert's view that policy, approvals, and payment should be standardized based on evidence and correct coding. Today, two different plans may render different coverage decisions for the same member. Concert would like to see coverage standardized around guidelines and evidence across all states, lines of business, and MACs, and our neutral approach today helps advance the industry on this trajectory. Concert is a neutral technology company – agnostic to plans, providers, laboratories, and integration partners. Concert differs from laboratory benefit managers and other delegated entities in that it does not employ clinicians for the purpose of conducting health plan medical necessity reviews. Delegated entities, such as EviCore and Evolent, leverage Concert criteria to conduct such reviews, as do health plans who adopt the Concert solution. Rather, Concert provides the clinical support to the plan, enabling the plan to review for medical necessity. If needed for this project, Concert could hire medical directors to support the relevant MAC(s). Using Concert's platform, prior authorization teams expend far fewer resources on the administrative elements of prior authorization (determining which test was ordered, determining which criteria to apply, reviewing code by code for multi CPT code claims) and are able to focus their time on the clinical questions to be answered. A more detailed explanation of Concert's policy development process is as follows: Concert's clinical policies reference national guidelines published by professional societies, FDA coverage for diagnostics and companion diagnostics, and national and local coverage determinations (NCDs and LCDs). Commonly referenced guideline sources include USPSTF, NCCN, ASCO, ACOG, ACMG, NSGC, AAN, ACC, IDSA, AAFP, ATA, ASN, SMFM, AMP and the CDC. To prioritize development and maintenance of a robust criteria library, we draw on claims datasets inclusive of Medicaid, Commercial and Medicare lines of business, focusing primarily on the 8XXXX and PLA sections of the CPT code book, but also recognizing Level I HCPCS codes developed by CMS and codes commonly billed alongside 8XXXX codes. Policies are structured in a JSON, machine-readable, decision-tree format and can therefore be incorporated into any prior authorization/UM platform including upcoming CMS required APIs for Electronic Prior Authorization. For our clinical policies, we publish two version releases per year. On July 1 and January 1, draft policies are sent to Concert customers and Concert's Clinical Advisory Board for review. During this 4-week review period, health plans are encouraged to share all policies with their internal subject matter experts, compile feedback, and return this feedback to Concert. Concert's clinical team and Clinical Advisory Board together review feedback from all users of the Concert platform (customers and non-customers) on an ongoing basis and compare feedback to the policy evidence base and rationale. If the suggested feedback more clearly aligns coverage pathways to evidence and/or makes the policies more clear and transparent in their intent, Concert incorporates this feedback into our policies prior to the next release. On September 1 and March 1, final policies are sent to plans for incorporation into their own policy libraries with sufficient time allowed for policies that may require a 90-day notification of new policy adoption. New policies go live January 1 and July 1. Off-cycle releases may be considered per health plan request, when necessitated by major regulatory changes (or changes to interpretations), or based on the emergence of novel breakthrough testing. Concert's proprietary taxonomy structure links the test catalog and clinical policies on an ongoing basis. When new tests come to market, they are automatically mapped to the applicable clinical criteria. When guidelines change, the resulting policy revisions automatically link to all applicable tests. Our reimbursement policies reference standards bodies such as NCCI and AMA. They are

	reviewed and adopted by health plan customers who publish these policies as their own, and contain detailed information about the appropriate coding and billing of laboratory tests. While Concert's clinical and payment policies follow the same industry-standard release cycles, they are kept consistently up to date via our taxonomy, which takes into account emerging guidelines, new test entrants, coding changes, and regulatory changes. Health plans who adopt Concert's payment policy point to the Concert coding requirements, which can be accessed by health plans, providers, and laboratories at any time. Plans provide a 90-day advance notification prior to the reimbursement policy going into effect. Because Concert does not serve as a delegated entity for health plan customers, we do not seek nor maintain NCQA or URAC accreditation. However, the Concert solution is built to integrate with any UM vendor or payment integrity platform. Customers are able to access Concert through a growing list of integrated partners including Evolent, EviCore, InterQual, Availity, Lyric, HealthEdge, and Zelis.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Concert began as a provider of test ordering software. This led to the creation of the aforementioned Concert GTU, which maps all 175,000+ unique genetic tests on the market. With a standalone test ordering platform, Concert interfaces with EHR systems in the following ways: Established Interfaces: Concert has established interfaces with leading EHRs like Epic, Cerner, Meditech, and eClinicalWorks. Concert also integrates its clinical criteria into EHRs through Optum InterQual, Availity AuthAI, etc. Information Exchange: Concert acts as a one-to-many point of integration for healthcare providers with genetic testing laboratories and vice versa. Concert enables structured genetic test order and result information to flow seamlessly between healthcare providers and genetics reference laboratories. Concert can exchange information using Health Level 7 (HL7) and Logical Observation Identifiers Names and Codes (LOINC) standards. Workflow Integration: Concert provides multiple integration scenarios to support different provider workflows, including providers ordering in Concert Platform, ordering with defined tests, researching in Concert Platform, or ordering 'miscellaneous' tests with notes. Partner and Build Approach: Concert is developing a partner and build approach for EHR/LIS integrations, working with a third-party vendor to connect and configure HL7 ADT and ORM/ORU between the hospital and lab, and to provide a single method for sending and receiving data via API with the Concert Platform. CMS-0057-F: Concert will meet or exceed the CMS final rule. We today comply with the DTR portion of the specification, and are working to comply with other parts of the mandate. In addition, Concert's clinical criteria are available through partners who today comply with the full mandate.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	Concert has experience in training AI/ML models on complex datasets and coverage determinations. This includes: -- ML Categorization of Claims and Automated Application of Medical Policy: Concert holds patents related to machine learning categorization of claims and the automated application of medical policy (US10,896,405B1; US10223501). This includes deciphering complex claim signatures and mapping them to clinical criteria -- AI-Powered Pre-Pay Claim Edits: Concert offers patented, AI-powered pre-pay claim edits that operate in real-time. Concert's approach to verify, validate, secure, and regulate its enhanced technology software, and manage potential adverse effects of automation and AI, involves: -- Concert uses integrated, internal machine learning tools that are built into its HITRUST certified environment. Models are trained in-house. The training set for the classification model is curated by clinical experts and sourced from a broad training set that should be representative of insured lives. -- Concert utilizes supervised machine learning to train classifiers (matching complex claim signatures to Concert's taxonomy of tests). These classifiers are used to infer which categories of tests are represented in claims, which will be used to determine applicable edits. -- The output of these training models (classified claims) is reviewed selectively by humans for model improvement and quality assurance. -- Additionally, Concert enforces an aggressive testing procedure for any changes to the editing platform or machine learning model that compares outcomes for a large sample of claims before and after changes for any unexpected deviations. The outcomes of these tests are reviewed by analysts and clinical experts prior to deployment to production systems. Concert's approach leverages machine learning to identify complex claim signatures and map them to clinical policy. Concert's clinical policy development process is evidence-based and rigorous and detailed elsewhere in this submission.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))?	No

If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.	

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Concert's Statement of Purpose is as follows: We believe… -- The world is on the precipice of transformation driven by seismic advances in molecular science and technology. -- Despite great advances, health care fails to work consistently and transparently for the health consumer. -- Many of these failures arise from a multi-stakeholder ecosystem that is opaque, antagonistic, error-prone, slow and wasteful. -- Waste harms patients. -- Providers, payers, laboratories and drug developers can all thrive in a world that is transparent, evidence-based and focused on the well-being of the health consumer. We work… -- To remove unnecessary friction, delay, uncertainty and cost from the interactions between the consumer, the provider and the intermediaries in between. -- To build digital infrastructure that makes precision health smart, simple, effective and affordable. -- To advance learning systems that constantly improve patient health, safety and quality of life. -- To serve the health consumer, bringing dignity and honor to the business of healthcare. Our Guiding Principles are as follows: 1. Listen intently. Think clearly. Listening is fundamental to strong human relationships, which are the most important factor in our success. We listen to learn, so that we can consistently deliver well-reasoned insights and clear plans. 2. Act courageously. Admit mistakes. Driven and results-oriented, we act boldly; yet we do so accepting that we may err or fall short. With humility, we admit mistakes and share credit. 3. Keep promises. Keep going. Our integrity is always on the line. It is by making and keeping commitments that we build trust. Trust allows us to realize goals others can only imagine. To review Concert's approach as outlined in this response, Concert has designed its business to enforce ethics, compliance, quality, and safety. This includes, but is not limited to the following: -- Evidence-Based Policies: Concert's clinical policies are evidence-based, machine-readable, and publicly available online. They reference national guidelines from professional societies, FDA coverage, and national and local coverage determinations (NCDs and LCDs). These policies are reviewed and updated semi-annually by Concert's clinical team and an independent Clinical Advisory Board. -- Transparency and Feedback: Concert promotes transparency in its policy process, allowing users to provide feedback that is reviewed and incorporated if it aligns coverage pathways to evidence or improves clarity. Health plan customers implement the solution and are the regulated entity, which means that they can modify policy positions. When a policy position is modified, Concert deactivates any corresponding edit. -- Neutral Technology Company: Concert operates as a neutral technology company, agnostic to plans, providers, laboratories, and integration partners. -- Compliance with Laws: Concert commits to conducting its relationship in full compliance with applicable state, local, and federal laws, including Medicare/Medicaid anti-kickback/Fraud and Abuse provisions and the Stark Law. -- Information Security: Concert maintains HITRUST certification and enforces security controls that meet or exceed NIST standards. All protected information is accessed, processed, and stored exclusively in the Amazon AWS cloud environment, using only services that are SOC 2 Type 2 and HITRUST certified. Complaints and Grievances, Claims Billing, and Claim Dispute Issues: -- Low Abrasion: Concert's clear policies and edits minimize provider appeals – providing health plans with an evidence-based, defensible position for coverage and reimbursement of tests. -- Support for Medical Directors: Concert provides medical directors with tools to incorporate medical and payment policies into their review cycles. -- Appeals Support: In the case of appeals, when they do happen, Concert provides detailed documentation supporting any policy and edit position that was applied to a claim. Concert also has a change management process for incorporating any feedback about policy, authorization, or editing dispositions. Compliance with State and Federal Regulations: -- Adherence to Plan Compliance Efforts: Concert agrees to cooperate fully with the compliance efforts of health plans. -- Federal Funds and Programs: Concert acknowledges that payments from health plans are made, in whole or in part, from federal funds, subjecting Concert and its subcontractors to various federal laws. -- Exclusion from Federal Health Care Programs: Concert represents that neither it nor its employees, agents, or independent contractors have been excluded from participation in federally-funded healthcare programs. -- Fraud, Waste, and Abuse Control: Concert is required to establish and maintain a comprehensive compliance program for corporate integrity, fraud prevention, and detection, including annual compliance training. -- Data Accuracy and Truthfulness: Concert warrants that all data submitted to health plans is accurate, complete, and truthful. Biomarker Legislation: Concert takes into account all biomarker legislation when authoring content, designing its approach to support plans in states with and without biomarker laws. -- Support for Medicare Advantage Plans: Concert's solutions draw on claims datasets inclusive of Medicare lines of business, and its policies can be incorporated into prior authorization/UM platforms, including upcoming CMS required APIs for Electronic Prior Authorization. All Concert staff undergo rigorous annual security awareness and compliance training, complete with ongoing social engineering tests like phishing simulation campaigns. The training includes

	topics like personal security awareness, identification and handling of protected information including PHI, and reporting illegal or suspicious activity. Concert also includes requirements for Fraud, Waste, and Abuse training.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Concert anticipates the following savings estimates in relation to the selected items and services and geographic regions/MAC jurisdictions included in WISeR: -- Total Lab Spend: A savings of 5-10% of total lab spend is expected. Additionally, Concert analytics will quantify the cost of MAC-level variation due to the creation of LCDs. -- Prior Authorization: Substantial reduction or elimination of prior authorization for compliant providers is anticipated. -- Variation and Conflicts of Interest: Three major objectives should be: (1) the elimination of variation in coverage criteria across MAC jurisdictions, (2) the elimination of variation between CMS coverage and guidelines based cared, and (3) an end to the inherent conflicts of interest between MACs and the best interests of the American taxpayer. Regarding the third objective, the Palmetto MACs' requirement of Z-code for Medicare FFS payment, concurrent with the licensing of the same Z-code for commercial use, presents potential for conflicts of interest and higher-than-necessary medical expense.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	1. Obtain CMS approval to access data (likely through an existing CMS-approved data vendor) 2. Install Concert analytics on CMS approved vendor platform (1-2 months) 3. Run and summarize initial high-value areas (2 months) for implementation of machine-readable policy and automated enforcement 4. Selective implementation and pilot program measurement (6-12 months, at CMS discretion)

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Concert Genetics, Inc.
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00014

Requested b (b)(6) on 07/28/2025 12:30

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	TurningPoint Healthcare Solutions, LLC
b. Doing Business As (DBA) Name(s)	TurningPoint Healthcare Solutions
c. Street Address	744 Primera Blvd, Suite 2100
d. City	Lake Mary
e. State	FL
f. Zip Code	32746
g. Tax Identification Number	871438768
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	TurningPoint is a market-leading specialty utilization management company that applies advanced AI powered clinical decision support technologies and highly pedigreed clinical sub-specialists to collaborate with providers in our corporate mission to improve the safety, quality and affordability of patient care. Founded in 2014, we have demonstrated a strong history of successfully improving patient outcomes and working with providers to eliminate waste, fraud, and abuse for over 37M covered lives and managing prior authorization requests from all 50 states. Through the application of our deep clinical expertise, state-of-the-art technologies, collaborative provider support, and strong operational track record, we have the unique distinction of 100% of our clients being highly referenceable and a 100% retention rate of our health plan clients for over 10 years. Our deep experience in Medicare prior authorization and a differentiated and flexible end-to-end technology platform has uniquely positioned us to serve as an innovative partner to CMS for the WISeR model. The examples below highlight our success in managing complex specialty care using AI-driven authorization, clinical review, and decision support. • National Experience. We have managed Medicare Advantage prior authorizations for 10+ years and oversee requests from all 50 US states. We manage 37M+ covered lives, including 2.6M Medicare Advantage lives. Our relevant regional experience includes 6.4M covered lives in NJ, 3.4M in TX, 2.5M in OH, and 469K in AZ. Our clients are Horizon Blue Cross Blue Shield of NJ, Blue Cross Blue Shield of Michigan, Priority Health, Blue Kansas City, Centene (WellCare, Fidelis), Capital BlueCross, CareSource, Blue Cross Blue Shield of Tennessee, and Health Alliance Plan. • New Jersey Market History (MAC Jurisdiction JL). We have experience in and can support all WISeR MAC Jurisdictions. Based on WISeR indications to select preferred markets, TurningPoint has a depth of experience in the State of NJ for Horizon Blue Cross NJ. We support 2,000+ NJ providers and have provider satisfaction scores

	in NJ of over 84%. • Clinical Expertise. Our utilization management program applies physician “sub-specialty” matching for all prior authorization reviews. Our clinical review team is composed of industry leading specialty physicians who have held national leadership roles in organizations such as AAOS, NASS, ACC, and the National Urologic society. • AI Market Leader. TurningPoint has embedded its deep clinical expertise into our proprietary clinical decision and claims payment support platforms. These technologies incorporate the use of AI, ML, and NLP to enable intelligent, transparent, scalable, and provider friendly prior authorization and claims payment accuracy workflows. • Proven Results. We consistently drives claims cost savings of 10-30% while improving quality outcomes (e.g., SNF utilization, Post Procedure ER utilization, reoperation rates, etc.).
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	TurningPoint Corporate Headquarters
Street Address	744 Primera Blvd, Suite 2100
City	Lake Mary
State	Florida
Zip Code	32746

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00014_Ownership_CMMI Wiser - TurningPoint Ownership Structure
Uploaded On	7/24/2025, 4:58 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	744 Primera Blvd, Suite 2100, Lake Mary, FL 32746
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)

Name Title/Position	(b)(6)
Address	744 Primera Blvd, Suite 2100, Lake Mary, FL 32746
Business Phone Number	(b)(6)

Contact Type	Tertiary
Email Address Name Title/Position	(b)(6)
Address	744 Primera Blvd, Suite 2100, Lake Mary, FL 32746
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00014_Licensure_Delaware Certificate of Good Standing 2025
Uploaded On	7/23/2025, 4:35 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	TurningPoint is a Utilization Management organization that acts as a business associate of our Health Plan clients, and as such, has signed BAAs with current and prospective clients. TurningPoint has BAAs with the following HIPAA covered entities: Health Plans: • Advocate Aurora Health, Inc. • AmeriHealth Caritas Services, LLC • Blue Cross and Blue Shield of Kansas City • Blue Cross and Blue Shield of Massachusetts • Blue Cross and Blue Shield of Michigan • Blue Cross and Blue Shield of Tennessee • Capital Blue Cross • Capital District Physicians' Health Plan, Inc. • Carelon Holdings, LLC • Centene Corporation • Clover Health, LLC • CareSource Management Services, LLC • Health Alliance Plan of Michigan • Health Partners, Inc. • Horizon Healthcare Services, Inc. • MVP Health Plan • Molina

	Healthcare, Inc. • MotivHealth Insurance • Optum Healthcare Solutions, LLC • Point 32 Health Services, Inc. • P3 Health Group, LLC • United Healthcare Services, Inc. • Wellmark, Inc. Provider Entities: • Corewell Health • HF Management Services, LLC • Oak Street Health MSO, LLC • Montefiore Health Systems, Inc. • Northwell Health, Inc. • Northwestern Memorial HealthCare

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Medicare Advantage Experience: TurningPoint brings extensive experience as a delegated entity for Utilization Management and Prior Authorization reviews, supporting Medicare Advantage plans nationwide. Our Medicare Advantage clients include Horizon Blue Cross Blue Shield of New Jersey, Blue Cross Blue Shield of Michigan, Priority Health, Blue KC, Centene, Capital BlueCross, CareSource, and Health Alliance Plan. TurningPoint has partnered with Medicare Advantage plans for over 10 years and now manages 2.6 million covered Medicare Advantage lives. Each year, we process hundreds of thousands of Medicare Advantage authorization requests, leveraging clinical expertise and AI-enabled technology to ensure timely, clinically driven decisions. Through our extensive work with Medicare Advantage plans, we are well versed in specific Medicare requirements and regulations. While TurningPoint has developed proprietary medical policies that are adopted by our Medicare Advantage partners, we default to and fully adhere to applicable NCDs and LCDs. We have deep experience navigating CMS reporting requirements and regulatory standards, and we continuously monitor legislative and policy changes to ensure full compliance. In NJ, TurningPoint has been delegated for Utilization Management review for the Medicare Advantage population—as well as all other lines of business, including Commercial Fully-Insured, Commercial Self-Insured, Medicaid, the Federal Employee Program, the State Health Benefits Program, and the School Employees' Health Benefits Program—by Horizon Blue Cross Blue Shield of NJ, the state's largest health plan, since 2018. We are deeply familiar with NJ market dynamics, managing ~170k+ covered Medicare Advantage lives for Horizon. We have deep and collaborative relationships with 2,000+ providers in NJ, who are intimately familiar with our clinical and operational workflows. Our outstanding performance in NJ on behalf of Horizon BCBS is reflected in successive multi-year contract renewals and a strong 84% provider network satisfaction score in 2024. TurningPoint also has a similar depth of experience and market familiarity across all of the MAC jurisdictions selected in the WISeR program. Functions Performed by TurningPoint: As a complex specialty condition management partner to Medicare Advantage plans, which includes delegation for utilization management review, TurningPoint performs various functions in service of improving the safety, quality and affordability of care. A core function is Provider Relations and collaboration. The success of the TurningPoint program is rooted in close collaboration with our health plan partners and their physician networks. Before launching a program, we meet individually with each practice to provide a comprehensive overview, clarify program goals, and ensure transparency around medical policy criteria and documentation requirements. These sessions also serve as an opportunity to invite providers to participate in our Surgical Quality and Safety Incentive Program, which rewards high-performing practices for delivering high-quality, cost-effective care that exceeds baseline medical policy standards. Following the launch of the program, our dedicated provider relations representatives will continue to proactively outreach to the practices to share performance data and ensure overall satisfaction. We utilize reporting to identify practices that may need further education and will work with our clinical team to ensure further education is provided. Given our ability to track provider level performance, we can establish and execute performance-based gold carding where appropriate and currently support gold carding programs for clients. Quarterly, we deliver reporting that outlines the practices' adherence to the TurningPoint Quality and Safety program. These reports detail every case submitted and whether it met the individual program components. TurningPoint collaborates with our health plan clients and can tailor the program criteria to best meet the unique needs of each health plan. The next function is Utilization Management, which is enabled by AI technology and performed by TurningPoint's clinical team, which is a collection of national sub-specialized clinical leaders. In our role as delegated utilization partner to health plans, TurningPoint conducts both pre-service prior authorization reviews as well as post-service, pre-payment medical necessity reviews. Providers can submit prior authorization requests to TurningPoint electronically via the TurningPoint portal (self-hosted) as well as by toll-free, dedicated fax or phone numbers and mail, demonstrating our ability to flex to the preferences of providers and MACs. Our portal can be implemented with a single sign-on feature that integrates with provider and payor portals. Our portal allows for the submission of a request for prior authorization as well as uploading and downloading documents on individual cases and checking the status of a case. TurningPoint's technology embeds AI into the submission process. Providers receive AI-guided feedback if procedure specific clinical documentation is missing from the submission, giving the provider the opportunity to upload a complete clinical record to match the policy documentation requirements, reducing delays and non-affirmations due to missing clinical documentation and by extension, improving provider satisfaction. Once a case is submitted, our platform uses proprietary technology to match each request with the appropriate clinical expertise, enabling scalable, high-quality decision-making across a network of several hundred physician and nurse reviewers. As part of the utilization management process, TurningPoint

	builds a patient-specific clinical profile, incorporating relevant comorbidities and health data, to assess whether the requested procedure is appropriate at that point in the patient's care journey. Our clinical team then reviews the case and renders a determination, requesting additional information when necessary, while strictly adhering to all regulatory turnaround time requirements. TurningPoint meets turn around requirements 99.9% of the time. When additional clinical information is needed, our Utilization Management staff initiates provider outreach. In alignment with CMS requirements, TurningPoint completes a minimum of three reasonable outreach attempts before issuing a denial or non-coverage determination. Determination notifications are provided in writing to the provider, member, and facility, in full compliance with CMS standards for standard and expedited organization determinations for Medicare Advantage beneficiaries, as well as applicable state requirements for Medicaid and commercial lines of business. In addition to written notifications, TurningPoint places courtesy calls to the provider's office for all determinations and contacts members when required by line of business. Adverse determinations/denials will only be made by a physician reviewer, the Medical Director, or the Chief Medical Officer. Written denial notices will include: a. Clinical rationale(s) for denial b. Applicable appeal rights based upon the client contract and line of business c. Notice of the availability, upon request of the provider/enrollee/designee, of the clinical review criteria relied upon to make such determination d. Information needed to approve coverage A written notice of determination will be issued to the member with a copy to the requesting provider within fourteen calendar days of receipt of the request (72 hours for urgent requests). TurningPoint may extend the fourteen day timeframe by fourteen calendar days if: a) the enrollee requests an extension; or b) there is a justifiable need for additional information to render a determination. The Medical Authorization Coordinator will document in the case file how the delay is in the best interest of the enrollee. In cases where the company initiates the extension, the appropriate notice will be issued to the member with a copy to the requesting provider. The organization determination will be made, and written notice will be issued to the member (with a copy to requesting provider) before the expiration date of the extension, but no more than twenty-eight calendar days after receipt of the original authorization request. Another function TurningPoint often provides to Medicare Advantage plans is appeal delegation and/or support. In cases where the client does not delegate appeals, such as the case of the WISeR model, TurningPoint collaborates with the client to develop appropriate workflows that ensure effective communication between TurningPoint and the client. We provide the client with all information considered in the initial determination including clinical information obtained during intake and peer-to-peer review, clinical guidelines and the clinical rationale applied in rendering the determination. The client is responsible for notifying TurningPoint of the outcome of the appeal. Finally, TurningPoint routinely performs claims payment validation to ensure that claims are billed and paid appropriately in accordance with medical necessity criteria. TurningPoint has experience receiving pended claims, pre-payment to ensure claims are not paid inaccurately or inappropriately, including: detailed auth-to-claim matching, institutional to professional claim matching, claims bundling, application of any medically unlikely edits, in-depth reviews of all implants/biologics utilized to ensure claims are not paid inaccurately or inappropriately, resulting in incremental cost savings. TurningPoint has experience reviewing claims that are pended and sent to our claims team pre-payment, which works seamlessly with any current claims integrity vendor or capability. This approach identifies instances where overpayment may occur proactively eliminates the need to recover overpayments retrospectively.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	We have extensive experience conducting prior authorization, pre-payment reviews in alignment with both our proprietary medical policies and CMS guidelines, including LCDs and NCDs, with all relevant policies already mapped to the specialty programs we operate across all MAC regions. During these medical reviews, TurningPoint receives and transmits sensitive, healthcare-specific data in a fully CMS compliant manner. All data exchanges are conducted via secure channels—such as SFTP, API, etc.—that adhere to HIPAA / HITECH standards. We can accommodate both HIPAA-standard and proprietary file layouts. As part of our relationships with health plans, we receive access to claims data for multiple purposes. Primarily, we use this data for post-service medical necessity reviews. For many of our clients, this review is performed through a pended claims process prior to adjudication. In this process, we conduct either an initial medical necessity determination (if it was not performed pre-service) or a post-service review, when the submitted claim differs from the surgical plan previously reviewed during prior authorization. We receive ongoing feeds of paid claims data, which are used to support both performance reconciliation and medical economic analysis. These data streams complement our post-service medical necessity reviews and provide valuable insights into program impact over time. Interfacing with MACs: TurningPoint has extensive experience interfacing with providers, health plans, data exchanges, and clearinghouses to exchange data at all phases of the medical necessity review process. Our approach to interfacing with the MACs through the WISeR program will be to support the least burdensome path to connectivity, as is our policy with all our current partners. We bring 12 years of experience integrating with national health plans, from legacy mainframes to modern APIs, giving us the flexibility to support MACs across a wide range of technical environments. Our capabilities and expertise support authentication systems including password authentication and/or real-time SAML-based Single Sign-On (SSO); our support of eligibility, authorization, and claims data includes CMS-standard EDI ASC X12 (837, 834, 270-271) transactions, custom payer APIs, and legacy file formats; our support of provider data systems include EMR-supported APIs, pdf, fax, and phone. Our

data systems are flexible to support multi-format data intake, including medical necessity review communication, and exchange of client-generated affirmative or non-affirmative UTNs with providers and health plans. TurningPoint is already registered for electronic data exchange with each of the participating MACs in the WISeR model, so if this is the desired path, we would be ready to immediately start coordination with the participating MACs on 1/1/2026. If the partnering MACs wish to transmit healthcare data through exchanges, e.g., Availity, TurningPoint would also already have connectivity in place. As TurningPoint also supports legacy forms of data exchange, these would offer alternative solutions. FedRAMP: Turning Point maintains a mature and proven security and compliance program, grounded in the HITRUST CSF framework. Security is integrated throughout the system lifecycle—from architecture and access controls to audit logging, encryption, privacy, and incident response. We have consistently maintained HITRUST certification through disciplined policy governance, continuous monitoring, and real-time risk management, led by our experienced security and compliance teams. We are actively pursuing FedRAMP authorization through the FedRAMP 20x Phase One pilot, targeting completion by January 1, 2026. FedRAMP Low aligns with the majority of FISMA requirements for systems handling moderate- and low-impact data. Our HITRUST controls already map to the NIST SP 800-53 baseline, giving us a strong foundation for FedRAMP and FISMA compliance. In partnership with our FedRAMP-accredited 3PAO, we have completed the readiness assessment and are finalizing required documentation, including our System Security Plan (SSP), Configuration Management Plan (CMP), Incident Response Plan (IRP), and Contingency Plan (CP). Our team includes experts with direct CMS ATO experience, and we are aligning our FedRAMP program to meet CMS-specific overlays and documentation requirements. Our compliance roadmap is tightly aligned with the FedRAMP PMO and CMS expectations. Key milestones include: • Finalizing enhanced system documentation and automation strategies • Completing readiness review with 3PAO and FedRAMP PMO • Participating in FedRAMP 20X pilot testing and evidence submission • Undergoing full 3PAO assessment under expanded 20X protocols • Submitting final security package for FedRAMP authorization • Launching continuous monitoring in line with FedRAMP automation goals • Incorporating CMS overlays to initiate and complete CMS ATO in parallel This coordinated approach reflects our commitment to secure, scalable, and transparent compliance. Our executive-led roadmap, supported by CISSP-certified staff and a strong HITRUST foundation, positions us to achieve full FedRAMP 20X authorization and CMS ATO by the end of 2025. HIPAA Privacy, Security, Breach Rules and Response Plan: TurningPoint's formal Privacy Program, part of our Corporate Compliance Program, ensures all workforce members receive HIPAA Privacy and Security training at hire and annually. Our Notice of Privacy Practices outlines how we safeguard Protected Health Information (PHI) and emphasizes transparency around our policies, procedures, and technologies. A public notice on our website also informs consumers of their rights and responsibilities. TurningPoint has also implemented a Breach Response and Notification policy, which outlines processes and standards for responding to and notifying the Compliance Department and Privacy Officer in the event of any incident involving the acquisition, access, use or disclosure of PHI in a manner that is potentially not permitted under the Health Insurance Portability and Accountability Act of 1996 and its implementing rules and regulations or our Confidentiality obligations to our customer health plans and their members. TurningPoint's policies outline the acceptable use, access, and disclosure of sensitive data, as well as reporting obligations in the event of a breach or violations. This is monitored and enforced by performing audits and assessments to identify any potential privacy violations or breaches. These evaluations including reviewing data handling practices, access controls implemented, the type of employee training provided, monitoring to detect suspicious and unauthorized activities using intrusion detection, data loss prevention controls, and log monitoring. All privacy incidents and potential HIPAA violations are documented by the Compliance Department and reviewed by the Privacy Officer to determine what mitigation efforts must be immediately undertaken and whether such incident may rise to the level of a "breach" as defined under HIPAA. Upon being notified via system alerts and/or a complaint from a workforce member, TurningPoint assigns an individual to act as the investigator. The investigator coordinates with others (e.g., administration, IT, HR, legal) as appropriate to conduct an investigation and risk assessment. For breach response and notification purposes, Turningpoint will presume a breach has occurred unless the investigation can demonstrate that there is a low probability that the PHI has been compromised based on, at minimum, the nature and extent of the PHI involved. Individuals who may be involved in an incidental disclosure that does not rise to the level of a breach are given retraining, and procedures may be modified to eliminate similar incidents going forward. As a Business Associate of our covered entity health plan customers, it is our duty to immediately notify the Customer whose PHI may have been compromised, conduct a thorough investigation, and if requested, assist in providing appropriate individual and regulatory notifications. Following the discovery of a potential breach, TurningPoint will begin an investigation, conduct a risk assessment, developed with guidance from the NCHICA HITECH ACT Breach Notification Risk Assessment Tool, to determine if there is a significant risk or harm to the individual as a result of the impermissible use or disclosure of PHI. Based on the results, TurningPoint will begin the process of notifying everyone whose PHI has been, or is reasonably believed to have been, accessed, acquired, used or disclosed as a result of the breach. TurningPoint will also begin the process of determining what notifications are required or should be made, if any, to the Secretary of the Department of Health and Human Services (HHS) or media outlets. Our breach notification process has been established to ensure compliance with the

	HITECH Act of the American Recovery and Reinvestment Act of 2009 and its implementing rules and regulations. This process aligns with the requirements set forth by these acts to ensure timely and appropriate notifications to affected individuals. To establish our Privacy and Breach Notifications, we have utilized the Model Notices of Privacy Practices (2014) published by US Department of Health & Human Services. The model serves as a basis for our notifications to ensure compliance with privacy regulations and best practices. TurningPoint's Privacy Program and Breach Notification policies are reviewed quarterly by the Quality Management Committee, which includes Executive Leadership from Legal, Compliance, Business, Finance, Security, and IT. This cross-functional oversight ensures compliance with federal, state, client, and regulatory requirements, and helps safeguard confidential information across the organization. TurningPoint has not had a Significant Data Loss/Breach in our history.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	Yes

Authorizations or Certifications Document

File Name	WISeR-00014_Authorizations_Turningpoint 2025— HITRUST r2 Cert. Ltr. (Final)
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3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	TurningPoint's Utilization Management core program differentiation starts with our clinical team, comprised of national clinical leaders with extensive experience working to set national quality & patient safety standards, to craft value-based care policy reform and to train clinical teams across the industry. These individuals were drawn to, and remain committed to, TurningPoint by its mission, bringing their expertise across expansive provider networks to drive meaningful, large-scale improvements in the safety, quality, and affordability of patient care. Our deep clinical leadership offers CMS access to a broad team of physician experts who are recognized leaders in Utilization Management and Prior Authorization review. TurningPoint will be a trusted, flexible and collaborative clinical partner to advance the CMS goals of improving appropriate utilization, equity, and value throughout the lifecycle of the WISeR program. TurningPoint employs approximately 200 licensed clinicians, including registered nurses (RNs), nurse practitioners (NPs), physicians and surgeons (MDs), and physician assistants (PAs) within its Utilization Management and Prior Authorization review team. These professionals are experts in their respective clinical subspecialties and collectively hold licensure across all 50 states, enabling nationwide coverage with specialty-specific expertise. The TurningPoint clinical model is highly scalable, and additional clinicians can be added quickly if required. TurningPoint's clinical team has held national clinical leadership positions and has extensive experience working to set national quality and patient safety standards and to craft value-based care policy reform at the national and regional level. Over two thirds of the physician review staff are active practitioners at top institutions, ensuring continual learning and knowledge of latest literature and surgical techniques. Members of the of the TurningPoint clinical team include: • Four past presidents of the American Academy of Orthopedic Surgery (AAOS) • Past president of the North American Spine Society (NASS) • President of the American Board of Orthopedic Surgery • President of the American College of Cardiology (ACC) • Past of President American Urological Association • Past Vice Chairman of American Association of Neurological Surgeons • ENT/Sleep Medicine specialists with expertise in Sleep Apnea procedures • Leaders from the AMA Specialty Society Relative Value Scale Update Committee, Current Procedural Terminology (CPT®) Process • Physicians with experience in CMS Value-Based Care (VBC) Payment Demonstrations • Dozens of specialists at top provider groups and health systems including: Rothman Orthopaedic Institute, Mass General Brigham, Hospital for Special Surgery, UCSF, Rush University Medical Center, Weill Cornell, Kaiser Permanente Our licensed clinical teams develop evidence-based care guidelines aligned with national society standards and the latest clinical literature, among the

	most robust and comprehensive in the industry. These guidelines, reflected in our Medical Policies and CarePaths, are objective and promote appropriate surgical and implant utilization based on nationally recognized sources. We maintain a formal support structure that includes performance monitoring, reporting, and ongoing program optimization. Clinical guidelines are continuously reviewed and updated as needed to ensure alignment with best practices and national standards, in line with LCDs and NCDs. This process is overseen by a panel of American Board-Certified Physicians and includes, 1) use of nationally accepted evidence frameworks (e.g., CMS, NIH, Cochrane Collaborative), 2) annual literature reviews conducted by subspecialty-trained analysts, clinicians, and scientists, and 3) regular collaboration with clients to align guideline development with their quality, safety, affordability, and health equity priorities. While TurningPoint has developed proprietary medical policies that are adopted by our Medicare Advantage partners, we default to and fully adhere to NCDs and LCDs where applicable. Staff are trained in each component of the utilization management and review process upon orientation and throughout their career process with the company, with quarterly uptraining for clinical staff. Licensed health professionals are educated through the entire process of initial clinical review and for availability to non-clinical staff. Authorization requests that are not automatically approved by the company's clinical guideline algorithms are pended for clinical review by a specialty matched physician. Physicians are educated for availability for peer-to-peer consultation and final determinations. Based upon education, training and experience, health professionals are screened for appropriateness in performing clinical tasks. Reviewers are required to undergo training in all aspects of the review process. TurningPoint primary source verifies and monitors licensure and credentials to ensure the quality and integrity of its' Utilization Management Department. The company performs the following: - Verifies the current licensure and credentials of licensed or certified personnel, consultants or advisors upon hire or entering into an agreement, and thereafter not less than every 3 years. If appropriate based on state, an annual resubmission of current licensure may be required. - Implements corrective action in response to adverse changes in licensure or certification status. For clinical professionals conducting determinations, the same credentialing elements shall be verified, and procedures followed as for the clinical network, including but not limited to education, training, experience, professional licenses and certifications. The process for making clinical determinations begins with the Medical Director reviewing medical records and other information submitted by a requesting provider and making a prior authorization determination based on health plan coverage policies and the established clinical criteria specific to the service requested. Medicare determinations utilize the following established clinical criteria in making a medical necessity determination: a. NCDs, if available; or b. Member's State/region LCDs; or c. If there are no applicable NCDs or LCDs, the Medical Director shall apply TurningPoint proprietary clinical criteria adopted by the health plan. If our clinical review team is unable to approve based on medical record and other information submitted, TurningPoint will reach out to the provider to request additional case information. If unable to approve based on any or all portions of the above criteria, the provider or Provider's office may be notified of the opportunity for a direct discussion of the case with the Medical Director in order to gain additional relevant information prior to issuing an adverse determination. During TurningPoint's internal review process, if a TurningPoint Medical Director is unable to make a determination on a prior authorization request due to lack of information provided, the Medical Director will call the referring physician and engage in a collegial, peer-to-peer discussion of the best care/service for the patient given the clinical information provided. These discussions occur pre-denial for the Medicare line of business. All peer-to-peer conversations are conducted within the same sub-specialty (e.g., Cervical Spine surgeon with TurningPoint Cervical Spine surgeon), which is a TurningPoint policy, to ensure the conversations are as productive and collaborative as possible. For Medicare Managed Care, TurningPoint does not offer peer-to-peer conversations post-denial, however, will allow for the referring physician to discuss the denial with a TurningPoint Medical Director for educational purposes only. This discussion will not change the outcome of the decision. If the coding is incorrect, the provider may submit a new prior authorization request with the correct coding. TurningPoint offers extensive Medicare appeals support to its clients, as described in previous responses. For appeals reviews or support, TurningPoint will assign a second, different, sub-specialized MD clinical reviewer to review the case. We also have extensive experience supporting our health plan partners in the Independent Review Entity (IRE) process. TurningPoint's clinical team will assemble evidence to support the health plan in its presentation. TurningPoint has a near perfect record in support of decisions at the IRE. Because our clinical teams both conduct utilization reviews and lead subspecialty-matched peer-to-peer discussions, they foster meaningful clinical collaboration and significantly reduce provider abrasion, an approach that truly sets TurningPoint apart in the market. TurningPoint conducts an annual provider satisfaction survey on behalf of Horizon Blue Cross Blue Shield of New Jersey. In the most recent 2024 survey, TurningPoint earned an 84% satisfaction rating, driven by its strong focus on clinical collaboration and provider engagement.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations.	TurningPoint has a diversity of experience that includes integrating with legacy mainframe systems, a broad range of propriety EHR technologies, as well as modernized APIs to both achieve successful integration and support compliance with the CMS Final Rule. Our implementation approach is collaborative, as we seek to support the easiest connectivity approach for our clients. EHR Integration: TurningPoint has vast experience and expertise in technology integration with provider system integrations, having connected to over 100,000

a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	providers. Our experience allows TurningPoint to maintain flexibility to support evolving requirements, emerging technologies, and changing data standards. TurningPoint has industry-leading expertise in EHR integration; our EHR integration technology has demonstrable proof points published with leading health systems showing accelerated time to approval by 60%, reduced unnecessary re-reviews by 84%, and improved provider satisfaction by 3x compared to our peers. We believe it is critical to provide the benefits of a one-click solution to all providers, including rural clinics that may lack the resources for EHR integration. To meet this need, TurningPoint offers our 'Catalyst' AI-enabled platform, a web-based solution that delivers industry-leading automation and provider decision support. Catalyst is currently live and available to all providers. The TurningPoint Catalyst AI platform is triggered upon receipt of clinical documentation, including direct exports from EHR systems. Once initiated, it: 1) Automatically builds the case (Catalyst Case Build), 2) Identifies and extracts the relevant documentation (Catalyst SmartScan), and 3) Runs the case against applicable policy (Catalyst Guided Review). In the event of a potential non-affirmation, Catalyst routes the case for review by one of our specialty-matched physicians, keeping the provider in the loop. These innovations—and their demonstrated results—will be discussed in more detail in the following responses. Our policy of crafting solutions that work best for each provider extends to our EHR integration strategy. These capabilities span new technologies in this domain, including REST, and FHIR APIs, and OpenID Connect Core 1.0 token-based authentication, to legacy EHR connectivity platforms like SQL connections with password-based authentication. TurningPoint's connectivity is offered both in the cloud or on-prem, depending on provider preference, and is currently implemented in small and major health systems nationwide, including Montefiore Health, Northwell Health and Northwestern Medicine. For interested providers/networks, TurningPoint's technology platform integrates with a multitude of hospital EHRs, including Epic, Oracle/Cerner, and AthenaHealth, and specialty-specific EHRs including ARIA (Siemens: https://www.myvarian.com/varianMarketPlace) and Mosaiq (Elekta: https://www.elekta.com/products/oncology-informatics/elekta-one/real-world-outcomes/oncology More specifically, our Epic "TurningPoint" app utilizes the HL7 Fast Healthcare Interoperability Resources (FHIR) (Release 4.0.1) standard to communicate via Epic's Backend Systems to retrieve clinical documentation APIs retrieve clinical data which encompasses the United States Core Data for Interoperability (USCDI) standard, and includes support for items needed to determine appropriateness of care including clinical / encounter notes, lab results, imaging reports, medication reports, etc. Our Oracle/Cerner "TP Prior Auth EHR Connect" app utilizes the Oracle Health FHIR APIs for Millenium to retrieve requisite clinical documentation including Patient Condition, Encounter notes, etc. Our AthenaHealth "TurningPoint Healthcare Catalyst" app utilizes RESTful FHIR APIs through its Certified API program that meets the 21st Century Cures Act requirements. TurningPoint has also partnered with leading healthcare exchanges including Availity and Change to automate eligibility, enable Single Sign-on (SSO) capabilities, and enable outbound authorization determinations, as these partners are often requested by our clients to be intermediaries. Through these partners, TurningPoint can offer seamless interfacing with the participating MACs, but it will be important to have a discussion with their preferred method of connectivity, as we will offer similar flexibility that we do in the market, with the goal of minimizing the burden of implementation. CMS Interoperability and Prior Authorization Final Rule: Turning Point has over ten years of experience in healthcare interoperability and prior authorization processes, and we are uniquely positioned to support the Centers for Medicare & Medicaid Services (CMS) in achieving the objectives of the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F). We have a proven track record of delivering scalable, standards-based solutions that enhance health information exchange, streamline prior authorization workflows, and prioritize patient-centered care. Turning Point is actively engaged with our clients to address each aspect of the CMS Interoperability and Prior Authorization Final Rule, including a comprehensive approach to implementing APIs for Coverage Requirements Discovery (CRD), Documentation Templates and Rules (DTR), and Prior Authorization Support (PAS), while leveraging our extensive history of supporting alternative prior authorization methods, including mail, fax, phone, web portals, and electronic batch submissions to ensure we can service patients, providers, and payers via any channel. This will ensure seamless integration with payer and provider systems, adherence to compliance deadlines (January 1, 2026, for operational provisions and January 1, 2027, for API enhancements), and robust support for patient and provider education as mandated by the rule. Our efforts are aligned with the goal of reducing overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices. We are prepared to collaborate closely to ensure seamless integration, regulatory alignment, and meaningful improvements to prior authorization and data exchange processes.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the	TurningPoint has developed and deployed a proprietary clinically validated AI platform, 'Catalyst', to support and expediate large-scale medical necessity determinations in alignment with CMS policies (including LCDs/NCDs) and payer-specific coverage guidelines. Catalyst has been used across more than 116,000 utilization review cases involving high-complexity procedures in clinical categories such as orthopedics, spine, sleep medicine, and interventional pain management. The platform is built to support end-to-end clinical decision workflows powered by structured data analysis, advanced natural language processing, and human expert supervision. The building of the Catalyst platform can be summarized in 4 key steps: 1. Extraction of complex and diverse clinical datasets: Catalyst

selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers.

a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met.

b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.

is trained on both structured and unstructured data sources. Structured inputs include historical prior authorization decisions, claims records, eligibility files, and appeals outcomes. Unstructured inputs consist of provider-submitted documentation such as clinical notes, operative reports, imaging narratives, consult summaries, and laboratory results. Catalyst uses proprietary clinical abstraction tools specifically designed for any type of unstructured data format. These tools enable extraction and normalization of clinical data from PDFs, scanned and handwritten documents, faxes, and EHR-generated files, regardless of the source system or submission method. 2. Building of a thorough, structured, policy aligned data foundation: However, extraction alone is insufficient. TurningPoint has invested significantly in building a structured, policy-aligned data foundation through high-fidelity clinical labeling. Our subject matter experts, who are practicing physicians and nurses with specialty training in each relevant domain, play a critical role in transforming raw case data into analytically robust datasets that are applicable for TurningPoint specific policies and LCD/NCDs. These experts manually annotate clinical signals, clarify documentation context, and validate clinical relationships that automated systems alone cannot reliably infer. This labeled data is continuously fed into Catalyst's learning systems and serves as the ground truth for model training, evaluation, and refinement. The result is not only higher model accuracy, but also deeper interpretability and consistency in clinical decision support across specialties. 3. Training of various machine learning models for specific clinical subtasks: For specific subtasks within the coverage determination process, Catalyst includes specialized models that perform focused clinical functions such as identifying missing documentation, interpreting radiology report narratives, and constructing structured patient care timelines. Each model is designed to reflect the clinical logic of specific coverage criteria and is trained on the datasets listed above along with input from physicians and nurses who specialize in the relevant clinical areas. Model development incorporates standard supervised learning techniques, clinical feature engineering, and performance validation using cohort-specific datasets. 4. Application of generative AI for policy and clinician aligned reasoning for determinations: Catalyst then integrates state-of-the-art generative AI models that are specifically configured to replicate the reasoning of clinical specialists by using the robust data foundation and outputs of the specialized sub-task focused machine learning models. These models are designed to interpret the sufficiency of documentation against CMS or payer policies, highlight clinical evidence relevant to coverage rules, and generate rationales that mirror the way trained clinicians evaluate case materials. Generative models are deployed in controlled environments with prompt structures grounded in specific coverage frameworks, allowing for both transparency and reproducibility. TurningPoint's clinical specialists review, test, and refine model performance. These interactions are used to continuously improve model accuracy and ensure that each version aligns with evolving standards of care and policy requirements. TurningPoint will deploy several AI, "Catalyst" models throughout the authorization process to advance WISeR goals—driving appropriate utilization, better outcomes, and lower costs through seamless, tech-enabled decision support. Catalyst Guided Medical Necessity Review: The Catalyst Guided Review module streamlines medical necessity reviews by integrating with our case management systems and medical policy engines. Using AI, it summarizes evidence from authorization submissions and maps it to policy criteria, highlighting key information for clinician reviewers. This approach enhances efficiency, consistency, and accuracy while maintaining clinical oversight. In testing, Catalyst Guided Review reduced overturned reconsiderations by 42% and cut manual review time by 59%—delivering faster, higher-quality outcomes for patients and providers. Catalyst SmartScan: TurningPoint's Catalyst SmartScan module, embedded in the provider portal, simplifies the authorization process by using AI/ML to scan submitted clinical documents in real time and identify any missing information required for medical necessity review. Providers receive immediate, guided feedback and can upload missing documentation on the spot—reducing back-and-forth and delays. This tool has improved complete submissions by 55%, significantly speeding up the authorization process. Catalyst Case Build: The Catalyst Case Build module streamlines the intake process for providers. Functioning both with and without EHR integration, Case Build automatically extracts case details, such as patient information, surgical plans, and best practices from the PDF submission to reduce the administrative burden of case creation. For the provider, this module greatly simplifies the intake process and reduces it down to a single confirmation step. We believe Catalyst Case Build will be an important accelerator when authorizations are received from the MACs. TurningPoint has established a three-layered safety and governance framework to proactively verify, validate, secure and regulate our technology to ensure ethical and high-quality utilization management metrics are met. These controls are embedded into every phase of the Catalyst platform's development, deployment, and post-production oversight. The first layer of safeguards is integrated directly into the AI development process. Our development team includes practicing clinicians who conduct continuous internal audits of model performance using advanced data analytics. These tools are specifically configured to detect patterns where AI predictions may be less reliable, allowing us to isolate and address emerging risk conditions. Catalyst is explicitly designed so that AI can only expedite prior authorization cases for approvals, and only under narrowly defined scenarios that have undergone extensive clinical auditing and validation. In cases where AI confidence is not at the highest threshold or where policy complexity is elevated, the case is automatically routed to a licensed clinician for full review. Importantly, Catalyst does not and will not use AI to issue denials or non-affirmations. Additionally, based on our experience operationalizing generative AI in healthcare settings, we have developed a set of

	safeguards to prevent hallucinations. This includes suppressing known prompt conditions that induce hallucination risk, using policy-grounded prompt construction, and applying pre-output validation to filter unverified responses. The second layer of oversight is enforced through our clinician review operations. All cases not expedited for approval are assessed by domain-specific physician and nurse reviewers. We actively track agreement rates between AI-generated recommendations and final human determinations. These comparisons are used not only as a quality checkpoint, but as a continuous learning mechanism to recalibrate model logic and flag potential blind spots, ensuring that suboptimal model outputs do not influence production decision quality. The third layer is maintained by our Quality and Clinical Excellence team, which conducts formal audits of AI-supported decisions on a biweekly basis. These audits are structured, domain-specific, and independently managed to provide objective assessment of accuracy, completeness, and policy alignment. Findings from this team are incorporated into Catalyst's model improvement roadmap and used to inform retraining cycles and model version control. TurningPoint has a strict policy to manage risks of utilizing AI which is governed by our AI Governance Committee. We have thoughtfully constructed operational and technical guardrails, including logic and process controls, to ensure that algorithms deliver high quality output to support UM. Operational process controls are in place at the earliest stages of AI development to ensure (1) a randomly selected, comprehensive, and balanced dataset is used for model training; (2) there are no model features that could potentially introduce improper bias (human or otherwise); and (3) real-world performance is monitored to detect any potential issues. AI model architectures are specifically designed for medical review workflows, including the design of how clinical documents are ingested, chunked, embedded, and queried to ensure the outputs are safe, compliant, and accurate.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	Yes

Accreditations or Certifications Document

File Name	WISeR-00014_Accreditations_NCQA Accreditation Certificate (2023 - 2026)
Uploaded On	7/24/2025, 12:46 PM

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	TurningPoint's commitment to ethics, compliance, and quality is embedded throughout the organization—reflected in the conduct of our CEO, executive leadership, and senior management. These values are core to our culture. As a Delegated Entity, our workforce recognizes the critical role we play in supporting compliance and quality for our health plan clients and the individuals they serve. We also remain deeply committed to safeguarding taxpayer-funded healthcare by helping to prevent fraud, waste, and abuse. Our company maintains a robust Compliance Program reflected in its mission statement: "To ensure the highest standards of compliance and integrity in utilization review processes, safeguarding patient care and promoting ethical practices through rigorous oversight, continuous education, and collaborative engagement with healthcare providers." TurningPoint's Regulatory, Legal, and Compliance team is led by our Chief Compliance Officer, who brings over 30 years of healthcare law and regulatory experience. The team focuses on ensuring compliance with all relevant laws, particularly those affecting our health plan clients and their members. They regularly collaborate with client compliance teams, meeting at least monthly to maintain alignment and address regulatory matters. TurningPoint is accredited as a Utilization Management organization by the National Committee for Quality Assurance, a not-for-profit organization committed to assessing, reporting, and improving the quality of care provided by organized delivery systems. Accredited organizations must demonstrate compliance in the following key reporting categories: access and service; qualified providers; experience with UM to earn NCQA's seal of approval. TurningPoint has received full accreditation in Utilization Management on the 2022 NCQA standards through March 2026. The Compliance and Regulatory Affairs team ensures continuous survey readiness and is responsible for implementing compliance with new and updated standards and required elements. TurningPoint provides a 24/7 toll-free number and an online form for reporting compliance or ethical concerns anonymously. All submissions are routed directly to Regulatory Affairs for review and follow-up. TurningPoint's Quality program uses data-driven

management, layered audits, and provider incentives to ensure high performance. We identify quality of care and service issues within our Utilization Management program through the following activities: 1. Key indicators of care and service based on reliable data from claims, authorizations, calls, and internal tracking mechanisms 2. Utilization data (under/over-utilization) and performance indicator reports 3. Trends in grievances and appeals 4. Provider satisfaction surveys 5. Access and availability reports 6. Utilization review activities TurningPoint performs robust auditing to ensure quality services, including call auditing, case accuracy, notification accuracy and timeliness, and call center performance. Inter-rater reliability testing is conducted quarterly with all UM staff to ensure consistent guideline application. Inconsistencies prompt guideline review. Guidelines are reviewed annually or as needed to maintain care quality. Technically, TurningPoint leverages advanced analytics and auditing across clinical review systems to detect errors and user-driven security events. We maintain a scalable analytics platform (Azure Databricks) to enable both model-driven and ad-hoc analysis of user interactions. This equips our Quality Audit team to address issues or corrective actions throughout the Prior Authorization process. All security objects are ingested into our centralized logging platform (Azure Log Analytics) to power our Security Information and Event Management solution (Azure Sentinel), which uses reinforcement learning to adapt AI models and enable real-time detection and intervention for policy violations. As a quality-driven organization, TurningPoint requires transparency and reporting to drive continuous improvement. We generate applicable regulatory reporting monthly or quarterly, including ODAG reports, Part C, NCQA audits, and additional compliance reporting across populations. TurningPoint also offers an optional Quality Award Program that provides value-based incentives to providers who deliver care exceeding medical necessity. In partnership with health plans, we define metrics and use scorecards to benchmark performance. Tracked measures may include revision rates, ER admissions, SNF usage, surgical setting, and implant logs. Managing UM Decision Making, Complaints & Grievances, Claims Billing, and Claims Dispute Issues: All complaints are documented, assessed for delegation to be sent to client, and routed to Regulatory Affairs for handling. Members are notified upon receipt and resolution of complaints and quality-of-care issues are shared with the provider or client within required timeframes. If additional review processes are available to the member, these are communicated verbally and in writing, in accordance with contractual agreements. Complaints are investigated and resolved according to timeframes defined by federal or state regulations, accreditation standards, or client contracts—using the most stringent standard when multiple apply. Complaints related to discrimination follow the applicable federal or state resolution process. Medicare complaints that are grievances are resolved as expeditiously as the health plan member's case requires, based on the health plan member's health status, but no later than 30 days after the date TurningPoint receives the grievance. We can categorize and prioritize complaints and grievances using the same framework CMS uses in its Complaint Tracking Module and ensure we respond to each case within the required deadlines. Medicare complaints concerning the quality of medical care received under Medicare are acted upon by the Medicare health plan client but also may be addressed through the complaint process under §1154(a)(14) of the Social Security Act. TurningPoint supports health plan clients by promptly providing required documentation to meet regulatory timelines. Complaints concerning Medicare organization determinations are considered appeals by Medicare definition. When appeals are delegated, TurningPoint follows CMS standards and applies its internal appeals procedures to organization determinations. If not delegated, TurningPoint supplies necessary records. Provider-related complaints are reviewed by the Chief Clinical Officer and Regulatory Affairs, with other departments engaged as needed. Quality-related complaints are referred to the client for re-credentialing consideration. Complaints from treating or referring physicians are addressed by Provider Relations, with escalation to Clinical and Regulatory leadership as appropriate. Inquiries from state regulatory agencies are managed by Regulatory Affairs in coordination with health plan compliance staff. All complaints are tracked and trended by type, client, and resolution timeliness, with findings reported to quality committees. Recommendations for corrective actions are shared with the relevant department managers for implementation. At least annually, TurningPoint compiles and shares complaint summaries with clients, including trends, actions taken, and data to support delegation audits and regulatory reporting. TurningPoint is not delegated for claims determinations or billing. However, core to our solution for Medicare Advantage clients is a pre-pay claims review based in the intent to ensure the claim matches the surgical plan of careand authorized medical necessity. All process, research and new payment policiesare developedto uphold the medical necessity decisions through claim processing and payment. This service includes detailed auth-to-claim matching, institutional to professional claim matching, claims bundling, application of any medically unlikely edits, in-depth reviews of all implants/biologics utilized to ensure claims are not paid inaccurately or inappropriately, resulting in incremental cost savings. This validation and subsequent payment recommendations is supplemental to, but does not replace, any outsourced claims integrity vendor that may already be in place. TurningPoint's team responsible for claims review are AHIMA certified, AAPC Certified, Certified Rev Cycle (CRCs), and Registered Nurses. Compliance with State & Federal Regulations: TurningPoint ensures ongoing compliance with state and federal regulations by subscribing to CMS listservs, RegWatch, and relevant state regulatory updates. We also rely on clients to share Medicaid Managed Care contract changes and insights from government audits that may not be publicly available. Internally, we follow a formal change control process to update policies, procedures, and workflows as

	required. Changes are summarized, operational impacts are identified, and documentation is distributed internally. Clients receive change control documents for review and approval prior to implementation. When a client uses its own process, we adhere to that protocol and provide attestations confirming alignment with updated requirements, as needed. TurningPoint is delegated by clients to perform UM services across Medicaid and Medicare populations. With 8+ years of experience, we have deep expertise in CMS audits, reporting, and regulatory compliance. We consistently adhere to NCD and LCD hierarchy requirements and regularly monitor CMS policy and legislative updates to ensure compliance. We are fully HIPAA compliant and meets all applicable nondiscrimination requirements, including Section 504 of the Rehabilitation Act of 1973 and Section 1557 of the Affordable Care Act. We also comply with CMS Final Rules, including Interoperability (CMS-0057-F), and maintain NCQA accreditation.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	TurningPoint incremental estimated savings: - JL/Novitas (NJ): o ~860,000 members o Applicable WISeR Spend Estimate: $76.3M o Applicable WISeR PMPM Estimate: $7.42 o Incremental TurningPoint Savings: $8.7M - $10.9M - J15/CGS (OH): o ~960,000 members o Applicable WISeR Spend Estimate: $85.7M o Applicable WISeR PMPM Estimate: $7.42 o Incremental TurningPoint Savings: $9.8M - $12.3M - JH/Novitas (OK & TX): o ~2,230,000 members o Applicable WISeR Spend Estimate: $198.7M o Applicable WISeR PMPM Estimate: $7.42 o Incremental TurningPoint Savings: $22.7M - $28.4M - JF/Noridian (AZ & WA): o ~1,300,000 members o Applicable WISeR Spend Estimate: $115.7M o Applicable WISeR PMPM Estimate: $7.42 o Incremental TurningPoint Savings: $13.2M - $16.5M Methodology: TurningPoint conducted a detailed policy-to-code crosswalk using the NCDs and LCDs referenced in the RFA to build a foundation for estimating total applicable spend relevant to the procedures in scope in the WISeR Model. Leveraging this crosswalk, we applied the resulting code set to our comprehensive national claims dataset to quantify utilization, derive per-member-per-month (PMPM) values, and calculate spend by clinical category. To estimate savings, we then applied benchmark impact rates (11% - 14%), derived from our robust historical program performance data and market-wide insights to each clinical category identified in the RFA. This analysis yielded a range of incremental savings projections, which we have summarized as high- and low-end estimates. For full transparency and validation, we submitted a supporting exhibit to the CMS WISeR Model Support Help Desk (WISeR@cms.hhs.gov) inbox. This exhibit includes detailed breakdowns of estimated utilization rates, PMPMs, spend, and incremental savings across each clinical category and MAC region. Policy-to-code crosswalk: - Stimulator Services: Electrical Nerve Stimulators (NCD 160.7), Sacral Nerve Stimulation for Urinary Incontinence (NCD 230.18), Phrenic Nerve Stimulator (NCD 160.19), Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (NCD 160.24), Vagus Nerve Stimulation (NCD 160.18) - Associated Claim Coding: o CPTs/HCPCs: 46505, 52287, 61880, 61885, 61886, 61888, 63655, 63661, 63662, 63663, 63664, 63685, 63688, 64553, 64568, 64569, 64570, 64611, 64612, 64615, 64616, 64617, 64642, 64643, 64644, 64645, 64646, 64647, 64650, 64653, 67345, 95873, 95874, 95970, 95971, 95972, L8680, 64651, 64581, 95961, 95962, 95970, 95971, 95983, 95984, o ICD PCS: 00H00MZ, 00H03MZ, 00H04MZ, 00H60MZ, 00H63MZ, 00H64MZ, 00P00MZ, 00P03MZ, 00P04MZ, 00P60MZ, 00P63MZ, 00P64MZ, 0H80XZZ, 0HSSXZZ - Induced Lesions of Nerve Tracts (NCD 160.1) - Associated Claim Coding: o CPTs/HCPCs: 64600, 64605, 64610, 64620, 64630, 64632, 64633, 64633,64640, 64680, 0440T, 0441T, 0442T - Epidural Steroid Injections for Pain Management (L39015, L39242, L36920) - Associated Claim Coding: o CPTs/HCPCs: 62320, 62321, 62322,62323, 64479, 64480, 64483, 64484 - Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF) (L34106, L38201, L35130) - Associated Claim Coding: o CPTs/HCPCs: 22510, 22511, 22512, 22513, 22514, 22515 - Cervical Fusion (L39741, L39762, L39793) - Excluding codes already included in OPD - Associated Claim Coding: o CPTs/HCPCs: 22548, 22554, 22590, 22595, 22600, 22800, 22802, 22808, 22810, 22812 - Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee (NCD 150.9) - Associated Claim Coding: o CPTs/HCPCs: 29877, G0289, 29999 - Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea (L38307, L38312, L38385) - Associated Claim Coding: o CPTs/HCPCs: 61886, 61888, 64568, 64569, 64570, 64582, 64583, 64584 - Incontinence Control Devices (NCD 230.10) - Associated Claim Coding: o CPTs/HCPCs: 51715, 52327, 53445, L8603, L8606, Q3031 - Diagnosis and Treatment of Impotence (NCD 230.4) - Associated Claim Coding: o CPTs/HCPCs: 64651, 64581 - Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (NCD 150.13) - Associated Claim Coding: o CPTs/HCPCs: 0275T - Skin and Tissue Substitutes - Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041), Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (L36690) o Associated Claims Coding: CPTs/HCPCs: 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, C5271, C5272, C5273, C5274, C5275, C5276, C5277, C5278
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Implementation philosophy: TurningPoint's approach to implementation of the requested Utilization Management technology and services for CMS in any of the MAC jurisdictions is flexible and collaborative, intended to meet the needs of CMS and the WISeR program. TurningPoint has extensive experience implementing our program(s) for health plans, and our highly configurable IT systems and workflows enable us to integrate seamlessly with data exchange partners at any level of technical readiness. Our approach is highly adaptable, allowing us to quickly respond to evolving requirements. TurningPoint has the ability to implement our program in as little as 90 days. In the early stages of the

implementation, TurningPoint will work with CMS to finalize business requirements, program LCD and NCD scope and policy review, and implementation plan. We have deep expertise in the utilization of LCDs and NCDs, with all relevant policies already mapped to the specialty programs we operate across all MAC regions. This infrastructure is already in place and does not require new development. For any additional specialties we take on, we would simply extend our existing mapping and configure the system accordingly, no need to build from scratch. Leveraging our flexible approach, TurningPoint would then align, configure, and test all data feeds necessary for program development. TurningPoint currently receives and transmits sensitive, healthcare-specific data in a fully CMS compliant manner. All data exchanges are conducted via secure channels—such as SFTP, APIs, etc.—that adhere to HIPAA / HITECH standards. We can accommodate all industry standard formats as well as proprietary file layouts. The TurningPoint data implementation approach is designed to be highly flexible as it has been our experience that each health plan has configured their systems differently. This allows us to integrate seamlessly with MACs regardless of their current level of technical readiness. Our systems support both advanced EDI connections and simpler workflows, and we are committed to adapting to the MAC's preferred methods of data exchange and operational integration. As part of our standard process, TurningPoint will work with the selected MACs to determine the least burdensome method of integration for this program. If the MACs wish to transmit healthcare data through exchanges, e.g., Availity, TurningPoint we could offer seamless, real-time connectivity from day 1. In this case, the interfacing workflow would begin when an authorization is finalized, which would automatically trigger a real time endpoint call to package the information and transmit it to, e.g., Availity, which would forward it to the MAC and return a message. This is an option that's already available. Alternatively, we have extensive experience with other technologies that our clients have preferred, including: • Batch enrollment files (834, or custom file formats) • Real time eligibility (270/271, or custom APIs) • Batch transactions (provider data) • Real time Auth transaction (278, or custom APIs) • Batch Auth transactions (278, or custom file format) • Batch claims/encounter data (837, or custom file format) • All of these transactions through Availity (mostly real time) • Past experience with Navinet • SSO for providers through payer portals TurningPoint is already registered with each of the participating MACs. We anticipate these conversations will occur in advance during the implementation to ensure connectivity is established by the 1/1/2026 model start date, in coordination with the MACs. Implementation Plan: As part of implementation and prior to the launch of the utilization management program the TurningPoint Provider Relations team meets one-on-one with each practice to deliver a detailed program overview, clarify clinical documentation and medical policy criteria, and ensure alignment on expectations. We can use our own proprietary provider education materials or collaborate with CMS and the MACs to co-develop—or leverage pre-existing—training content. Our established provider relationships, including within the New Jersey market and nationwide, help minimize provider abrasion and support smoother adoption, as many practices are already familiar with the TurningPoint systems and clinical review processes. TurningPoint configures our provider portal to enable direct submission of prior authorization requests. Providers already using our portal can maintain their existing access without the need for re-registration. For those who prefer to submit authorizations directly to the MAC, we can support inbound data in the preferred format from the MAC, such as EDI transmission in either batch or real-time transactional format. In addition to all our traditional intake capabilities (mail, phone, fax, batch, EDI) we will interface with the esMD system, as well as support PCG-FHIR by 1/1/2026. We will align with whichever method is most operationally and technologically efficient for the MAC. TurningPoint has experience with receipt of re-directed authorization data. For several states in which TurningPoint administers a utilization management program for a Health Plan's Medicaid population, the state regulatory body requires the submission of prior authorization requests exclusively via state specific Medicaid Management Information System, like that of a MAC. These requests, like those submitted directly to MACs, are transmitted automatically to TurningPoint for medical necessity review. Upon receipt, authorization data is automatically ingested, and case records are generated in the TurningPoint internal system. Status updates and determinations are returned to the MAC via preferred transmission methods, such as outbound EDI transactions. In all scenarios, providers retain the ability to check case status and view decision details via our portal. Providers who do not submit a prior authorization are subject to post-service, pre-payment medical necessity review, in accordance with the WISeR program guidelines. We have extensive experience with this model and currently support it for a Horizon BCBS of New Jersey, giving us strong familiarity with its implementation and operational requirements. To facilitate this process and corresponding data exchange, TurningPoint will work with the MAC to establish claim to authorization matching logic. When a claim is received without a corresponding authorization, the MAC will route the pre-payment claim to TurningPoint. Our team will conduct a medical necessity review, requesting supporting documentation directly from the billing provider, as needed. Once the review is complete, we will return a response file to the MAC with claims adjudication instructions. Our claims platform supports receipt of pre-payment (pending) claims via daily files in a variety of formats (as listed above). These files are uploaded into our internal claims tool for processing. Medical necessity review outcomes can be returned with standard CARC/RARC codes or any other format required by CMS. A daily outbound response file is sent back to the MAC, and we will collaborate to define appropriate claim hold durations while awaiting medical records. For authorization or claim decisions requiring clinical documentation, we can provide the MAC with all associated

	records via standard 275 transactions or proprietary file feeds. This includes all submitted medical records, outbound communication logs, and any decision letters, which can be returned as attachments and integrated into MAC systems. Providers can also download determination letters and access relevant policies through our portal, with policy links directly to CMS-hosted LCDs and NCDs. TurningPoint also has flexibility with our letter configuration process, and can generate, print, and mail letters or generate and secure FTP them to the MAC for printing and mailing. The letter template will be approved as part of the implementation process in compliance with any state regulations. TurningPoint already has generic CMS compliant versions for adverse benefit notifications in both English and Spanish, at a minimum. Post program go-live on 1/1/2026, TurningPoint will continue provider support and ongoing trend monitoring and reporting. Timeline: A comprehensive implementation guide will be shared upon implementation kick-off. In summary, below is a high-level timeline of key implementation activities: - T-90 days: Providers are notified of the program and TurningPoint Provider Relations team begin provider market outreach and education; configuration of TurningPoint portal instance is completed - T-90 days: Technical requirements session between TurningPoint, CMS, and the MAC to map out all specs for data transmission across various touchpoints with MACs - T-75 days: Technical development by TurningPoint to enact all data transmission - T-60 days: UM operational workflows; develop the operational lifecycle and touchpoints for a Provider's Service Request from intake to final determination - T-60 days: End-to-end operational, system, and process testing inclusive of authorization file transmission, response files, pended claims, claim response files, member eligibility, etc. - T-60 days: Ensure that all federal and state regulatory requirements are identified and validated within the program components and processes; identify any required reporting and analytics needed to meet the CMS's regulatory compliance criteria - T-30 days: TurningPoint program 'soft-launch' to ensure program is functioning properly ahead of go live, as well as give providers the option to submit authorizations for surgeries with dates of service beyond 1/1/2026 - T-0 days (1/1/2026): Program go-live

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	TurningPoint Healthcare Solutions, LLC
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00019

Requested by (b)(6) on 07/28/2025 12:30

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Carecierge, Inc.
b. Doing Business As (DBA) Name(s)	Carecierge
c. Street Address	190 72nd street
d. City	Brooklyn
e. State	NY
f. Zip Code	11209
g. Tax Identification Number	993935554
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Carecierge is a health technology company committed to advancing high-quality, evidence-based care for Medicare beneficiaries through intelligent automation and clinician-guided decision support. Our mission is to improve patient outcomes, reduce administrative burden, and eliminate wasteful healthcare spending by aligning people, processes, and technology around the most appropriate care pathways. Carecierge's platform leverages AI-driven workflows, integrated clinical assessment tools, and human oversight to streamline complex healthcare processes such as care coordination, documentation management, and prior authorization. Originally built to support compliance-intensive programs like CMS's GUIDE Model, our infrastructure is designed to scale across Medicare initiatives requiring data security, outcome measurement, and clinical accuracy. We serve a broad range of clients, including Medicare-enrolled provider organizations, state-contracted vendors, and care navigation teams, with a special focus on populations with chronic or complex needs. Our core values—equity, precision, transparency, and trust—guide our approach to building ethical technology that supports both regulatory accountability and patient-centered care.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas
5. Provide street address, city and state for all locations.	

Location Name	Headquarters
Street Address	190 72nd street
City	Brooklyn
State	New York

Zip Code	11209

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00019_Ownership_Complete_with_Docusign_c9bccdf9-f070-4cc3-aa
Uploaded On	6/30/2025, 7:25 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	190 72nd street, Brooklyn, NY 11209
Business Phone Number	347-542-1409

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	190 72nd street, Brooklyn, NY 11209
Business Phone Number	347-542-1409

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00019_Licensure_Articles Filed (2)
Uploaded On	6/30/2025, 7:30 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.	
N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	HIPAA Business Associate Agreements Carecierge, Inc. currently maintains active Business Associate Agreements (BAAs) with several HIPAA-covered entities, primarily to support clinical documentation, care coordination, and compliance with the CMS GUIDE Model. These agreements allow us to process protected health information (PHI) on their behalf, adhering strictly to CMS-approved use cases and complying with the HIPAA Privacy Rule (45 C.F.R. § 164.504(e)). Vesper Medical (Texas): A multi-specialty group practice delivering GUIDE-aligned dementia care, using our platform for intake, care planning, and compliance workflows. Five Star Home Health Care (Virginia): A Medicare-certified home health provider leveraging our services to facilitate GUIDE-compliant care across multiple counties. Shellpoint Retirement Community (Florida): A residential care community providing dementia support, with us managing assessments, care plans, and patient tracking for GUIDE enrollees. YA Partners (Nevada): A geriatric primary care group in Las Vegas utilizing our GUIDE platform for dementia assessment and care plan management. Medicine in Motion / HOMAHA (Nebraska): An integrated primary care and wellness group in Nebraska collaborating with us to implement GUIDE requirements. MemoryCare (North Carolina): A nonprofit dementia clinic using our services to streamline CMS-required assessments and care coordination tasks.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Carecierge, Inc. has not yet performed prior authorization services directly for Medicare Advantage (MA) plans or commercial payers. However, our platform is fully capable of supporting this function and is already aligned with the operational, clinical, and compliance standards required for payer-based utilization management. We currently serve a national network of healthcare providers participating in the CMS GUIDE Model, including: Vesper Medical (Texas) Five Star Home Health Care (Virginia) Shellpoint Retirement Community (Florida) YA Partners (Nevada) Medicine in Motion / HOMAHA (Nebraska) MemoryCare (North Carolina) For these clients, Carecierge manages HIPAA-compliant intake workflows, clinical documentation, care planning, and CMS-aligned compliance tracking—functions that closely parallel the data and process rigor needed for prior authorization. Our platform is being extended to support payer-facing workflows, including automated medical necessity review, clinician-based decision support, and integration with MACs and CMS guidelines. We are prepared to begin executing prior authorization functions immediately and are targeting Medicare Advantage pilot partnerships in 2026. Carecierge has the infrastructure, team, and execution readiness to operate as a WISeR participant.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans	Carecierge, Inc. has extensive experience working with health care-specific data through our role supporting CMS's GUIDE Model across multiple provider organizations. Our platform is designed to collect, store, and process protected health information (PHI), clinical assessments, care plans, and outcomes data in a way that directly aligns with CMS documentation and compliance standards. We have developed workflows that incorporate: Structured data collection for CMS-required tools such as CDR, FAST, ZBI, PROMIS-10, PRAPARE, and others. Task-driven implementation of CMS-aligned care planning logic, including the mapping of G-code-based service delivery and reimbursement milestones. Interpretation and application of CMS guidance, including select Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) used by our provider clients to align services with Medicare criteria. While we do not currently perform prior authorization or pre-payment review functions, our infrastructure and documentation protocols closely reflect those required in those processes. All platform features are

a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	designed with audit-readiness and medical necessity documentation in mind, supporting seamless adoption of pre-service review responsibilities. a. Experience with MACs and CMS Data Systems Carecierge has worked with provider clients under multiple Medicare Administrative Contractor (MAC) jurisdictions, including Novitas (JH and JL), CGS (J15), and Noridian (JF). While we have not yet integrated directly with MAC systems, our teams are familiar with MAC-specific documentation expectations, LCDs, and claim review logic, particularly as it relates to provider-side compliance under the GUIDE program. We are in active technical planning to enable direct MAC-facing integrations in the context of prior authorization and WISeR-aligned workflows. b. Data Security Certifications Carecierge, Inc. does not currently hold FedRAMP or FISMA authorization. However, our infrastructure is hosted on DigitalOcean, which maintains industry-standard data security certifications including: SOC 2 Type II ISO/IEC 27001 HIPAA compliance support We are pursuing future security reviews and partnerships that will allow us to move toward FedRAMP readiness should CMS or WISeR participation require it. Documentation from our infrastructure provider is available upon request. c. HIPAA Compliance and Data Breach Response Plan Carecierge, Inc. maintains strict adherence to the HIPAA Privacy, Security, and Breach Notification Rules. Our compliance framework includes: Business Associate Agreements (BAAs) with all client covered entities Role-based access controls and encryption of data in transit and at rest Annual HIPAA training for all staff and contractors with access to PHI Regular audits and system monitoring to identify risks and enforce secure workflows Data minimization policies that restrict access and retention of PHI to only what is necessary Data Incident Response Plan: In the event of a suspected data incident or breach, we follow a 5-step response protocol: Immediate containment and access lockdown Internal investigation and impact assessment Notification to affected covered entities and, if applicable, patients Regulatory reporting in accordance with HHS Breach Notification Rule timelines Remediation and post-incident audit to prevent recurrence We are prepared to work closely with CMS or WISeR partners to align with any additional data use, reporting, or incident handling requirements.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Carecierge, Inc. is equipped with the clinical infrastructure necessary to support medical reviews for coverage determinations, peer-to-peer resubmissions, and evidence-based decision-making in accordance with CMS guidelines. While we have not yet acted as the final authority in rendering medical necessity determinations, our platform is designed to collect and present the full clinical picture needed to support such decisions. Through our work on the CMS GUIDE Model, we have supported clinicians in organizing assessments, documenting diagnoses, and aligning patient care plans with applicable Medicare coverage standards. We maintain a Clinical Review Panel comprised of licensed physicians, nurses, and social workers with experience in: Geriatrics and dementia care (primary to GUIDE) Care coordination for Medicare beneficiaries Review of CMS coverage policies (NCDs/LCDs) Documentation for appeals and audit defense This panel is currently used to validate documentation quality, assess medical appropriateness of plans of care, and support provider compliance. These clinicians are available for expansion into formal medical necessity review roles and peer-to-peer determinations under the WISeR Model. Staffing Structure for Medical Review Our clinical review model includes: Chief Medical Consultant (MD, board-certified in Internal Medicine) providing oversight on clinical integrity, policy alignment, and review procedures. Network of consulting clinicians, available by contract, with flexible scaling to meet volume demands across multiple MAC regions. Internal clinical review manager (RN) to coordinate intake routing, coverage criteria matching, and documentation quality checks. All reviewers are U.S.-licensed and undergo regular HIPAA and CMS policy training. This staffing structure ensures that every recommendation made under WISeR will be clinically sound, policy-aligned, and fully

	documented for audit and appeal purposes. We are prepared to expand this team immediately to support full deployment in any selected MAC jurisdiction.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Carecierge, Inc. is committed to seamless integration with Electronic Health Record (EHR) platforms and payer systems to support automated, policy-aligned prior authorizations. Our application is designed as a modular, API-ready platform capable of embedding within clinical workflows and enabling real-time data exchange between providers, payers, and review systems. While Carecierge does not currently embed directly into EHR interfaces, our system is built to operate adjacent to EHR platforms and can ingest or export clinical data in structured formats including HL7 FHIR, C-CDA, and CSV. This design supports rapid alignment with both provider-side documentation systems and payer-side review workflows. a. Current EHR Compatibility Carecierge is compatible with the following EHR platforms via data exchange and/or third-party integration: Epic – Compatible via FHIR API and CSV batch export Cerner – Via SMART on FHIR and document bundle parsing Athenahealth – Through API and secure file-based exchange eClinicalWorks – Structured data compatibility through HL7/CCD PointClickCare – For home health and senior care clients NextGen – Via flat-file import/export and structured API layers We continue to expand interoperability support based on provider demand and use-case prioritization. b. Alignment with CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) Carecierge is actively aligning with the CMS-0057-F rule and supports the following capabilities: FHIR API Readiness: Our backend is fully compatible with HL7 FHIR Release 4, enabling structured access to clinical data required for prior authorization. Planned Integration of Da Vinci PAS and CDex APIs: We are preparing support for the Da Vinci Project's Prior Authorization Support (PAS) and Clinical Data Exchange (CDex) APIs to ensure full compliance with CMS-required standards. Audit-Ready Logging and Transparency: All data exchanges, including prior authorization requests and determinations, are automatically timestamped and stored with complete provenance for compliance reporting. Provider Burden Reduction: Our intake automation reduces provider workload by auto-populating required clinical fields, validating coverage criteria, and routing cases to reviewers based on service type and jurisdiction. Scalable Payer-Side Adoption: The Carecierge platform is modular and designed to deploy across multiple payers, MACs, or delegated entities—ensuring consistency in decision-making and easing the adoption of shared federal standards. We are prepared to support CMS and WISeR participants by serving as an interoperable, standards-aligned technology partner focused on improving data exchange and streamlining the prior authorization lifecycle.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	Carecierge, Inc. is building an AI-driven decision support system designed to improve clinical review efficiency, reduce administrative burden, and ensure Medicare-covered services meet evidence-based medical necessity standards. We are currently developing a modular AI + clinician hybrid review framework, with models trained on: De-identified Medicare claims data (where permissible via synthetic sets and simulations) CMS LCD/NCD documentation Peer-reviewed clinical literature Structured GUIDE Model documentation, such as assessments, diagnoses, care plans, and utilization patterns submitted across our current provider base This foundation supports Carecierge's approach to intelligent coverage determination: our AI flags service cases likely to meet or not meet criteria, based on real-time intake documentation and cross-referenced CMS guidelines. All determinations are ultimately reviewed and finalized by licensed clinicians to ensure compliance and avoid fully autonomous medical decision-making. AI Algorithms and Frameworks for WISeR To implement WISeR alongside MACs, we plan to deploy the following architecture: NLP + Rule-Based Hybrid Pipeline using: spaCy and Hugging Face Transformers for language interpretation XGBoost and Scikit-learn models for decision trees and feature ranking Ontology-based tagging engine using UMLS/ICD-10/LOINC mappings to match clinical documentation against CMS medical necessity language FHIR-aware data models trained to identify gaps in preauthorization submissions Human-in-the-loop dashboards for final clinical validation, ensuring transparency and defensibility This system is modular, explainable, and tuned for the WISeR context: flagging inappropriate care before it becomes wasteful spending. a. Validation, Ethics, and Quality Assurance Our enhanced technology undergoes the following safeguards to ensure safe, high-quality use: Manual validation of training outputs by board-certified clinicians during model iteration Bias detection audits to ensure AI models do not disadvantage specific populations or care settings Version-controlled decision logs for every coverage recommendation Regular third-party security scans and penetration testing to ensure PHI safety Clinical policy lock-ins: models cannot override or alter CMS coverage standards, which are codified in rule-based modules Explainable AI (XAI) interfaces to ensure MAC reviewers and CMS regulators can interpret AI suggestions b. Managing Potential Adverse Effects of Automation To proactively mitigate risks associated with AI and automation in utilization management, Carecierge employs: Human-in-the-loop review models: no determination is made without clinician approval Escalation protocols for ambiguous, complex, or novel coverage scenarios Patient safety guardrails to flag potential delays or denials of medically urgent care Audit pathways for post-decision review, retraining, and continuous model improvement Transparent feedback loops with providers and MACs to refine recommendations and avoid misalignment with clinical realities Our approach ensures that automation serves as a support tool, not a replacement for medical judgment—meeting the ethical demands of the WISeR Model while unlocking scale, speed, and savings for Medicare.

6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Carecierge, Inc. is grounded in a culture of integrity, clinical responsibility, and transparent collaboration. Our approach to ethics and compliance is embedded in every level of our platform and operations, ensuring the safety of patients, the trust of providers, and the accountability expected by payers and regulatory bodies. We maintain a multi-tiered framework that includes: HIPAA-compliant architecture and operations Role-based access and PHI minimization policies Clinical oversight by licensed medical professionals Internal code of ethics and conduct training for all staff and contractors Audit-ready logs for clinical reviews, platform actions, and user interactions Alignment with CMS standards (LCDs, NCDs, PAAF, GUIDE documentation, etc.) We prioritize transparency, fairness, and evidence-based decision-making in all patient-facing and provider-facing processes. a. Quality Assurance for Utilization Management, Complaints, and Claims Carecierge's approach to utilization management and quality control includes the following safeguards: Clinical Decision Review Protocols: All determinations related to coverage, documentation completeness, or appropriateness are reviewed and signed off by licensed clinicians before submission or recommendation. Grievance Handling Procedures: We maintain a defined process for providers and patients to raise disputes or concerns regarding a clinical review outcome. Each case is tracked, time-stamped, and reviewed by our compliance team within 48 hours. Claims and Billing Alignment: While Carecierge does not process billing directly, we support claims alignment through documentation export, diagnosis mapping, and flagging of incomplete prior authorization packages. When supporting prior authorization or WISeR reviews, we will implement structured communication with MACs and providers to track claims disputes and ensure fair outcomes. Utilization Pattern Monitoring: Carecierge tracks approval/denial rates, clinician-level variations, and outlier behavior to ensure consistency and accuracy in utilization management. b. Compliance with State and Federal Regulations Carecierge actively monitors and complies with all applicable state and federal regulations relevant to our operations, including: HIPAA (Privacy, Security, Breach Notification Rules) HITECH Act CMS documentation standards under GUIDE, PAAF, and LCD/NCD frameworks State-specific telehealth, licensing, and data retention laws We maintain an internal Regulatory Compliance Matrix, updated quarterly, that maps all operational touchpoints to governing laws and payer rules by jurisdiction. This matrix informs product design, staff training, and client onboarding processes. Additionally, we regularly consult with external legal and regulatory advisors to ensure our platform remains compliant as policies evolve—especially as we expand into utilization management and payer services through the WISeR Model.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Carecierge, Inc. anticipates generating Medicare savings of $3.2–$5.1 million annually per jurisdiction covered under WISeR, based on our projected impact across the three selected service categories (skin and tissue substitutes, electrical nerve stimulators, and knee arthroscopy for osteoarthritis). Assumptions & Basis: Focus on one MAC region (e.g., JH – Novitas) initially, with provider density across Texas, Oklahoma, and surrounding areas. Estimated prevalence of target services: ~18,000–25,000 annual cases in region. Inappropriate utilization rate conservatively estimated at 14–20% (based on OIG, GAO, and CMS historical reports). Average Medicare spend per targeted service: Skin/tissue substitutes: $2,200 Nerve stimulators: $8,000 Knee arthroscopy: $3,500 Projected Annual Impact (MAC JH example): ~4,000–5,000 flagged inappropriate services prevented Average denial value: $900–$1,500 Gross Medicare savings: $4.2M Net WISeR savings (after shared savings to participants): ~$3.2M–$3.5M These figures scale proportionally with regional volume and case mix. If expanded to additional MAC regions (e.g., JL or JF), the aggregate multi-jurisdictional savings could exceed $10–15M per year within 2–3 years, based on our platform's scaling capacity and AI-clinician hybrid review model. Carecierge will deliver these savings through a combination of: Automated inappropriate service flagging Clinician-reviewed medical necessity determinations Early detection and prevention of wasteful utilization Provider education loops to drive long-term behavior change
9. Please provide a timeline and	Carecierge, Inc. is prepared to meet all technical, security, and operational requirements to

implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	interface with Medicare Administrative Contractors (MACs) and process sensitive Medicare beneficiary data under WISeR. Below is our 90-day implementation plan from the date of selection: Phase 1: Initial Compliance & Technical Preparation (Days 1–30) Objective: Establish secure, policy-aligned infrastructure and finalize MAC integration plan. Actions: Assign dedicated WISeR project lead and compliance officer Finalize Business Associate Agreements (BAAs) and MAC data use terms Conduct internal HIPAA Security Risk Assessment Provision and isolate production environment (DigitalOcean – SOC2, ISO 27001, HIPAA-compliant) Begin credentialing and background screening of clinicians and technical staff Define FHIR-compatible data exchange schema for MAC submission/response Confirm MAC-specific prior authorization requirements and endpoints Phase 2: System Configuration & Clinician Onboarding (Days 31–60) Objective: Deploy operational workflows and train reviewers for MAC-aligned reviews. Actions: Finalize integration with MAC APIs or data portals (test environment) Configure clinical review interface per MAC region (e.g., JH – Novitas) Deploy AI model filters and coverage determination logic (LCD/NCD rulesets) Train clinical reviewers on WISeR criteria and CMS documentation thresholds Configure audit logging, access control, and breach detection alerts Dry-run review simulations with de-identified cases Phase 3: Secure Data Access & Go-Live (Days 61–90) Objective: Establish full operational readiness and begin accepting real MAC data. Actions: Initiate secure access to live MAC systems/data streams under approved agreement Begin production-level prior authorization or prepayment review cases Conduct daily validation of audit logs and reviewer activity Monitor system performance, reviewer turnaround time, and compliance alerts Submit initial savings and performance dashboard to CMS/WISeR coordinators Enable 24/7 support for MAC interaction and provider inquiries Ongoing Compliance & Monitoring (Post-Day 90) Quarterly HIPAA audits and MAC reporting Continuous retraining and calibration of AI models based on CMS feedback Real-time error and anomaly detection for compliance monitoring Expansion to additional MAC jurisdictions as directed

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Carecierge, Inc.
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00050

Requested by (b)(6) on 07/28/2025 12:32

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	EviCore healthcare MSI, LLC
b. Doing Business As (DBA) Name(s)	EviCore healthcare
c. Street Address	730 Cool Springs Blvd., Suite 800
d. City	Franklin
e. State	TN
f. Zip Code	37607
g. Tax Identification Number	621615395
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Purpose Today's health care landscape is challenged with an increase in the number of lives covered, shrinking resources, and rising costs. Thus, a sound strategy is essential to effectively overcome these challenges while also ensuring the highest quality of care and the most favorable clinical outcomes for all stakeholders. EviCore is committed to making a positive impact in health care. Our evidence-based approach utilizes our proven talent and leading-edge technology to realize better outcomes. EviCore developed our proposal in response to CMS's interest in delivering a quality, clinically appropriate, and cost-effective medical benefits management (MBM) solution. Mission Statement To transform utilization management and improve the patient experience and provider well-being while reducing costs. Services EviCore's comprehensive MBM solution suite, which today provides coverage to 100+ million lives (as of January 2025), includes the following: - Cardiovascular - Gastroenterology - Lab Management - Medical Oncology - Musculoskeletal - Post-Acute Care - Radiation Oncology - Radiology - Durable Medical Equipment (DME) - Sleep. Clientele EviCore's clients include local, regional, and national health plans and management programs for the Accountable Care Organization delivery model. EviCore has extensive experience and expertise in working with Medicare Advantage, Public Exchange, and Medicaid populations. Our Quality Management and Compliance departments ensure that all required licenses are in place, and that all UM notifications meet state, federal, and Centers for Medicare and Medicaid Services (CMS) standards and regulations. EviCore adheres to all of the guidelines issued within the Medicare Managed Care Manual, Chapter 13 — Medicare Managed Care Beneficiary Grievances, Organization Determinations, and Appeals Applicable to Medicare Advantage Plans, Cost Plans, and Health Care Prepayment Plans (HCPPs), collectively referred to as Medicare Health Plans. Covered Lives As of January 2025, the breakdown of lives by line of business across

	all EviCore programs is as follows: - Commercial: EviCore currently manages 56.95 million Commercial lives across more than 50 client relationships in all 50 states. - Medicare Advantage: EviCore currently manages 17.85 million Medicare Advantage members across more than 50 of our client relationships. EviCore has managed the Medicare line of business since the inception of the company in 1994. - Medicaid: EviCore currently manages 25.2 million lives for 35 Managed Medicaid clients across 30 states and six fee-for-service Medicaid state clients.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JF Noridian

5. Provide street address, city and state for all locations.

Location Name	Primary Business Address
Street Address	730 Cool Springs Blvd., Suite 800
City	Franklin
State	Tennessee
Zip Code	37067

Location Name	Secondary Business Address
Street Address	1575 Garden of the Gods Road
City	Colorado Springs
State	Colorado
Zip Code	80919

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00050_Ownership_EviCore Ownership Interest
Uploaded On	7/25/2025, 9:51 AM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address Name Title/Position	(b)(6)
Address	730 Cool Springs Blvd., Suite 800, Franklin, TN 37067
Business Phone Number	(b)(6)

Contact Type	Tertiary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	730 Cool Springs Blvd., Suite 800, Franklin, TN 37067
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00050_Licensure_EviCore Incorporation and Licensure
Uploaded On	7/25/2025, 9:38 AM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	☐

Disclosures

Individual or Entity	See Below
Federal, State, or Tribal Agency or Licensing Body	See Below
Description of Infraction (including date)	Date: Ongoing. EviCore, including its parent company and affiliates (collectively “EviCore”) is involved in litigation and investigations arising, for the most part, in the ordinary course of business. While the outcome of litigation and investigations involving EviCore cannot be

	determined, they are not anticipated, at this time, to result in losses that would be material to results of operations, liquidity, or financial condition. Please refer to Form 10-K and Form 10-Q for an updated description of material legal proceedings. These documents are available online at https://investors.cigna.com/financials/sec-filings/default.aspx. Confidentiality concerns, together with the pending nature of a number of lawsuits and investigations, preclude further comment or description.
Resolution Status	In Progress
Resolution Date	

Individual or Entity	Department of Justice/HHS-OIG
Federal, State, or Tribal Agency or Licensing Body	Federal
Description of Infraction (including date)	Date: 09/29/2023.On September 29, 2023, The Cigna Group announced it had fully resolved pending legal matters related to certain past Medicare Advantage risk adjustment practices. Under agreements with the federal government, The Cigna Group paid approximately $172 million and moved beyond industry-wide legal disputes to maximize the company's focus on delivering value to customers and taxpayers. The agreements resolved a False Claims Act lawsuit and an investigation related to past risk adjustment submissions from certain types of patient records, some dating back more than a decade. As part of the resolution, The Cigna Group also entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is designed to promote ongoing compliance with federal health program requirements over a period of 5 years. Rather than continue with the uncertainty of civil litigation, Cigna Healthcare decided to fully resolve its DOJ matters related to risk adjustment reimbursement with no determination of liability. Effective April 24, 2025, the Office of Inspector General suspended the Company’s obligations under the CIA.
Resolution Status	Resolved
Resolution Date	4/24/2025

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	CONFIDENTIAL INFORMATION AND NOT SUBJECT TO FOIA 1199 SEIU National Benefit Fund Aetna Health Management, LLC Alabama Medicaid Agency AmeriChoice of New Jersey, Inc. AultCare Insurance Company, AultCare Health Insuring Corporation, and AultCare HMO ("AultCare") Banner Health Network BCBSM, Inc. d/b/a Blue Cross and Blue Shield of Minnesota Blue Cross & Blue Shield of Rhode Island Blue Cross and Blue Shield of Alabama Blue Cross and Blue Shield of Arizona, Inc. Blue Cross and Blue Shield of Kansas City Blue Cross Blue Shield of Michigan and Blue Care Network Blue Cross Blue Shield of North Dakota Boston Medical Center HealthNet Plan in Massachusetts and Well Sense Health Plan in New Hampshire Cambia Health Solutions, Inc. Capital BlueCross CareFirst of Maryland Inc. (CFMI), Group Hospitalization and Medical Services, Inc. (GHMSI), and CareFirst BlueChoice, Inc. (BlueChoice) CareSource Management Services LLC Cigna Health and Life Insurance Co. Clover Insurance Company Community Health Network of Connecticut, Inc. Compass Rose Benefits Group Comprehensive Health Management, Inc. Covered Entity with which EviCore has BAA Emblem Health Services Company LLC Evolent Health LLC Excellus Health Plan, Inc. Fallon Community Health Plan, Inc. Fulcrum Health, Inc. Government Employees Health Association Health Alliance Connect, Inc. Health Alliance Plan of Michigan Health Care Service Corporation Health Choice Arizona, Inc. Health First Shared Services, Inc Health New England, Inc. Health Partners Plan, Inc. Highmark Inc. Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey Humana Inc. Independence Blue Cross, LLC Johns Hopkins HealthCare LLC Landmark Healthplan of California, Inc. Mass General Brigham Health Plan (formerly Allways and formerly Neighborhood Health Plan, Incorporated) Medical Mutual of Ohio Moda Health Plan, Inc. MVP Health Plan, Inc. Network Health Plan and Network Health Insurance Corporation Oscar Healthcare Point32Health Services, Inc. (formerly Tufts Associated Health Plans, Inc.) Premera Blue Cross Priority Health Government Programs, Inc., Priority Health Insurance Company, and Priority Helath Managed Benefits, Inc. ("Priority Health") Prominence HealthFirst Providence Health Plan Rhode Island Medicaid - SBS Sanford Health Plan Scott and White Health Plan Security Health Plan of Wisconsin, Inc. Sentera Health Plans, Inc. SummaCare, Inc. The Health Plan of West Virginia, Inc. Triad Healthcare IPA, Inc. Triad Healthcare, Inc. TriWest Healthcare Alliance Corp. Trustmark Life Insurance Company and Affiliates UHA Health Insurance United Healthcare Plan of the River Valley United HealthCare Services, Inc. USAble Mutual Insurance Company d/b/a Arkansas Blue Cross Blue Shield Vaya Health WellCare of New

	York, Inc. Wellmark, Inc. Wisconsin Medicaid FFS Wisconsin Physicians Service Insurance Corporation Yamhill County Care Organization Zing Health Holdings, Inc.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	EviCore works with 100+ health plans representing more than 100 million lives – about 1 in 3 Americans, meaning our scale is robust enough to take on any request. On average, EviCore receives 100,000 prior authorization requests daily and engages with over 800,000 providers annually. We developed a fully owned and integrated set of benefits management solutions that allow us to adapt to the diverse needs of the patients, providers, and plans we service. Covered Lives As of January 2025, the breakdown of lives by line of business across all EviCore programs is as follows: - Commercial: EviCore currently manages 56.95 million Commercial lives across more than 50 client relationships in all 50 states. - Medicare Advantage: EviCore currently manages 17.85 million Medicare Advantage members across more than 50 of our client relationships. EviCore has managed the Medicare line of business since the inception of the company in 1994. - Medicaid: EviCore currently manages 25.2 million lives for 35 Managed Medicaid clients across 30 states and six fee-for-service Medicaid state clients. Medicare Advantage Plans EviCore has extensive experience and expertise in working with Medicare Advantage, Public Exchange, and Medicaid populations. Our Quality Management and Compliance departments ensure that all required licenses are in place and that all utilization management notifications meet state, federal, and Centers for Medicare and Medicaid Services (CMS) standards and regulations. EviCore adheres to all the guidelines issued within the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance to Medicare Advantage (MA) Organizations, Medicare Cost Plans, and Health Care Prepayment Plans (HCPPs), collectively referred to as Medicare Health Plans. Through our comprehensive solution suite, EviCore manages benefits on behalf of more than 17.85 million Medicare Advantage members. EviCore continues to invest in Medicare Advantage capabilities and products. Our strategy includes the application of dedicated leadership and teams, compliance and operational improvements, and product enhancement and development. One key change that we have deployed to support our Medicare Advantage membership includes: - Coverage determinator capability to manage NCDs/LCDs: Given the complexity of managing, updating, and correctly applying NCDs and LCDs, EviCore has made significant investment in tools, systems, and capabilities to ensure that we are always following the applicable guidelines in our decision-making processes. Our tools and protocols ensure: + Nurse reviewers and medical directors are proactively guided through the appropriate LCD, NCD, or EviCore policy when reviewing the case + The appropriate rationale is inserted into the case decision. Our investment in this area also includes standardizing rationales to meet all requirements and best practices for clarity and readability.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans. EviCore is well positioned to support the CMS WISeR model because of its extensive expertise in prior authorization, advanced technology infrastructure, and strong commitment to transparency and efficiency. With significant experience applying National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and general coverage and benefit conditions to prior authorization requests, EviCore ensures that all determinations are clinically appropriate, timely, and aligned with Medicare standards. Over half of our client base requires us to apply LCDs and NCDs within the MA space, and approximately 35% of our expected 30M annual case volume this year will apply MA coverage hierarchy. In cases where Medicare coverage criteria are not fully established in statute, regulation, or policy, EviCore is able to apply its publicly accessible, evidence-based clinical criteria to guide decision-making. These guidelines are embedded directly into its clinical decision tools, ensuring that all determinations are evidence-based, auditable, and scalable supporting CMS's interoperability goals and streamlining the prior authorization process. When services are denied, EviCore provides clear rationale and references, reinforcing WISeR's emphasis on transparency and informed decision-making. Additionally, EviCore's infrastructure supports both real-time and retrospective pre-payment reviews, helping to identify low-value or unnecessary services, prevent fraud and abuse, and ensure timely Medicare payments. Its automated workflows and point-of-care decision support tools also reduce administrative burden for providers, enabling faster, more accurate care delivery. EviCore has experience with Post-Service Medical Necessity Determination (PSMND), post service, and pre-claim finalization of the medical necessity review (MND) where delegated by the client. In all instances, the client holds the claim. They may either provide the clinical record via secure email or file transfer, prompting the creation of a case identification number, or they may utilize the client facing technology portal to self-create the case. An MND review is then performed and the recommendation is returned via secure email or file transfer. EviCore is also developing additional MND processes for our Claims Studio services. These include allowing the claim to be processed in the MC400 system with a request for clinical documentation or holding the claim for a specified time frame before releasing it to the client,

who may then choose to request the clinical record. In both instances, the claim will undergo MND review and be returned via secure email or file transfer. a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs). EviCore applies CMS's Medicare coverage hierarchy to guide prior authorization and coverage determinations. This includes prioritizing National Coverage Determinations (NCDs), followed by Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs), in accordance with CMS policy. When NCDs lack sufficient detail, LCDs from the appropriate Medicare Administrative Contractor (MAC) are used to adjudicate requests. The organization collaborates with MACs as needed to ensure alignment with jurisdiction-specific policies and accurate application of medical necessity criteria. b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. Cigna is designated as a "contractor" and not a Cloud Service Provider (CSP) within the FedRAMP process and therefore does not require a FedRAMP ATO (Authority to Operate) on the solutions that we use to provide healthcare services. However, we still need to follow a rigorous process to ensure FedRAMP compliance standards are met and commit to the following validations for the FedRAMP Program at Cigna/Evernorth. The FedRAMP program at Cigna/Evernorth is focused on data security and protection. We have determined that the scope of the federal data that we handle falls in the FedRAMP Moderate impact level. On that premise, we ensure that when used public cloud is used, as part of healthcare service delivery, that following the practices are applied, consistent with the Moderate impact level. HITRUST The HITRUST is specifically a collaboration with health care, business, technology, and information security leader organizations and has established the Common Security Framework (CSF). CSF is a certifiable framework that can be used by any and all organizations that create, access, store, or exchange personal health and financial information. EviCore originally became HITRUST CSF certified effective August 15, 2016. EviCore receives a HITRUST attestation every two years, with the most recent August 14, 2024. EviCore additionally achieves a HITRUST attestation every year. We have provided a copy of our most recent HITRUST certification letter. The scope of this certification includes all core business applications, analytics and reporting systems, claims systems, telecommunications systems, and IT infrastructure and data centers. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach. Information Security Program EviCore management has developed and documented formal policies and procedures, in accordance with HITRUST CSF 9.6, to guide the organization in the implementation of industry security standards. The HITRUST CSF 9.6 framework consists of a comprehensive set of controls that includes information security and compliance requirements. The information security program ensures plans for security testing, training and monitoring activities are developed, implemented, maintained, and reviewed for consistency with the risk management strategy and response priorities. Privacy and Compliance with Applicable Laws EviCore is committed to ensuring the privacy and security of protected health information (PHI). Federal and state laws and regulations have established standards with which health care organizations must comply to ensure the security and confidentiality of PHI. EviCore management has developed and documented formal policies and procedures, in accordance with state, federal, NCQA, URAC, Self-Insured, Medicaid, Medicare, FEP, and HIPAA laws and regulations. EviCore has a formally appointed Privacy Officer responsible for the privacy of covered information. We maintain both Privacy and Security Officers as part of the organizational structure, to ensure the adequacy of HIPAA-compliant practices and to coordinate any necessary corrections. Business Associate Agreements are implemented for all vendors and clients with whom EviCore shares confidential health information. Breach Detection and Escalation Our breach detection and escalation processes are documented in our Corporate Privacy Policies managed by the Privacy office. Procedures: - Any reports of potential reportable breaches are immediately forwarded to the EviCore Privacy mailbox. The Privacy Office collects whatever data are immediately available and perform the appropriate risk assessment. - For confirmed, reportable breaches, EviCore will consult with the health plan to determine who shall notify each individual whose unsecured protected health information has been or is reasonably believed to have been accessed or disclosed. If EviCore will be doing the notification, it will be done without reasonable delay but no later than 60 calendar days after the discovery of the breach. In the event contact information is insufficient or out-of-date for 10 or more individuals, a conspicuous posting on the EviCore website shall be implemented for a period of 90 days. In the event the imminent misuse of disclosed information is expected and the situation is deemed urgent, notice may be provided by telephone as well as in writing. - For a breach of unsecured protected health information involving more than 500 residents of a state or jurisdiction, EviCore shall notify prominent media outlets serving the state or jurisdiction without reasonable delay and in no case later than 60 calendar days from its discovery. - For a breach of unsecured protected health information, EviCore will provide notice to the Secretary of Health and Human Services (SHHS) in the manner specified by the Health and Human Resources website. - As a business associate, EviCore will provide notification of breaches as required to the covered entity's Privacy Officer as soon as possible but no later than 3 business days from the discovery. - EviCore will provide training of all staff who are affected by the policy and procedure Breach Notification for Unsecured Protected/Individually Identifiable Health Information. - EviCore does not

	threaten, coerce, discriminate against, or take any other retaliatory action against any individual who complies with this regulation. - All reports of potential or actual breaches are reported to the Quality Management Committee to consider responsive improvement initiatives.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	Yes

Authorizations or Certifications Document

File Name	WISeR-00050_Authorizations_EviCore HITRUST Final Summary Report 2024-2026
Uploaded On	7/25/2025, 11:00 AM

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Coverage Determinations When a provider completes an authorization request, clinical information submitted by the ordering provider is compared to the clinical guidelines through a structured series of questions designed to determine whether the requested procedures are appropriate or if alternative procedures or treatments should be considered. Once the questions are answered, the provider will be advised whether additional clinical information is required. We offer the ability to submit medical records via the Web portal, or to provide information verbally via the phone. The clinical guidelines applied are based on EviCore's Medicare Hierarchy. EviCore has significant experience applying National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and general coverage and benefit conditions to prior authorization requests. EviCore ensures that all determinations are clinically appropriate, timely, and aligned with Medicare standards. In cases where Medicare coverage criteria are not fully established in statute, regulation, or policy, EviCore is able to apply its publicly accessible, evidence-based clinical criteria to guide decision-making. Peer-to-Peer Discussions The breadth of specialties encompassed by our medical team sets us apart from our competitors. Peer-to-peer consultations can be conducted with a like specialty EviCore clinician in consultation with the ordering physician or clinician. As with all of EviCore's processes, the peer-to-peer discussions between our medical directors and the requesting providers are designed to ensure that every patient receives the most appropriate diagnostic or therapeutic procedure to meet their needs, without unnecessary exposure to potentially harmful substances or situations. As a result, these discussions are usually collegial in nature. During these conversations, the requesting providers usually supply additional clinical information regarding their patients' conditions, and EviCore's medical directors provide insights regarding the applicable evidence-based guidelines. By doing so, the primary mission of meeting the patients' needs while increasing their quality of care and safety is accomplished. During the authorization process or after a review determination is delivered, the treating provider can request a peer-to-peer conversation. This is true across all procedures within all EviCore clinical solutions. Our clinical peer reviewers have in-depth experience in their field and can assist the provider in understanding clinical rationale and the evidence-based guidelines. Ordering physicians seeking to request a peer-to-peer consultation with an EviCore medical director can call our prior authorization line to schedule a peer-to-peer for a convenient date/time. EviCore's availability of expertise across a wide scope of specialties enables us to accommodate the need for the ordering physician or clinician to engage in a peer-to-peer consultations with a same- or similar-specialty EviCore clinician upon specific request. A team of EviCore service representatives manages the coordination of these activities for the physician teams. When a provider contacts EviCore to request consultation regarding cases for which decisions have been rendered, the EviCore Physician Support Unit will facilitate Peer-to-Peer scheduling and can help coordinate a real-time consultation, if appropriate. Depending on EviCore clinicians' availability (by specialty) and the requesting provider's time constraints, the scheduling of a discussion with a same- or similar-specialty peer may be requested. Clinical Staffing EviCore employs clinical review staff that meets NCQA, URAC, and all state and federal mandates. EviCore maintains multiple Contact Centers, as well as, remote

	employees throughout the U.S. All facilities, including remote agents, act as a single Contact Center utilizing next-in-queue technology protecting against regional effects to operations. Employees of all skill levels are available in each Contact Center and remote environments. EviCore's Contact Centers are 100% voice, data, and application redundant across geographically diverse, critical-reliability data centers. Employees must meet minimum qualifications for their position. Following are several sample job functions and their minimum qualifications: Clinical Reviewer Job function: Responsible for all clinical-certification activities, which include capturing telephone requests for authorization of radiology services from physician offices/and or imaging centers, evaluating requests against established clinical protocols, and authorizing services or referring requests for expert clinical review as appropriate. Minimum qualifications: Registered professional nurse, licensed practical nurse, or currently licensed health professional with previous clinical and managed care experience. Experience with computer data entry, customer service, medical terminology, and managed care. Clinical Appeals Reviewer Job function: Responsible for reviewing cases that request reconsideration of a non-certified case. Minimum qualifications: A licensed heath professional with clinical and managed care experience with knowledge of industry regulatory requirements, strong communication and analytical skills, and knowledge of principles and procedures of utilization management. Clinical Auditor Job function: Responsible for assisting Clinical Review staff with review activities, including research of issues, mentoring of Care Management Unit staff, training as needed, ongoing monitoring for quality service, and providing input on employee evaluations based on monitoring outcomes. Minimum qualifications: Active license as registered nurse or licensed practical nurse with previous managed care experience preferred. Previous quality-measurement or training experienced preferred. Clinical Manager Job function: The Imaging Care Management Unit clinical manager oversees and coordinates the operations of the Care Management Unit and works collaboratively with the vice president of clinical services to facilitate the clinical certification processes. Minimum qualifications: Currently licensed registered professional nurses are preferred. At least two years previous supervisory or managed care experience with knowledge of industry regulatory requirements. Ability to independently evaluate and analyze related information in order to plan, develop, and monitor Care Management Unit activities to meet program goals and objectives. Clinical Supervisor Job function: The Clinical Decision Support Supervisor oversees and coordinates the day-to-day operations of the Clinical Decision Support Unit and works collaboratively with the Vice President of Clinical Services and other supervisors to facilitate the notification processes for radiology services. Minimum qualifications: Minimum one year clinical experience and at least two years previous supervisory or managed care experience with a knowledge of utilization and quality management programs and industry regulatory requirements. Ability to independently evaluate and analyze related information in order to plan, develop, and monitor notification activities to meet program goals and objectives. Medical Director Job function: Supervise compliance with corporate medical policy regarding overall medical management and quality assurance programs. Minimum qualifications: The medical director will be board certified with an unrestricted license to practice in one or more states. Clinical Guideline Application Per EviCore's Medicare hierarchy, EviCore adheres to national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in traditional Medicare laws. EviCore's publicly accessible evidence-based guidelines are only be applied when coverage criteria are not fully established in Medicare statute, regulation, NCD, or LCD. EviCore's proprietary guidelines are based on published practice guidelines from national and international medical specialty societies and peer-reviewed clinical literature. EviCore's clinical guidelines can be found on our website: www.EviCore.com. Links to references are listed within the guideline documents. EviCore's clinical guidelines undergo a thorough review and revision process annually, at a minimum. This is a three-tiered process: (1) Internal Review by Medical Directors; (2) Medical Advisory Board Review; and (3) Medical Advisory Committee Review. The review is managed by EviCore's ICOG (Clinical Oversight and Guidance) team, under the purview of the Executive Medical Director. 1. Internal Review EviCore's ICOG team authors the guidelines based on timely evidence-based, peer reviewed sources. A review of EviCore's clinical guidelines is conducted with EviCore's Medical Directors and clinicians who represent a comprehensive range of specialties aligned with EviCore's product suite. All clinical updates are supported by references from peer-reviewed journals and/or published practice guidelines from relevant medical specialty societies. 2. Medical Advisory Board (MAB) Review The clinical guidelines undergo review by an external panel of physicians made up of medical specialists and academicians from well-regarded institutions. These reviewers are referred to as the Medical Advisory Board (MAB). 3. Medical Advisory Committee (MAC) Review The revised guidelines then undergo review by EviCore's Medical Advisory Committee (MAC), which is EviCore's utilization management committee meeting all requirements set forth in the CMS CFR. The MAC is a group composed of internal and external physicians of diverse specialties. The MAC meets on bimonthly basis, at a minimum, to review guideline updates. All revisions to the clinical guidelines must be approved by the MAC before being considered "final."
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations.	Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. EviCore integrates with any EHR that can supply a standard X12 278R interface message, customized HL7 ORM message, FHIR APIs, including FHIR PAS. We have several existing EHR integrations used for expediting prior authorization processes with multiple provider sites both through direct integrations with hospital systems and

a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	indirect integrations via channel partners such as revenue cycle management companies. Our connections allow for the transmission of prior authorization case-creation information (including payor, procedure, provider, and patient data) automatically triggered by the ordering and/or scheduling of procedures as well as the transmission of clinical documentation via FHIR APIs, directly from the EHR to support the medical necessity of a prior authorization request. This connectivity enables seamless transactions, including those that leverage our automation, to provide appropriate real-time approvals and other statuses written back directly into the EHR. EviCore can provide step-by-step documentation or consultative guidance in the integration with these systems. In addition to existing implementations, EviCore is actively working on new connectivity strategies, including via Epic Payor Platform, to scale connectivity in the provider space as well as more comprehensive FHIR connectivity as mandated by CMS, explained in further detail below. a. Please also include a list of EHR platforms your application or suite is compatible with. EviCore has successfully integrated with Epic, Cerner, Fuji, Medinformatics, Athena, Allscripts, NextGen, eClinicalWorks, and other homegrown systems. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices. EviCore is actively implementing a scalable and future-ready solution to support payer compliance with the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F). The EviCore Enterprise Interoperability Compliance Program (EIC) is designed to improve healthcare data exchange and reduce administrative burden through integration with various systems across the healthcare landscape. We are leveraging FHIR-based API technologies aligned with HL7 Da Vinci Implementation Guides—specifically Prior Authorization Support (PAS) and Documentation Templates and Rules (DTR)—to streamline prior authorization workflows. Our solution is designed to reduce provider and patient burden by automating clinical documentation exchange, improving data accessibility, and enabling real-time authorization decisions. We are building this infrastructure with a strong emphasis on interoperability, compliance, and reusability across lines of business, ensuring alignment with HHS-adopted data standards and reducing administrative friction across the healthcare ecosystem. List of APIs in development: 1. Prior Auth Status: Covers provisions of patient access, provider access, and payer to payer access. Prior Auth status and updates are sent out in Explanation Of Benefit (EOB) FHIR resource as response. 2. DTR (Documentation Template & Rules) - collection of data before submission of PA. 3. PAS (Prior Auth Support): Allows provider systems to send (and payer systems to receive) prior authorization requests using FHIR to transport the prior authorization, simplifying processing for either or both exchange partners. EviCore has an initial version of this API live in production with one of our channel partners. 4. PAS Inquiry: Post-submission prior auth status inquiry Implementation of the PA Inquiry API for retrieval of prior authorization status based on specific filters. 5. PAS CDEX (Clinical Data Exchange): Sharing of clinical data during or after PA submission. 6. Subscription: Push mechanism for authorizations. Entity subscribe to service to receive authorization information.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	Our organization brings more than a decade of experience in developing and deploying AI solutions in healthcare, with a strong focus on utilization management (UM) and prior authorization (PA). IntelliPath AI, EviCore's industry-leading technology, offers real time approval for physicians who consistently practice within clinical guidelines. IntelliPath AI recognizes ordering patterns, applies clinical guidelines, and ensures appropriate procedures are performed at the right time for the right reason. EviCore uses sophisticated, proprietary algorithms that enhance decision-making processes while improving the response times for patients and physicians. The algorithms are embedded throughout the utilization management workflow and reflect the combined input of leading-edge clinical expertise and logic; advanced technology; sophisticated machine learning; and relevant information about the patient, physician, and clinical condition that supports a robust and insightful review. Processing millions of requests each year, EviCore has gained a valuable repository of data that is used to identify the vital common factors associated with appropriate requests. These factors include, but are not limited to: - The patient's presenting complaint or known disease - Relevant specifics of the patient's individual characteristics - The identity of the requesting provider - The specific requested procedure - The record of any prior procedures for the same condition or issue - The clinical indication and purpose of the requested procedure. Our algorithmic solutions do not ever render adverse determinations. If a request does not demonstrate adherence to the clinical guidelines, through the use of such solutions, then the request is transferred to a clinical reviewer and/or physician to independently complete the review. Under the hood, IntelliPath AI, contains a comprehensive suite of AI-powered capabilities designed to streamline the PA process across the healthcare ecosystem, including the ability to: - Approve PA requests in real-time based on structured case data - Predict relevant clinical guidelines for a given clinical scenario - Surface relevant evidence using NLP on clinical documentation - Assess if specific criteria are met based on relevant evidence identified - Perform HIPAA verification on incoming clinical documents to ensure appropriate case matching - Segment, classify, and filter clinical documentation to only what is relevant To accomplish this, we leverage a sophisticated AI architecture that combines: - Rule-based engines aligned with CMS

	coverage criteria - Supervised and unsupervised ML models for classification and triage - Advanced NLP models for extracting clinical context from unstructured data - Rich data assets spanning years of operation as the largest medical benefits manager in the US a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. At EviCore, our approach to verifying, validating, and securing our enhanced technology software—particularly IntelliPath AI—is grounded in rigorous clinical standards, robust machine learning (ML) evaluation methodologies, and enterprise-grade security protocols. These efforts ensure that our utilization management solutions are accurate, reliable, and aligned with the highest standards of healthcare delivery. Verification and Validation Through Clinical Gold Standards All datasets used to train and evaluate our ML models are derived from a rigorously curated gold standard of cases, each reviewed and validated by expert clinicians. This ensures that our models are grounded in real-world clinical decision-making and reflect best practices in evidence-based care. We employ standard ML evaluation methodologies, including: - Cross-validation and holdout testing to assess generalizability and prevent overfitting. - Precision, recall, F1-score, and AUC-ROC metrics to evaluate classification performance. - Confusion matrix analysis to understand false positives and false negatives in the context of clinical appropriateness. - Drift detection and monitoring to identify changes in model performance over time as clinical practices evolve. Model performance is benchmarked against historical clinical reviewer decisions and continuously monitored in production to ensure consistency and accuracy. Security and Quality Assurance We implement a multi-layered security framework to protect sensitive healthcare data and ensure system integrity: - HIPAA-compliant infrastructure: All data handling, storage, and transmission processes meet or exceed HIPAA requirements. - Role-based access control (RBAC): Access to data and model outputs is tightly controlled and audited to ensure only authorized personnel can interact with sensitive information. - Redundancy and failover systems: Our infrastructure is designed for high availability and resilience, ensuring uninterrupted service delivery. To maintain high-quality outputs, all AI systems include: - Real-time audit logging of model decisions and system actions. - Automated alerts for anomalous behavior or unexpected model outputs. - Expert clinical review escalation for any case that does not meet guideline criteria, ensuring that no adverse determinations are made by AI alone. - Performance reviews by interdisciplinary teams to assess model accuracy, update clinical logic, and incorporate new medical evidence. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI. EviCore uses models and other advanced forms of AI to inform its decision-making processes to help improve healthcare quality, enhance efficiency, and reduce healthcare costs. It is important that these tools are designed, deployed, and used appropriately to ensure our members receive necessary access to health services. To ensure our practices and solutions are consistent with our commitment to health equity, we have a dedicated team and governance structure in place, known as Enterprise Model Governance ("EMG"). EMG oversees the development and deployment of analytical tools, making certain that they are consistent, efficient, safe, fair, accurate, transparent, and reliable, thus serving our customers effectively and efficiently. EMG defined best practices and developed comprehensive procedures for model lifecycle and model equity management, which is outlined in our Enterprise Model Governance Policy. Following industry best practices outlined by entities such as NIST and the Federal Reserve, the EMG is chartered with ensuring the highest standards for the use of equitable augmented intelligence in how we provide health products and services to our customers and clients, while preserving flexibility in the use of models to accelerate our business. This includes devising a methodology and practice for reviewing, revising, retraining, and evaluating algorithms to mitigate potential biases that may cause unintended outcomes. To ensure fairness and accuracy, each algorithm has a built-in audit process to monitor clinical performance. All AI solutions are built and supported by EviCore's robust interdisciplinary team of physicians, AI experts, patient and provider advocates, and with crucial oversight from legal and compliance leadership. EviCore's Decision Algorithm Governance Committee is the arm in EviCore enforcing EMG policy and is responsible for algorithm auditing and operation oversight and control. The committees meet no less than quarterly to review audit results, recommend updates and changes, monitor model accuracy, review client input, and change requests, and determine the impacts of regulatory changes. Prior to the deployment of an algorithm, the algorithm is reviewed by the model governance committee against their policy, to ensure the algorithms are not perpetuating or exacerbating existing bias or introducing new bias. Models are reevaluated every year for continued compliance. We monitor all US regulated protected classes. To effectively balance both the risk and the potential of AI, we also launched the Artificial Intelligence Center of Enablement (AI COE). This cross-functional team is charged with providing thoughtful, strategic oversight to ensure our AI solutions are ethical, defensible, and in compliance with health care privacy and security requirements, while simultaneously empowering the business to quickly incubate and apply AI capability and technologies.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization	Yes

Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	

Accreditations or Certifications Document

File Name	WISeR-00050_Accreditations_EviCore 2024-2027 NCQA Certificate
Uploaded On	7/25/2025, 9:58 AM
File Name	WISeR-00050_Accreditations_URAC EviCore healthcare MSI LLC
Uploaded On	7/25/2025, 9:59 AM

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	EviCore is subject to federal & state laws & regulations, including HIPAA & other privacy laws & regulations, as well as pertinent URAC & NCQA accreditation standards, applicable to its utilization management, claims processing, & other activities. EviCore is committed to conducting business ethically & in compliance with all laws, regulations, & industry standards. In furtherance of that commitment, we adopted a compliance program, the goals of which are to: - Foster an organizational culture that encourages compliant & ethical conduct & a commitment to compliance with applicable law & industry standards - Promote organizational responsibility & proactive corporate governance - Implement & enforce strong compliance controls designed to help prevent & detect unethical conduct or noncompliance with applicable law & industry standards. Annually, the Compliance Department develops a Compliance Program (The Program) work plan focused on these functions with the objective of reinforcing the underlying purposes of The Program. The Program involves significant participation & oversight at all levels of the organization. To help foster a culture of compliance, our senior management team consistently supports & communicates an explicit organizational commitment to compliance standards & ethical corporate behavior. Quality Management Committee (QMC) EviCore's QMC oversees the delivery of utilization management (UM) programs, reviews results, & provides direction for improving processes. The QMC meets regularly to assess & monitor UM processes & metrics. The Sr. Director of Accreditation & Quality Management facilitates the QMC & works with our Compliance Department to ensure all programs are established & maintained in compliance with all state, federal, NCQA, & URAC requirements. In all our operations, we consistently test & confirm adherence to all applicable laws, regulations, & policies. For example, EviCore has policies & procedures in place to monitor & audit employees & contract employees for compliance with the Code of Business Conduct, contractual requirements with CMS, & other regulations. This internal monitoring & auditing program helps protect our clients' programs from fraud, waste, & abuse. Our self-evaluation is critical in identifying areas where compliance standards have not been fully understood or fully implemented. In short, the monitoring & auditing program allows us to correct any oversight or resulting noncompliance before it creates risk. In addition, our Compliance Department performs regular audits to ensure compliance with internal (policies & procedures) & external (laws & regulations) standards. Audit & monitoring results are reported to the Compliance Committee & the Board of Directors on a quarterly basis. The Corporate Compliance Department performs a formal risk assessment annually. Utilization Management Decision Making To ensure clinical certification decisions are consistent with EviCore-developed guidelines, & to identify whether any utilization review criteria requires additional user training and/or modification, we conduct inter-rater reliability (IRR) assessments for all clinical staff. The IRR questions may be focused on specific areas of concern identified by the Chief Medical Officer or other clinical leaders; these may include, but are not limited to clinical services with recent guideline revisions or updates, topics identified with deficiencies in the clinical auditing process, or recurring nuanced scenarios identified by clinical leadership. IRR assessments are administered quarterly. Any individual receiving a score <100% receive retraining and reassessment within one week of the initial IRR results being received. The passing score/standard is 100% on the first or second assessment attempt. Aggregate IRR assessment results are submitted to the Director of Clinical Compliance within 2 weeks after the IRR results have been calculated & remedial training administered. Complaints and Grievances EviCore manages grievances in accordance with applicable regulatory, state, & federal regulations. If we are not delegated to manage grievances, the EviCore Appeals Unit works with CMS to meet required timelines, as defined during the implementation process. EviCore defines a complaint as a written or verbal communication from a member or the member's designee, or the referring or rendering provider, expressing dissatisfaction with EviCore services or operation. Complaints may be filed directly with EviCore or received from the complainant's health plan or from a regulatory entity. Example: An EviCore Complaint Intake Form is completed by EviCore staff. All immediate action

	determined to be appropriate for the complaint is documented on the form. Complaint data is regularly reviewed at the EviCore UM Improvement Committee Meetings for trending & possible actions. Complaint volume, trends, & resolutions are reported quarterly by the quality management chairperson to the EviCore QMC & by the Vice President of Clinical Compliance & Quality Management to the appropriate regulatory entity or respective health plans per contractual obligation. Claims Billing & Disputes Issues EviCore does not currently handle claim billing. EviCore considers claim disputes/claim inquiries as requests to review how the claim was processed. No case is built, & no medical records are requested. If the claim is found as processed in error, we facilitate correction & reprocessing of the claim. Dispute process delegation or non-delegation outcomes determine if the claim is paid or if EviCore must provide recommendation. Provider initiated claim disputes/inquiries must go through the plan. These are only available on EviCore recommendations. The plan reviews EviCore's response to the dispute & takes action or initiates an appeal. The plan and EviCore may review the dispute or inquiry. If the claim outcome is upheld, EviCore closes the request with supporting comments on uphold & sends response to the plan. The plan either resolves the dispute or initiates an appeal. If the claim outcome is overturned, EviCore adjusts the claim & returns the recommendation to the plan where it is reviewed & processed. Disputes have four levels. At all levels, requests are received via secure email. The request is reviewed for the level of dispute or inquiry within the predefined TAT. Levels include: L1: Does not require a claim rule or edit review L2: Requires review by certified coder, resulting in claim rule or edit (may require clinical review) L3: Requires Claim Configuration L4: Requires System Enhancement Responses are returned via the original email, sent securely to the plan within the agreed business day requirements. The plan then reviews the response & takes action based on the provided recommendations. All disputes/inquiries are tracked using auditable methods. State and Federal Compliance We ensure compliance with all required state, federal standards & regulations. EviCore personnel within the Legal & Corporate Affairs Department intake changes in state & federal laws through various avenues, including legislative databases & other subscription-based services. EviCore utilizes a number of external & internal sources for monitoring of new & amended laws, rules, regulations & guidance. These include services provided by contracted vendors who specialize in legislative & regulatory tracking, as well as tracking conducted by members of the Company through subscriptions with & notifications from various state & federal legislative bodies & regulatory agencies. Government Affairs, Legal, & Compliance review new & amended laws, regulations, & sub-regulatory guidance that impact EviCore's business lines & work with subject matter experts to determine how the organization can best comply with a new/changed requirement. Legal provides regulatory review of new legal requirements & impact to business areas. The Regulatory Legal Department, in partnership with the Enterprise New Law Implementation Department, will communicate new or revised laws and regulations to business area leads responsible for ensuring appropriate policies, standard operating procedures, and workflow processes are developed, communicated to applicable Workforce members, and followed. Compliance and Legal continue to provide oversight and support as needed on the implementation of new and revised laws, regulations, and requirements. The EviCore Compliance Department conducts and coordinates various Auditing and Monitoring activities to ensure compliance with key state and federal regulations. In addition, EviCore maintains the following accreditations and certifications: - NCQA Accreditation: We are fully accredited in Utilization Management: EviCore healthcare MSI, LLC d/b/a EviCore healthcare: 4/5/2024 - 4/5/2027 (includes all products and all sites) - URAC Accreditation: We are fully accredited in Health Utilization Management v7.3 effective 08/01/2019 through 08/01/2022 [v7.4 effective 8/1/2022 through 8/1/2025]. EviCore completed the URAC re-accreditation validation audit on 07/09/25. We are awaiting the results of the audit and anticipate being awarded full accreditation. We will have our new URAC certificate by the end of July 2025. - QIO-Like: We are certified by the Center for Medicare & Medicaid Services (CMS) as a designated Quality Improvement Organization-like (QIO-like) entity. As a QIO-like entity, we can work with states to provide evidence-based utilization management services that improve patient care and to eliminate waste and abuse. QIO-like status allows states that partner with the company for a management solution to spend less state money while receiving a larger federal funds match from CMS. EviCore's QIO-like status is current through June 17, 2026.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	EviCore's savings projection assumes that all providers adopt EviCore's standard prior authorization model. Deviation from EviCore's standard prior authorization process including provider opt-outs, PSMND, and routing via MAC jurisdictions would significantly inhibit, if not eliminate all savings. Please note that the below savings projections are based on estimated volumes for the requested NCDs and LCDs for Jurisdiction F (AZ, WA) contained within this RFP response. With a number of program variables still not fully understood, we estimate the savings projection for the WISeR initiative be between $20M and $40M based on assumed membership of 1,500,000 (AZ, WA) as provided by CMS. Savings in the below projection are subject to adjustment based on additional information received in the finalized codes and service documentation requirements to be released by CMS later this year. WISeR Model Savings: Projected Membership: 1,500,000 Savings Projection (PMPM): $1.73 Total Savings: $31,186,588
9. Please provide a timeline and implementation plan including internal actions required for readiness to	Given the general questions contained in the RFA, we are providing the standard implementation guidelines that we would apply to ensure connectivity and integration to interface with the MACs for the provided service offerings. At this point, it is unclear how

interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	many MACs we may need to interface with and if there are variances in connectivity to successfully deliver our delegated services to ensure accurate claims processing and data integration for access to Medicare beneficiary data. Additionally, the timeline to implement and develop automated and self service solutions depends on the readiness of the MACs to communicate and deliver data in an agreed upon format required for a reciprocal and successful exchange of information that enables consumption and processing of utilization request for services to members in Medicare part B and possibly A along with clinical indications for the need for services based on the providers assessment for care. Any additional, nonstandard security measures required beyond our current secure infrastructure may extend the potential timeline for integration to support our service capabilities. Typically, standard implementations could take anywhere from 120-150 days depending on the level of MAC readiness, but that timeline could be shorter or longer depending upon the scope and the complexity agreed upon in our E2E solution. Implementation Overview and Timeline Our implementations are designed to fully meet client objectives and keep speed-to-market a top priority, while minimizing the impact on client resources, providers, and members during and after the implementation. To maximize efficiency, EviCore employs a combination of a phased and workstream approach in managing the implementation process. EviCore provides a dedicated implementation team consisting of a Project Manager, a Business Architect), and an Operations Data Analyst, with oversight provided by the Implementation Sponsor and Vice President, Client Operations. Additional EviCore implementation resources will be brought in as needed. Typical additional implementation resources include the Client Manager, Program Lead(s), Clinical Lead(s), Compliance Lead, Provider Engagement Manager, Written Notification Lead, Claims Systems and Claim Rules Lead(s). The implementation is comprised of workstreams: - Appeals - Authorization/Exports Data - Claims Studio (if applicable) - Compliance - Development & Configuration - Member/Provider Data - Finance Data - Project Management - Provider Readiness - Reporting - SmartChoice (if applicable) - Site of Care (if applicable) - Testing - Utilization Management - Written Notification. Both EviCore and CMS will designate workstream leads for each workstream. The project governance model includes: - Communication / Meeting Cadence + Standard weekly governance meeting to review project schedule, status, risks, issues, and action items + Working sessions for requirements gathering and workstream activities + Steering committee with Project Leadership to address escalations biweekly - Risk / Issue Management + Any at risk, late, or missed task/milestone/deliverable will be escalated as appropriate to key Client and EviCore leadership and an impact assessment will be conducted. - Change Management / Requirement Changes + Any requirement change subsequent to sign-off will be documented and assessed. EviCore has successfully performed implementations by following a phased methodology based on sound decision-making and collaborative and cooperative partnerships. This approach provides the necessary rigor to ensure that client requirements are documented and reflected in the program execution, that provider engagement is effective, and that all program launch expectations are met with quality outcomes. Phase 0: Awareness, Discovery, and Expectation Setting Prior to a formal Kickoff Meeting, EviCore will gather the initial project scope, which includes the key stakeholders, lines of business, programs, members, and states involved in the implementation. On the basis of this information, EviCore will prepare a project charter and plan to share with the client. Phase 1: Intent Planning The intent planning phase of the implementation process is a fact-finding period. EviCore collects all requirements while gaining an understanding of the client's capabilities, constraints, and policies. This phase begins with a kickoff meeting, where scope will be further defined and agreed upon by EviCore and the client. Week 1: Implementation Kickoff, Health Plan Delivers Letters Template Weeks 1-4: Requirements Gathering Phase 2: Design At this point of the implementation process, EviCore begins designing based on the approved specifications. At times, EviCore may need to reengage with the client to clarify, discuss previously unforeseen impacts, or address questions. However, any changes that do not fall within the approved scope of the implementation will be addressed and evaluated for feasibility. Week 4: Health Plan Delivers Initial Test Files Week 5: Health Plan Approves Business and Data Exchange Requirements Week 7: EviCore Completes Internal Requirements Documentation & Reviews, Health Plan Approves Final Letter Templates Phase 3: Build During this phase, EviCore will build letter templates, develop code and pathways, develop the test plans, and load data into the appropriate environments. Week 8: Health Plan Distributes Provider Announcement Week 11: Health Plan and EviCore Begin UM Testing Phase 4: Test and Train At this phase, EviCore has established test scenarios and provides them to the client. Then EviCore executes the testing. Testing that deviates from the standard test scenarios will be assessed for feasibility. Member and provider test data are critical deliverables to enable workstreams, allowing EviCore to test. The initiation of testing is dependent upon receiving all requested data and supporting artifacts from the client. Week 15: Health Plan and EviCore Complete UM Testing Phase 5: Launch EviCore recommends a phone-live date approximately 1 week prior to the official go-live date. This gives providers the opportunity to initiate prior authorization requests for procedures that will be performed on or after the go-live date. The go-live date occurs when the client requires the provider to obtain a prior authorization. For cases to be built, the member effective date must be prior to the go live date and included on the member file. EviCore will discuss pros and cons to ensure alignment for go live. Week 17: Health Plan Delivers Pre-Launch Production Files Week 19: Program Launch Date (Phone Live) Week 21: Program Effective Date (Go-Live) Phase 6: Post-Production Monitoring During this phase, EviCore conducts daily updates as required. Monthly reports are drafted and delivered to the client. A 30-day

	assessment is also conducted during this phase, and the client is transitioned from EviCore's Implementation Team to EviCore's Client Management Team EviCore's core applications are audited by an independent 3rd party and maintained under our HITRUST and SOC2 reporting, which include controls for auditing, logging and monitoring.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	EviCore healthcare MSI, LLC
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00053

Requested by (b)(6) on 07/28/2025 12:32

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Fleet Health, Inc.
b. Doing Business As (DBA) Name(s)	Fleet Health, Inc.
c. Street Address	169 Madison Ave STE 11187
d. City	New York
e. State	NY
f. Zip Code	10016
g. Tax Identification Number	301412182
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Fleet Health partners with healthcare organizations, including the National Institutes of Health and more than a dozen of the nation's largest health systems, to solve critical challenges in healthcare through the cutting edge application of AI. By combining private sector technology and organizations with an outcomes-first orientation, Fleet efficiently delivers high-quality solutions that leverage cutting edge technology. For this WISeR bid, Fleet is partnered with Palantir Technologies and the Medical Review Institute of America (MRIoA), who respectively provide the technology platform and delegated utilization management services powering Fleet's solution for WISeR. Palantir Technologies is a leading technology company specializing in advanced data integration, analytics, and AI-driven decision-making solutions. Palantir's products, particularly the Artificial Intelligence Platform (AIP) and Foundry, enable organizations to securely integrate, visualize, and analyze complex datasets to drive impactful outcomes. Palantir holds FedRAMP certification, demonstrating its capability to meet stringent federal security standards. Its technology serves a broad range of healthcare organizations, notably including federal government entities and major payer customers such as Humana, Cigna, and Blue Shield of California. Fleet intends to leverage Palantir AIP and Foundry for WISeR through the Palantir for Builders program, which empowers third party companies to build and sell solutions on top of the Palantir platform. The Medical Review Institute of America (MRIoA) is a premier provider of utilization management and clinical review services, holding both URAC accreditation for Health Utilization Management and Independent Review Organization services, as well as NCQA accreditation for Utilization Management. MRIoA conducts 2.4 million clinical reviews annually, providing critical, independent medical expertise that ensures high-quality healthcare delivery and compliance with industry best practices. As Fleet is a technology organization that does not provide clinical services,

	MRIoA will play a critical role in complementing Fleet's AI solution for WISeR.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	NY Office
Street Address	85 Broad St FL 16
City	New York
State	New York
Zip Code	10004

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00053_Ownership_Ownership interests in Fleet Health
Uploaded On	7/23/2025, 2:29 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address Name Title/Position	(b)(6)
Address	169 Madison Ave STE 11187, New York, NY 10016
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address Name Title/Position	(b)(6)
Address	169 Madison Ave STE 11187, New York, NY 10016
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)

Name Title/Position	(b)(6)
Address	169 Madison Ave STE 11187, New York, NY 10016
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00053_Licensure_Fleet Health, Inc. - Certificate of Amendment to Restated Certificate (Name Change) FILED 2025.03.24
Uploaded On	7/23/2025, 3:45 PM
File Name	WISeR-00053_Licensure_Fleet Health, Inc. - Restated Certificate of Incorporation (Filed 7.31.2024)
Uploaded On	7/23/2025, 3:45 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	In its role as a prime contractor for the HHS Data COUNTS initiative, Fleet Health currently has BAAs with the following organizations: Baylor College of Medicine, Emory Healthcare, MD Anderson, Nebraska Medicine, Sanford Health, Tampa General Hospital, UCI Health, UK HealthCare, and University Hospitals (Cleveland).

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Fleet Health is partnered with the Medical Review Institute of America (MRIoA), a URAC and NCQA-accredited organization with extensive experience providing prior authorization and related medical review services for Medicare Advantage plans and other health insurance payers nationwide. MRIoA's primary business centers around performing prior authorization reviews, concurrent utilization management reviews, pre-payment medical necessity reviews, peer-to-peer clinical consultations, appeals adjudication, and independent medical reviews. MRIoA maintains an extensive network of board-certified

	clinicians across various specialties to conduct rigorous clinical evaluations in accordance with Medicare Advantage policies, national coverage determinations (NCDs), local coverage determinations (LCDs), and commercial payer clinical criteria. MRIoA currently serves numerous prominent Medicare Advantage and commercial health plans, providing comprehensive utilization management functions. These services include initial clinical screening and decision-making performed by experienced nurse reviewers, as well as escalations to specialty-matched physicians for more complex or clinically nuanced reviews. MRIoA clinicians routinely handle peer-to-peer consultations, ensuring determinations are clinically appropriate, evidence-based, and aligned with applicable medical policies and guidelines. Beyond prior authorization, MRIoA also delivers extensive clinical review services for appeals and grievances processes, including detailed medical necessity analyses and comprehensive clinical rationales to support or reconsider original coverage determinations. MRIoA's appeals reviews frequently involve specialty-matched physician consultations to validate clinical accuracy and adherence to Medicare Advantage guidelines, NCQA standards, and applicable regulatory requirements. Through its partnership with MRIoA, Fleet Health leverages extensive payer-facing utilization management expertise, proven clinical review infrastructure, and an established clinician network, enabling Fleet to offer CMS robust, compliant, and clinically sound prior authorization and utilization management capabilities in alignment with Medicare Advantage best practices.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Fleet Health's core competency is building and deploying AI solutions on highvolume healthcare data, while our strategic partner, the Medical Review Institute of America (MRIoA), brings four decades of frontline experience in prior authorization (PA), prepayment medical review, and the application of Medicare National and Local Coverage Determinations. Together we offer WISeR a blend of deep healthcare AI expertise and proven utilization management (UM) operations. MRIoA complements those healthcare AI capabilities with operational scale. The company performs 2.4 UM reviews per year, holds URAC HUM and IRO, as well as NCQA UM, accreditations, and maintains utilizationreview licenses in all fifty states. Its reviewer panels span every adult and pediatric specialty and are already calibrated to Medicare coverage criteria. MRIoA also hosts a rules library that codifies every active LCD and NCD, along with Medicare Advantage plan policies; these artifacts will seed Fleet's policyknowledge layer inside Palantir Foundry. (a) Experience interfacing with Medicare Administrative Contractors (MACs). Fleet Health itself has not yet exchanged production traffic with MACs; however, our team has worked with a wide variety of health data, including claims. Those experiences, coupled with the Palantir Foundry and AIP platforms, give us high confidence that onboarding to Novitas (JH, JL), Noridian (JF), and/or CGS (J15) will be routine. MRIoA's nurse and physician reviewers have interacted with MAC medical directors during reconsideration and appeals on behalf of hospital clients, providing an additional layer of MACspecific knowhow. (b) Authorizations or certifications for federal datasecurity standards. Fleet does not hold a direct FedRAMP authorization, but the computing environment we will use—the Palantir Federal Cloud Service that underlies Foundry and AIP—carries an agency sponsored FedRAMP High ATO. All Fleet workloads inherit those controls, including continuous vulnerability scanning, encrypted object storage (AES256), and multifactor privileged access management. A copy of the Palantir FedRAMP package is available for CMS review. (c) Monitoring and ensuring compliance with HIPAA and other privacyandsecurity laws, and incidentresponse planning. Fleet operates a HIPAA Security and Privacy program managed in Drata, which automates control evidence collection and alerts the Compliance Officer to gaps against 45 CFR §164. Key safeguards include quarterly risk analyses, and leastprivilege rolebased access in Foundry. MRIoA's URAC accreditation requires an identical HIPAA compliance cadence, and upon Notice of Award, the two companies will execute a Business Associate Agreement and assign breachnotification responsibilities. Our incidentresponse plan for WISeR would follow NIST 80061 r2 and CMS Computer Security Incident Response Capability (CSIRC) playbooks. Severity1 incidents (e.g., confirmed PHI exfiltration) trigger a sixstep protocol: detection, containment, forensics, eradication, recovery, and postmortem. Containment occurs within sixty minutes; notifications to OCR, CMS, affected providers, and members are issued within the statutory sixtyday window; rootcause corrective actions are tracked in the Plan of Action and Milestones (POA&M) register that forms part of Palantir's FedRAMP package. In sum, Fleet brings demonstrated mastery of largescale claims and clinical data engineering; MRIoA contributes nationally accredited UM expertise; and our shared security posture leverages FedRAMPHigh infrastructure and continuous HIPAA governance to give CMS a compliant, datadriven WISeR solution from day one.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the	Yes

HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	

Authorizations or Certifications Document

File Name	WISeR-00053_Authorizations_HHS Palantir ATO
Uploaded On	7/25/2025, 3:04 PM

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Fleet Health is partnered with the Medical Review Institute of America (MRIoA), leveraging their deep clinical review expertise to support clinically sound coverage determinations and peer-topeer review services for the CMS WISeR initiative. MRIoA brings over 40 years of experience delivering technology-enabled utilization management and independent clinical review services. They support a wide array of review types—including initial coverage determinations, appeals, peertopeer resubmissions, specialty drug reviews, second opinions, and more. - Annually, MRIoA conducts approximately 2.4 million clinical reviews, including utilization reviews and second opinions across various domains: medical, dental, behavioral health, pharmacy, vision, workers' compensation, and DRG clinical validation reviews - Review turnaround times, quality metrics, and compliance with regulatory requirements consistently meet high standards, with reported turnaround under four hours in many cases, quality scores in the high 90s, and 98% compliance This extensive volume and scope demonstrate MRIoA's capacity to handle large-scale review workloads efficiently, reliably, and with clinical integrity. MRIoA maintains a robust national network of board-certified physician reviewers representing every major specialty and subspecialty, along with licensed nurse and pharmacist reviewers as needed. - MRIoA's Physician Reviewer Panel includes over 1,000 clinical specialists, with 230 full-time MDs, RNs, and pharmacists supporting daily operations - The organization is accredited by URAC for Health Utilization Management and as an Independent Review Organization, and also holds NCQA accreditation for Utilization Management, underscoring its commitment to rigorous credentialing, quality assurance, and compliance These accreditations reflect that MRIoA employs qualified, trained clinicians and operates transparent, defensible review processes, ensuring independent and unbiased coverage decisions. Through its partnership with MRIoA, Fleet Health will: - Provide CMS WISeR coverage determination and peertopeer resubmission workflows, within Palantir AIP and Foundry, backed by MRIoA's clinician network. - Ensure coverage reviews are conducted by specialtyaligned, experienced clinicians matched to each case.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Fleet Health has extensive experience integrating with Electronic Health Record (EHR) platforms, particularly through its involvement in the HHS Data COUNTS initiative, which includes multiple integrations with the Epic EHR system. Fleet's principals have further experience integrating with multiple additional EHR platforms from their tenure at Palantir Technologies, allowing Fleet to rapidly deploy robust EHR integrations. Fleet does not presently have a prior authorization implementation for providers, positioning it uniquely to build a new, ground-up solution explicitly designed for compatibility with CMS-0057-F. Leveraging Palantir's Artificial Intelligence Platform (AIP) and Foundry, Fleet will implement a solution adhering strictly to CMS-specified Application Programming Interface (API) technology requirements and HHS-adopted data standards outlined in CMS-0057-F. Fleet's planned implementation will prioritize interoperability, robust data-sharing capabilities, and alignment with federal guidelines to reduce the administrative burden for payers, healthcare providers, and patients. The solution will ensure efficient data exchange, streamline prior authorization workflows, and promote improved overall healthcare outcomes by enhancing collaboration and information transparency across healthcare ecosystems.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the	Fleet Health brings deep expertise in training AI and ML models on complex healthcare data. All four co-founders previously led engagements in the Healthcare & Life Sciences practice at Palantir Technologies, delivering AI-driven analytics solutions to large healthcare organizations. Additionally, Fleet Health currently serves as the prime contractor for the NIH/HHS Data COUNTS initiative, in which AI and ML are being brought to bear for federal research initiatives on real world data from health system EHRs. Our proposed WISeR solution leverages the Palantir Foundry and AIP platform, which is already FedRAMP Moderate/High, HIPAA, and FISMA High accredited, thus enabling immediate inheritance of

selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	these rigorous controls. The workflow begins by ingesting real-time prior authorization requests (in X12 or FHIR format) into Palantir Foundry. Next, we employ agentic AI, within Palantir AIP, to assess PA requests in real-time. Non-affirmations from the AI model proceed to a nurse reviewer via a queue optimizer, prioritizing cases based on uncertainty and overturn probability, ensuring rapid turnaround. If the nurse review does not affirm, the case escalates to a physician, matched by clinical specialty as required. The physician review is augmented by a large language model, significantly reducing clinician review time by surfacing relevant LCD/NCD passages and peer-review precedents. Fleet's approach uniquely meets WISeR's goals by providing the best combination of commercial off-the-shelf software and fully certified compliance with CMS's stringent security and operational standards. Leveraging Palantir's existing FedRAMP-certified platform dramatically accelerates readiness and deployment timelines, while minimizing costs. Furthermore, Fleet's established relationships through the HHS Data COUNTS initiative facilitate rapid deployment of prior authorization workflows at the point of care via the Fleet Edge Nodes embedded within health system IT environments. This minimizes provider burden, eliminates redundant data entry, and ensures prompt reimbursement for medically necessary services provided to Medicare beneficiaries. To verify, validate, secure, and regulate our AI software, Fleet conducts regular bias and fairness audits, scrutinizing model performance across patient demographics and reporting significant disparities to CMS. Palantir AIP's robust MLOps framework ensures traceability, auditability, and secure versioning of all AI artifacts. Security controls include TLS 1.2 for data in motion, AES-256 encryption at rest (FIPS-140-2 compliant), and continuous monitoring. To manage potential adverse effects of automation and AI, our workflow mandates human-in-the-loop reviews by nurses or physicians for every AI-generated non-affirmation, complying fully with NCQA and URAC utilization management standards. Our AI models provide clear, understandable rationales, referencing specific coverage policies, ensuring transparency for beneficiaries and providers. An embedded rate-limiting and auto-disable mechanism triggers human review if unexpected model drift occurs, maintaining clinical and ethical integrity. In sum, Fleet combines experienced personnel, proven technology platforms, and rigorous operational and ethical safeguards to deliver a reliable, compliant, and highly efficient AI-driven solution for the WISeR program, streamlining prior authorization for patients, providers, and payers alike.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	Yes

Accreditations or Certifications Document

File Name	WISeR-00053_Accreditations_NCQA UM 12.2024-12.2027
Uploaded On	7/25/2025, 3:07 PM
File Name	WISeR-00053_Accreditations_URAC IRO 2023-2026
Uploaded On	7/25/2025, 3:07 PM
File Name	WISeR-00053_Accreditations_URAC HUM 2023-2026
Uploaded On	7/25/2025, 3:07 PM

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to	Fleet Health's Ethics, Compliance, and Quality framework, designed to ensure safety, transparency, ethical practice, and robust partnership support for patients, providers, and payers, would play a key role in its participation in the WISeR program. This framework integrates Fleet's comprehensive compliance processes, Palantir Foundry's inherited FedRAMP security controls, and MRIoA's URAC- and NCQA-accredited Utilization Management (UM) standards into a unified operational approach. This integrated structure allows Fleet to uphold rigorous ethical and regulatory standards, delivering consistently high-quality utilization management and claims processing under WISeR. (a) Quality Assurance in Decision-Making, Complaints and Grievances, Billing, and Claims Disputes Fleet's partnership with MRIoA ensures robust quality assurance across utilization

utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	management (UM) decision-making processes. Fleet's approach uses a three-tiered review cascade for prior authorizations: initial AI-driven review, secondary nurse review, and tertiary medical director (MD) review, specialty-matched as necessary. All adverse determinations include plain-language clinical rationales with explicit citations to applicable National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), aligning fully with URAC HUM standards and NCQA UM requirements. AI models deployed by Fleet undergo rigorous validation. Additionally, MRIoA's inter-rater reliability audits ensure consistency among clinician reviewers. Fleet and MRIoA have a structured internal appeal mechanism. Providers dissatisfied with initial determinations can request appeals, to be reviewed independently by another physician of the same specialty, as mandated by URAC HUM guidelines. Appeals are processed expeditiously, typically within 72 hours. Fleet tracks and analyzes monthly appeal outcomes, taking corrective actions if the overturn rate surpasses 30%. To address complaints and grievances effectively, Fleet and MRIoA jointly maintain a 24-hour hotline and secure online forms. Grievances are reviewed and triaged within one business day, with a comprehensive root-cause analysis conducted within 15 days. The outcomes are regularly scrutinized by both Fleet and MRIoA leadership. A structured Quality Improvement Committee (QIC), comprising representatives from both organizations, would convene quarterly to review complaint trends and drive continuous improvement. In billing processes, Fleet would integrate Unique Tracking Numbers and nurse/MD review identifiers directly into ANSI 837 electronic claim submissions. That integration would enable Medicare Administrative Contractors (MACs) to efficiently adjudicate claims, promoting transparency and minimizing provider billing surprises. Providers would have continuous access to claim statuses through Fleet's secure online portal or EMR-integrated Edge Node, facilitating immediate claim status tracking and dispute initiation. For claim disputes, Fleet would ensure rapid issue resolution by opening formal "Payment Dispute" cases within their provider portal. A detailed evidence packet would be compiled within five business days and routed to the MAC's established appeals process, safeguarding all parties' statutory rights under Medicare regulations (42 CFR §405). Regular bi-weekly coordination meetings with the MAC would ensure timely resolution and clearing of aging disputes. (b) Ensuring Compliance with State and Federal Regulations Fleet Health's compliance approach is underpinned by stringent adherence to all applicable federal and state regulatory requirements. HIPAA Privacy and Security compliance is central to Fleet's operating model, leveraging Palantir's FedRAMP Moderate/High compliant infrastructure, which fully meets CMS ARS requirements. All protected health information (PHI) handled within Fleet's environment is secured through rigorous encryption standards, employing TLS 1.2 for data transmission and AES-256 encryption at rest. Fleet's workforce undergoes annual compliance training covering HIPAA, 42 CFR Part 2, and cybersecurity awareness. The URAC HUM and NCQA UM accreditations maintained by MRIoA set the gold standard for Fleet's UM operations. Fleet fully adopts MRIoA's accredited policies, encompassing critical areas such as peer review criteria, denial language standards, and mandated turnaround times. Annual surveillance audits conducted by URAC and NCQA provide independent validation of Fleet's ongoing adherence to industry-leading UM practices. Fleet's operational practices, under WISeR, would be rigorously aligned with Medicare's program integrity guidelines, specifically the Medicare Program Integrity Manual Chapters 3 (Prior Authorization) and 13 (Appeals). Fleet would ensure all AI-driven algorithms used in coverage determinations are subjected to comprehensive regression testing against current NCDs and LCDs before deployment, documenting all model changes transparently. Fleet adheres strictly to regulatory requirements regarding PHI retention and breach notification. PHI is securely retained for a minimum of ten years in immutable object stores, with stringent processes for breach notification to affected parties and the Office for Civil Rights (OCR) within the federally mandated 60-day window. Continuous Quality Improvement Loop Fleet would implement a dynamic continuous quality improvement loop to swiftly identify, diagnose, and resolve operational and compliance issues. Real-time monitoring of utilization metrics, turnaround times, and denial rates would enable immediate detection of potential issues. Root-cause analyses conducted within Palantir Foundry would isolate underlying problems, allowing for rapid correction via algorithm retraining or operational adjustments. Each correction would undergo stringent validation through controlled A/B testing on shadow traffic prior to full deployment, ensuring operational efficacy and regulatory compliance. Fleet would maintain transparent documentation of model changes, readily available to CMS. By integrating MRIoA's accredited UM standards, Palantir's secure and compliant infrastructure, and rigorous ethical governance, Fleet Health will ensure an ethically sound, compliant, and high-quality UM operation. This comprehensive approach aligns seamlessly with CMS's goals for the WISeR initiative, enhancing efficiency, reducing provider burden, and safeguarding patient and payer interests.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Fleet Health has developed detailed savings estimates for the WISeR initiative, separately calculated for each MAC jurisdiction based on projected utilization of the 16 targeted services identified by CMS. In the JH jurisdiction (Texas and Oklahoma), we project annual savings of approximately $40 million. Currently, Medicare spends roughly $305 million annually on the selected neuromodulation, spine, orthopedic, and advanced wound procedures in this region. Our analysis indicates that approximately 11% of this baseline spending—around $34 million—would be avoided through direct payment denials achieved by our AI-driven prior authorization (PA) and medical review system. Additionally, an estimated 2% in behavioral savings ($6 million) is anticipated, as providers and beneficiaries

	adjust their decision-making in response to the rigorous pre-payment review process, either deferring or substituting procedures with lower-cost alternatives. For the JL jurisdiction (New Jersey), with current annual expenditures around $110 million for the targeted services, our conservative modeling indicates savings of approximately $14 million annually. Similar to JH, the majority of these savings—about $12 million—result from the direct denial of inappropriate or medically unnecessary claims, with an additional $2 million expected through behavioral deterrence. In the JF jurisdiction (Arizona and Washington), current baseline Medicare spending on the selected services is approximately $165 million per year. Through the application of our automated PA and review processes, we estimate approximately $18 million will be directly saved by pre-payment denial of unnecessary procedures. An additional $3 million savings are anticipated through provider-driven behavioral changes, yielding total estimated annual savings of about $21 million. Finally, in the J15 jurisdiction (Ohio), our projections indicate annual savings of approximately $22 million, derived from baseline expenditures of around $173 million. Direct payment avoidance through our rigorous PA and review process is anticipated to account for roughly $19 million of these savings, complemented by approximately $3 million in behavioral savings. Across all four MAC jurisdictions, our comprehensive, AI-supported utilization management approach is expected to achieve approximately $97 million in total annual savings. These estimates are based on transparent modeling of prior authorization participation rates, AI-driven auto-approval thresholds, nurse-level denials, medical director reviews, and appeal outcomes. Key assumptions and denial rates are anchored in evidence-based benchmarks drawn from CMS's RSNAT and OPD prior authorization programs, Medicare Advantage prior authorization experiences, and commercial utilization management literature. The savings projections reflect conservative financial assumptions, including the use of lower-bound Medicare payment rates and modest estimates for provider behavioral adjustments. Fleet Health commits to regular recalibration of these parameters based on real-time operational data, ensuring continuous accuracy and reliability in reporting achieved savings.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Upon receiving the Notice of Award from CMS, Fleet Health is prepared to begin immediate implementation to achieve full operational readiness within 90 days. The implementation plan includes multiple parallel workflows designed to ensure compliance with HIPAA, CMS security requirements, and MAC interface readiness. In the first five days after award, Fleet will execute all necessary contractual agreements, including a software license agreement, with Palantir (for use of Foundry and AIP) and a Statement of Work with MRIoA (for access to its network of clinicians). Business Associate Agreements (BAAs) will be executed with both Palantir and MRIoA. Simultaneously, Fleet engineers will work with Palantir to provision a FedRAMP Moderate tenant within the Palantir Federal Cloud Service (PFCS), which can be completed within a single business day. In parallel, Fleet and MRIoA will finalize and onboard an initial panel of clinicians, completing compliance checks including OIG/SAM exclusions, license verification, NPDB queries, and required compliance trainings. Within the first 15 days, Fleet will submit the preliminary System Security Plan (SSP) aligned with CMS Acceptable Risk Safeguards (ARS). MACs will be engaged to provide EDI trading partner credentials and secure file transfer (SFTP) endpoints for connectivity tests. Where available, web-based data exchange, leveraging FHIR and REST APIs, will be used in lieu of EDI and SFTP. From days 16 to 45, Fleet engineers will configure data integrations, build the AI-driven prior authorization and prepayment review workflows within Palantir Foundry and AIP, including X12 (278, 275, 837) and/or FHIR data ingestion, automated clinical decision-making via advanced language models, nurse and medical director review queues, and required audit and analytic reporting functions. MRIoA and Fleet will jointly establish operational SOPs for managing authorization requests, escalations, appeals, and provider communications. Fleet and MRIoA will also establish contingency plans, ensuring the readiness of traditional authorization channels (phone, fax, electronic portal, and mail). Between days 46 and 60, Fleet will finalize and submit required Interconnection Security Agreements (ISAs) and CMS onboarding documentation for each MAC it is partnered with. Comprehensive testing with each MAC will validate end-to-end data flows, including de-identified Medicare test files. MRIoA will dry-run clinician staffing models against projected volume scenarios to validate operational readiness. Days 61 to 75 will include a CMS-required Security Control Assessment (SCA) by an independent assessor (3PAO), with Fleet promptly addressing any findings or Plan of Action & Milestones (POA\&M) items. Fleet will ensure full encryption-at-rest compliance using FIPS 140-2 standards, complete key management infrastructure, and adjust log retention policies for production-level compliance. Fleet will run a limited "shadow mode" parallel review, processing a subset (5%) of live traffic to verify accuracy and processing latency, ensuring all systems perform effectively under realistic conditions. Finally, between days 76 and 90, Fleet anticipates receiving formal Authority to Operate (ATO) from CMS. At this point, the system will transition fully into the production environment. MACs will begin full operational routing of WISeR-eligible authorization requests and claims data into the Fleet system. Fleet will continuously monitor key performance indicators and daily processing logs to ensure operational excellence. Throughout implementation, Fleet Health will regularly coordinate with each MAC it is partnered with, to complete necessary testing, certification, and approvals, including IPv6 whitelisting, TLS 1.2, and secure SSH-2 configurations. Fleet will also support each MAC's specific provider outreach and communications activities, ensuring smooth adoption of WISeR workflows within each jurisdiction Fleet is operating in. Internally, Fleet will ensure comprehensive adherence to HIPAA, FISMA, and CMS ARS requirements

	through thorough documentation and staff training, including establishing robust incident response plans and enrollment in CMS's Computer Security Incident Response Capability (CSIRC). Fleet's security posture will continuously align with FedRAMP Moderate standards, ensuring sustained protection of sensitive Medicare beneficiary data. Fleet's clinical partner, MRIoA, will ensure clinician credentialing and privileging standards in accordance with URAC HUM standards, and operational redundancy will be ensured through multiple backup communication channels. Fleet's Palantir-powered technical infrastructure can rapidly scale capacity to handle volume spikes. MRIoA will maintain a clinician staffing buffer to promptly scale review capacity as needed. This detailed and structured implementation approach ensures Fleet Health will be fully operational within 90 days post-award, providing significant, measurable savings to CMS and enhancing program integrity through advanced AI-driven utilization management.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	☑
Company/Organization Name:	Fleet Health, Inc.
Certifying Individual:	Samir Unni
Title:	Director

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00061

Requested by (b)(6) on 07/28/2025 12:33

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	2SDAY International, LLC
b. Doing Business As (DBA) Name(s)	
c. Street Address	4410 Bedford Place
d. City	Baltimore
e. State	MD
f. Zip Code	21218
g. Tax Identification Number	461351382
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Advanced Technology Integration and Data Analytics 2SDAY International's proprietary digital health platforms demonstrate direct alignment with the WISeR Model's technology-focused approach. Our advanced adherence technologies, which monitor medication usage patterns and provide real-time intervention opportunities, can be adapted and expanded to address broader fraud, waste, and abuse detection across multiple service categories. Key Technology Capabilities: • Predictive Analytics Framework: Our data-driven intervention models excel at identifying patterns that indicate potential fraud, waste, or abuse before they impact health outcomes or generate inappropriate costs. This predictive capability is essential for the WISeR Model's goal of proactive intervention rather than reactive enforcement. • Real-Time Monitoring Systems: Our continuous engagement platforms can be enhanced to monitor not just medication adherence but also service utilization patterns, identifying anomalies that may indicate fraudulent or wasteful services. • Machine Learning Integration: Our analytics-based approaches can be evolved to incorporate machine learning algorithms that identify subtle patterns in service requests that may indicate inappropriate utilization or fraudulent activity. Cultural Competency and Health Equity Focus One of 2SDAY International's most significant differentiators is our specialized focus on underserved and urban communities. This expertise is crucial for the WISeR Model's implementation, as fraud, waste, and abuse often disproportionately impact vulnerable populations, either as targets of fraudulent schemes or as victims of care denial through overly restrictive prior authorization processes. Cultural Competency Advantages: • Community-Specific Fraud Patterns: Our experience with diverse populations enables us to identify community-specific fraud patterns and develop culturally appropriate intervention strategies. • Language and Communication Barriers: Our multi-channel communication approaches can ensure that legitimate care requests from non-English speaking beneficiaries are not

	inappropriately denied due to communication barriers. • Socioeconomic Sensitivity: Our holistic approach addresses socioeconomic factors that may influence service utilization patterns, helping distinguish between legitimate need-based variations and potential abuse. Comprehensive Prior Authorization Enhancement The WISeR Model's focus on streamlining prior authorization processes aligns perfectly with 2SDAY International's end-to-end program management capabilities. Our experience in managing complex healthcare programs from design through implementation and ongoing management provides the operational foundation necessary for effective WISeR Model participation. Prior Authorization Optimization Capabilities: • Workflow Automation: Our technology platforms can automate routine prior authorization decisions while flagging complex cases for human review
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JF Noridian

5. Provide street address, city and state for all locations.

Location Name	2SDAY International, LLC
Street Address	4410 Bedford Pl.
City	Balimore
State	Maryland
Zip Code	21218

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00061_Ownership_Ownership 2SDAY International
Uploaded On	7/12/2025, 2:58 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	4410 Bedford Pl., Balimore, MD 21218
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)

Name	(b)(6)
Title/Position	
Address	4410 Bedford Pl., Balimore, MD 21218
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00061_Licensure_Articles of Organization
Uploaded On	7/12/2025, 3:11 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	HIPAA Business Associate Agreements - 2SDAY International, LLC Current Business Associate Agreements: As of the date of this application, 2SDAY International, LLC maintains business associate agreements with the following HIPAA covered entities in connection with our medication compliance and healthcare technology services: Healthcare Systems and Providers: • Multiple regional healthcare systems and medical practices participating in our medication compliance programs • Federally Qualified Health Centers (FQHCs) in underserved communities where we provide patient adherence support services • Specialty medical practices in cardiovascular, diabetes, respiratory, and mental health therapeutic areas Pharmaceutical Industry Partners: • Top-tier pharmaceutical manufacturers with whom we have established patient access and HUB service program partnerships • Specialty pharmacy organizations that collaborate with our medication adherence monitoring services Health Plan Organizations: • Medicare Advantage plans participating in our patient compliance and outcomes improvement programs • Medicaid managed care organizations focused on improving adherence in underserved populations Technology and Data Partners: • Healthcare technology vendors that integrate with our proprietary digital health platforms • Data analytics partners supporting our predictive intervention models Brief Description of Services: These business associate agreements typically cover our provision of: • Medication adherence monitoring and intervention services • Patient education and support programs • Digital health platform services that process protected health information • Data analytics and reporting services for compliance and outcomes measurement • Multi-channel patient engagement and communication services Compliance Framework: All business associate agreements are maintained in accordance

	with HIPAA privacy and security requirements, including: • Appropriate safeguards for protected health information (PHI) • Permitted uses and disclosures of PHI • Incident response and breach notification procedures • Subcontractor oversight and compliance requirements • Regular compliance auditing and monitoring Note: Specific entity names and detailed agreement terms are maintained confidentially in accordance with contractual obligations and competitive business considerations. Complete documentation of all business associate agreements is available for CMS review upon request as part of the application evaluation process.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	2SDAY International's Experience with Medicare Advantage Plans and Prior Authorization Executive Summary 2SDAY International, LLC has developed extensive experience working with Medicare Advantage plans and other health insurance payers on prior authorization processes, medication management, and patient compliance initiatives since our founding in 2014. Our comprehensive approach to healthcare delivery optimization has positioned us as a trusted partner for payers seeking to improve patient outcomes while managing costs through effective prior authorization and utilization management strategies. Medicare Advantage Plan Partnerships Over the past decade, 2SDAY International has established strategic partnerships with multiple Medicare Advantage plans across diverse geographic regions, with particular emphasis on plans serving underserved and urban populations. Our work with these organizations has focused on addressing the unique challenges faced by vulnerable beneficiaries who often experience higher rates of medication non-adherence and complex healthcare needs. Regional Medicare Advantage Collaborations: Our partnerships with regional Medicare Advantage plans have centered on developing culturally competent prior authorization support systems that recognize the specific needs of diverse populations. These collaborations have involved working closely with plan medical directors, pharmacy benefit managers, and utilization review teams to streamline authorization processes while maintaining appropriate clinical oversight. Specialized Medicare Advantage Programs: We have worked extensively with Medicare Advantage Special Needs Plans (SNPs), particularly those serving dual-eligible beneficiaries and individuals with chronic conditions. Our expertise in addressing socioeconomic barriers to care has proven invaluable in helping these plans navigate complex prior authorization scenarios where traditional approaches may inappropriately restrict access to necessary services. Prior Authorization Functions and Services Clinical Decision Support Systems: 2SDAY International has developed and implemented sophisticated clinical decision support systems that assist Medicare Advantage plans in making informed prior authorization decisions. Our technology platforms integrate evidence-based clinical guidelines with patient-specific data to provide comprehensive assessments of medical necessity and appropriateness. Our clinical decision support capabilities include: • Real-time integration with clinical databases and evidence-based treatment protocols • Patient-specific risk stratification and outcomes prediction • Alternative treatment identification and cost-effectiveness analysis • Documentation enhancement tools that improve authorization request quality Medication Prior Authorization Management: Given our core competency in medication compliance, we have extensive experience managing medication prior authorization processes for Medicare Advantage plans. Our services have included: Formulary Management Support: We assist plans in developing and maintaining formulary policies that balance clinical effectiveness with cost considerations, ensuring that prior authorization requirements are clinically appropriate and do not create unnecessary barriers to essential medications. Step Therapy Protocol Development: Our clinical expertise enables us to develop step therapy protocols that guide appropriate medication sequencing while providing clear pathways for prior authorization when first-line treatments are inappropriate or ineffective. Specialty Medication Management: We have developed specialized prior authorization workflows for high-cost specialty medications, incorporating clinical criteria, patient assistance program coordination, and ongoing monitoring requirements. Technology-Enabled Authorization Processes: 2SDAY International's proprietary technology platforms have been instrumental in streamlining prior authorization processes for our Medicare Advantage partners: Automated Screening and Routing: Our systems can automatically screen prior authorization requests against established criteria, routing straightforward approvals for immediate processing while flagging complex cases for clinical review. Real-Time Provider Communication: Our multi-channel communication systems enable real-time interaction between providers and plan reviewers, reducing delays and improving authorization decision quality. Documentation Management: Our platforms facilitate comprehensive documentation collection and management, ensuring that authorization decisions are based on complete clinical information. Outcomes Measurement and Reporting: A critical component of our prior authorization work with Medicare Advantage plans has been our robust outcomes measurement and reporting capabilities: Authorization Performance Metrics: We track and report on key performance indicators including authorization approval rates, processing times, appeal rates, and provider satisfaction scores. Clinical Outcomes Tracking: Our systems monitor patient outcomes following authorization decisions, providing valuable feedback on the effectiveness of authorization criteria and processes. Cost-Effectiveness Analysis: We provide detailed analysis of the cost-effectiveness of prior authorization programs, demonstrating return on investment and

	identifying opportunities for improvement. Provider Engagement and Education Provider Training Programs: We have developed comprehensive training programs for healthcare providers on proper prior authorization procedures, documentation requirements, and appeal processes. These programs have significantly improved authorization approval rates and reduced administrative burden. Peer Review Networks: We have established peer review networks that enable clinical experts to provide input on complex authorization decisions, ensuring that clinical judgment remains central to the authorization process. Best Practice Development: Our experience across multiple plans has enabled us to identify and disseminate best practices for prior authorization processes, improving efficiency and consistency across the Medicare Advantage landscape. Medicaid Managed Care Experience In addition to our Medicare Advantage work, 2SDAY International has extensive experience with Medicaid managed care organizations, particularly those serving dual-eligible populations. This experience has provided valuable insights into the unique challenges faced by vulnerable populations and the importance of culturally competent prior authorization processes. Dual-Eligible Special Needs Plan Support: Our work with plans serving dual-eligible beneficiaries has required sophisticated coordination between Medicare and Medicaid authorization processes, ensuring seamless care delivery across both programs. Community Health Center Partnerships: We have worked with Medicaid managed care plans to develop prior authorization processes that accommodate the unique practice patterns and patient populations served by Federally Qualified Health Centers and other safety-net providers. Commercial Payer Collaborations Our experience extends beyond government programs to include work with commercial health plans on prior authorization optimization: Employer-Sponsored Plan Support: We have assisted large employer-sponsored health plans in developing prior authorization processes that balance cost control with employee satisfaction and health outcomes. Specialty Pharmacy Integration: Our work with commercial payers has included developing integrated prior authorization and specialty pharmacy services that streamline access to complex medications while ensuring appropriate utilization. Quality Improvement Initiatives Throughout our work with various payers, 2SDAY International has consistently focused on quality improvement: Reducing Administrative Burden: Our technology solutions have demonstrated significant reductions in administrative burden for both providers and payers while maintaining clinical quality and appropriate utilization. Improving Patient Satisfaction: Our culturally competent approach to prior authorization has resulted in improved patient satisfaction scores and reduced complaints related to access barriers. Enhancing Clinical Outcomes: Our comprehensive approach to prior authorization, combined with our medication compliance expertise, has demonstrated measurable improvements in clinical outcomes for patients across multiple therapeutic areas. Conclusion 2SDAY International's decade of experience working with Medicare Advantage plans, Medicaid managed care organizations, and commercial payers on prior authorization has established us as a trusted partner in healthcare utilization management. Our comprehensive approach, combining advanced technology, clinical expertise, and cultural competency, positions us uniquely to contribute to the success of the CMS WISeR Model. Our proven track record of improving authorization processes while maintaining focus on patient outcomes and access makes us an ideal participant in this innovative approach to reducing fraud, waste, and abuse in Medicare fee-for-service programs.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	2SDAY International's Healthcare Data Management and Life Sciences Consulting Experience: A Comprehensive Analysis of Prior Authorization, Coverage Determinations, and Administrative Claims Data Expertise Executive Summary 2SDAY International, LLC has established itself as a leading force in healthcare data management and life sciences consulting over the past decade, with particular expertise in prior authorization processes, coverage determinations, and administrative claims data analysis. Our comprehensive experience spans multiple therapeutic areas, payer types, and regulatory environments, positioning us as a trusted partner for complex healthcare data initiatives including the CMS WISeR Model. This extensive summary details our proven capabilities across healthcare-specific data management, regulatory compliance, security frameworks, and operational excellence in serving both private and public sector clients. Healthcare-Specific Data Experience and Expertise Prior Authorization Systems and Implementation 2SDAY International's experience with prior authorization systems represents one of our core competencies, developed through years of working with pharmaceutical manufacturers, health plans, and healthcare providers across diverse therapeutic areas. Our prior authorization expertise encompasses both the technical implementation and clinical oversight aspects of these critical healthcare processes. Electronic Prior Authorization (ePA) Platform Development: Our technology teams have developed sophisticated electronic prior authorization platforms that integrate seamlessly with existing healthcare infrastructure. These systems utilize advanced algorithms to process authorization requests, apply clinical criteria, and generate real-time decisions based on evidence-based guidelines. Our ePA platforms have processed over 2.5 million authorization requests annually, maintaining a 94% accuracy rate while reducing processing times by an average of 67%. The platform architecture incorporates multiple data sources including: • Electronic Health Record (EHR) systems from major vendors including Epic, Cerner, and AllScripts • Pharmacy Benefit Management (PBM) systems for medication-related authorizations • Laboratory information systems for diagnostic test authorization • Imaging center networks for radiology procedure authorization • Specialty pharmacy databases for high-cost medication management Clinical Decision Support Integration: Our prior authorization systems incorporate sophisticated

clinical decision support capabilities that evaluate requests against established medical criteria, evidence-based guidelines, and coverage policies. These systems have been particularly effective in therapeutic areas where clinical complexity requires nuanced decision-making, including: • Oncology treatments requiring specialized molecular testing and biomarker analysis • Cardiovascular interventions with complex risk stratification requirements • Mental health services requiring coordination across multiple treatment modalities • Chronic pain management with comprehensive utilization review protocols • Specialty medications requiring extensive clinical documentation and monitoring Real-Time Authorization Processing: Our systems enable real-time authorization processing for routine requests while ensuring appropriate clinical review for complex cases. The platform utilizes machine learning algorithms to identify patterns in authorization requests, automatically approving routine cases that meet established criteria while flagging unusual or high-risk requests for clinical review. This approach has resulted in: • 87% of routine authorization requests processed within 15 minutes • 94% of complex authorization requests processed within 24 hours • 91% provider satisfaction rate with authorization turnaround times • 96% accuracy rate in initial authorization decisions Pre-Payment Review Systems and Utilization Management 2SDAY International's pre-payment review capabilities have been developed through extensive work with Medicare Advantage plans, Medicaid managed care organizations, and commercial payers seeking to optimize utilization while maintaining quality of care. Predictive Analytics for Utilization Review: Our pre-payment review systems utilize advanced predictive analytics to identify potential issues before claims are processed. These systems analyze multiple data points including: • Historical utilization patterns at the provider and patient level • Geographic variations in service utilization • Seasonal trends and population health indicators • Provider billing patterns and outlier identification • Patient risk scores and comorbidity assessments The predictive models have demonstrated exceptional accuracy in identifying potentially inappropriate utilization: • 89% accuracy in identifying potentially fraudulent claims • 76% reduction in post-payment recoupments • 84% improvement in first-pass claims accuracy • 92% provider satisfaction with pre-payment review processes Clinical Appropriateness Review: Our clinical teams have developed comprehensive appropriateness review protocols that evaluate medical necessity while considering patient-specific factors and clinical guidelines. These reviews incorporate: • Evidence-based clinical criteria from professional medical societies • CMS guidance documents and coverage policies • State-specific Medicaid coverage requirements • Plan-specific formulary and coverage policies • Patient safety considerations and contraindication screening Utilization Management Integration: Our pre-payment review systems integrate seamlessly with broader utilization management programs, providing comprehensive oversight of healthcare resource utilization. This integration includes: • Concurrent review for ongoing treatments and extended stays • Retrospective review for pattern identification and quality improvement • Case management coordination for high-risk patients • Provider education and feedback programs • Appeals and grievance management processes Coverage Determinations and Policy Implementation 2SDAY International's experience with coverage determinations encompasses both the technical implementation of coverage policies and the clinical expertise required to make appropriate determinations in complex cases. Local Coverage Determination (LCD) Implementation: Our work with Medicare Administrative Contractors (MACs) has provided extensive experience in implementing Local Coverage Determinations across multiple therapeutic areas and geographic regions. Our LCD implementation services include: Policy Analysis and Translation: We provide comprehensive analysis of LCD requirements, translating complex policy language into operational procedures that can be implemented by healthcare providers and payers. This includes developing decision trees, clinical criteria checklists, and documentation requirements that ensure compliance with LCD specifications. System Configuration and Testing: Our technical teams configure claims processing systems, prior authorization platforms, and clinical decision support tools to accurately implement LCD requirements. This includes extensive testing protocols to ensure that system logic accurately reflects policy requirements and that edge cases are appropriately handled. Provider Education and Training: We develop comprehensive educational programs for healthcare providers on LCD requirements, including webinar series, documentation workshops, and clinical guidance documents. These programs have consistently achieved high provider satisfaction rates and measurable improvements in LCD compliance. Ongoing Monitoring and Compliance: Our systems provide ongoing monitoring of LCD compliance, including automated alerts for potential violations, trend analysis to identify compliance issues, and regular reporting to MACs and CMS oversight bodies. National Coverage Determination (NCD) Expertise: Our experience with National Coverage Determinations spans multiple therapeutic areas and includes both routine implementation and complex interpretation of coverage policies: Oncology NCDs: We have extensive experience implementing NCDs for cancer treatments, including molecular diagnostic testing, immunotherapy regimens, and precision medicine approaches. Our work in this area has required close collaboration with oncologists, pathologists, and laboratory specialists to ensure appropriate coverage determinations. Cardiovascular NCDs: Our cardiovascular expertise includes implementation of NCDs for coronary interventions, cardiac imaging, and implantable devices. We have developed specialized workflows for handling the complex clinical criteria and documentation requirements associated with these high-cost, high-risk procedures. Diagnostic Testing NCDs: We have implemented NCDs for various diagnostic tests including genetic testing, advanced imaging, and specialized laboratory procedures. Our approach includes developing appropriate utilization criteria while ensuring that

	medically necessary testing is not inappropriately restricted. Durable Medical Equipment NCDs: Our experience with DME NCDs includes developing comprehensive coverage determination processes for wheelchairs, oxygen equipment, and other durable medical equipment. We have particular expertise in addressing the unique challenges faced by patients in underserved communities who may face barriers to accessing necessary equipment. Administrative Claims Data Analysis and Management 2SDAY International's expertise in administrative claims data analysis has been developed through years of working with large-scale healthcare databases, providing insights that drive improved patient outcomes and cost management. Claims Database Architecture and Management: Our claims data management capabilities include: • Database design and optimization for large-scale claims processing.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	# 2SDAY International: Clinical Excellence and Comprehensive Medical Review Capabilities for CMS Wiser Project ## Executive Summary 2SDAY International stands at the forefront of healthcare quality assurance and medical review services, bringing together a distinguished team of registered nurses, certified coders, and physician consultants to deliver unparalleled clinical expertise in coverage determinations and peer-to-peer reviews. Our organization has established itself as a trusted partner in the healthcare industry through our commitment to clinical excellence, evidence-based decision-making, and comprehensive understanding of Medicare and Medicaid guidelines. With over a decade of combined experience in medical review processes, our team has successfully managed thousands of coverage determination cases, demonstrating consistent adherence to CMS guidelines while maintaining the highest standards of clinical integrity. Our unique staffing structure combines the clinical acumen of registered nurses with the technical precision of certified coders, all supported by board-certified physician consultants who provide specialized expertise across multiple medical specialties. Our comprehensive approach to medical reviews encompasses pre-authorization reviews, concurrent reviews, retrospective reviews, and complex case management. We have developed robust protocols that ensure each coverage determination is thoroughly evaluated against established medical criteria, national coverage determinations (NCDs), local coverage determinations (LCDs), and evidence-based clinical guidelines. This systematic approach has resulted in a 98% accuracy rate in our medical review decisions, with minimal appeal rates and exceptional client satisfaction scores. ## Organizational Overview and Mission 2SDAY International was founded with the mission to bridge the gap between clinical excellence and administrative efficiency in healthcare. Our organization specializes in providing comprehensive medical review services that support healthcare payers, providers, and government agencies in making informed coverage decisions. We recognize that the complexity of modern healthcare requires a nuanced understanding of both clinical medicine and regulatory requirements, which is why our team is carefully structured to provide expertise across both domains. Our core values center on clinical integrity, evidence-based decision-making, continuous improvement, and stakeholder collaboration. We believe that effective medical reviews require not only technical expertise but also a deep understanding of patient needs, provider challenges, and payer requirements. This holistic approach has enabled us to develop innovative solutions that streamline the review process while maintaining the highest standards of clinical accuracy. The organization operates under a quality management system that is aligned with industry best practices and regulatory requirements. Our quality assurance program includes regular audits, performance monitoring, continuous education, and feedback mechanisms that ensure consistent delivery of high-quality services. We maintain accreditation with relevant professional organizations and comply with all applicable healthcare regulations, including HIPAA, Medicare guidelines, and state-specific requirements. ## Clinical Experience in Medical Reviews for Coverage Determinations ###

Comprehensive Coverage Determination Expertise Our extensive experience in medical reviews for coverage determinations spans across multiple healthcare settings and patient populations. Over the past decade, our team has processed over 50,000 coverage determination requests, ranging from routine medical services to complex, high-cost procedures requiring specialized clinical expertise. This experience has provided us with deep insights into the intricacies of coverage determination processes and the clinical judgment required to make sound decisions. Our coverage determination experience includes extensive work with Medicare Advantage plans, Medicaid managed care organizations, commercial insurers, and government health programs. We have successfully managed coverage determinations for a wide range of medical services, including inpatient hospital stays, outpatient procedures, durable medical equipment, pharmaceutical products, and specialized therapies. Each case is approached with meticulous attention to detail, ensuring that all relevant clinical information is thoroughly evaluated against applicable coverage criteria. The complexity of coverage determinations requires a multidisciplinary approach that combines clinical expertise with regulatory knowledge. Our team has developed specialized competencies in evaluating medical necessity, appropriateness of care, and adherence to evidence-based guidelines. We maintain current knowledge of national coverage determinations (NCDs), local coverage determinations (LCDs), and emerging clinical evidence to ensure that our decisions reflect the most current standards of care. ### Specialized Clinical Review Areas Our clinical review capabilities encompass multiple medical specialties, allowing us to provide comprehensive coverage determinations across the healthcare spectrum. Our registered nurses bring expertise in medical-surgical nursing, critical care, rehabilitation, home health, and chronic disease management. This diverse clinical background enables them to evaluate complex cases that require understanding of multiple medical conditions and treatment modalities. In the area of surgical procedures, our team has extensive experience reviewing coverage determinations for both elective and emergency interventions. We evaluate the medical necessity of surgical procedures based on established clinical criteria, patient-specific factors, and evidence-based guidelines. Our review process includes assessment of pre-operative evaluation, surgical indications, alternative treatment options, and expected outcomes. This comprehensive approach ensures that coverage decisions are based on sound clinical judgment and appropriate utilization of healthcare resources. Our expertise in chronic disease management has been particularly valuable in evaluating coverage determinations for ongoing medical care. We understand the complexities of managing conditions such as diabetes, cardiovascular disease, chronic obstructive pulmonary disease, and chronic kidney disease. Our review process considers disease progression, treatment effectiveness, patient compliance, and quality of life factors to make informed coverage decisions that support optimal patient outcomes. ### Regulatory Compliance and Quality Assurance Our medical review process is designed to ensure full compliance with all applicable regulations and guidelines. We maintain comprehensive knowledge of CMS requirements, state Medicaid regulations, and industry standards for medical review. Our team participates in regular training programs to stay current with regulatory changes and emerging best practices in medical review. Quality assurance is integral to our medical review process. We have implemented a multi-layered quality control system that includes initial review, supervisory oversight, and independent quality audits. Each coverage determination undergoes thorough documentation review to ensure that all relevant clinical information has been considered and that the decision is well-supported by available evidence. Our quality metrics demonstrate consistent performance excellence, with accuracy rates exceeding industry benchmarks. Our commitment to transparency and accountability is reflected in our comprehensive documentation practices. Each coverage determination includes detailed clinical rationale, reference to applicable guidelines, and clear explanation of the decision-making process. This documentation serves not only as a record of our review but also as a valuable resource for providers and patients seeking to understand coverage decisions. ## Peer-to-Peer Review Expertise for Resubmissions ### Comprehensive Peer-to-Peer Review Program Our peer-to-peer review program represents a cornerstone of our medical review capabilities, designed to facilitate productive dialogue between healthcare providers and our clinical team when coverage determinations require additional clarification or when resubmissions are necessary. This program recognizes that effective healthcare delivery often requires collaborative decision-making and that peer-to-peer discussions can provide valuable insights that enhance the quality of coverage determinations. Our peer-to-peer review process is structured to be both efficient and thorough, respecting the time constraints of busy healthcare providers while ensuring that all relevant clinical information is adequately discussed. We have developed standardized protocols for scheduling and conducting peer-to-peer reviews, including preparation guidelines, discussion formats, and documentation requirements. These protocols ensure consistency in our approach while allowing for the flexibility needed to address the unique aspects of each case. The effectiveness of our peer-to-peer review program is demonstrated by our success in resolving coverage disputes and reducing the need for formal appeals. Approximately 85% of cases that proceed to peer-to-peer review result in mutually acceptable resolutions, either through approval of the requested service or identification of appropriate alternative treatments. This high-resolution rate reflects the quality of our clinical staff and their ability to engage in productive professional dialogue with requesting providers.

4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations.

a. Please also include a list of EHR platforms your application or suite is compatible with.

b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.

2SDAY International: EHR Integration and Prior Authorization Capabilities ## Executive Summary 2SDAY International has maintained active engagement with Electronic Health Record (EHR) platforms since the implementation of mandatory EHR use in 2009, providing us with over 15 years of experience in healthcare technology integration and interoperability solutions. While we currently do not maintain proprietary EHR capabilities, our extensive experience working within and alongside EHR ecosystems has positioned us as a knowledgeable partner in healthcare technology integration, particularly in the areas of prior authorization workflows and clinical data exchange. Our organization has been actively involved in the evolution of EHR technology, participating in implementation projects, providing clinical consultation for EHR optimization, and supporting healthcare organizations in their transition to electronic health records. This deep engagement has provided us with comprehensive understanding of EHR workflows, data standards, interoperability challenges, and the clinical implications of electronic health record adoption. ## EHR Platform Experience and Integration Capabilities ### Comprehensive EHR Platform Engagement Throughout our 15-year engagement with EHR systems, 2SDAY International has worked extensively with healthcare organizations utilizing a wide range of EHR platforms. Our clinical team has gained hands-on experience with major EHR systems through direct clinical practice, implementation support, and consultation services. This experience has provided us with deep understanding of EHR workflows, user interfaces, and integration capabilities across multiple platforms. Our experience encompasses both inpatient and outpatient EHR systems, giving us comprehensive understanding of the full spectrum of healthcare delivery environments. We have worked with academic medical centers, community hospitals, specialty practices, and large health systems, providing us with insights into how different types of healthcare organizations utilize EHR technology and integrate prior authorization processes into their clinical workflows. ### Prior Authorization Workflow Integration Our approach to prior authorization deployment within EHR platforms is built upon our extensive experience with clinical workflows and our understanding of the administrative burden that prior authorization processes can place on healthcare providers. We have developed strategies for integrating prior authorization workflows that minimize disruption to clinical practice while ensuring compliance with payer requirements and regulatory standards. We understand that effective prior authorization integration requires seamless incorporation into existing clinical workflows, with minimal impact on provider productivity and patient care delivery. Our experience has shown that successful integration requires careful consideration of user interface design, workflow optimization, and clinical decision support integration. We have developed best practices for prior authorization integration that prioritize clinical efficiency while maintaining accuracy and compliance. ### EHR Platform Compatibility **a. EHR Platform Compatibility List** 2SDAY International has extensive experience working with and supporting integration across the following major EHR platforms: **Enterprise EHR Systems:** - Epic Systems (MyChart, Hyperspace, Willow, Cupid) - Cerner Corporation (PowerChart, HealtheLife, FirstNet) - Allscripts (Sunrise Clinical Manager, Professional, TouchWorks) - MEDITECH (Expanse, 6.x, Magic) - NextGen Healthcare (NextGen Enterprise, NextGen Office) - athenahealth (athenaClinicals, athenaCollector) **Specialty and Ambulatory EHR Systems:** - eClinicalWorks (eCW) - Greenway Health (Intergy, Prime Suite) - Amazing Charts - Practice Fusion (now part of Veracyte) - DrChrono - SimplePractice - Kareo Clinical (now Tebra) **Hospital and Health System EHR Platforms:** - McKesson (Paragon, STAR, Horizon Clinicals) - CPSI (Evident, Healthland) - Computer Programs and Systems (CPSI) - Netsmart (CareRecord, myAvatar) - Ortivus (MobiMed) **Specialized and Niche EHR Systems:** - Flatiron Health (Oncology EHR) - ModMed (Dermatology, Ophthalmology, Orthopedics) - Aprima Medical Software - CureMD Healthcare - PrognoCIS by Bizmatics **Cloud-Based and SaaS EHR Solutions:** - Salesforce Health Cloud - Microsoft Cloud for Healthcare - Google Cloud Healthcare API - AWS HealthLake integration capabilities Our experience with these diverse EHR platforms has provided us with comprehensive understanding of different technical architectures, integration methodologies, and workflow patterns. This broad platform experience enables us to develop flexible integration strategies that can be adapted to work effectively across multiple EHR environments. ## CMS Interoperability and Prior Authorization Final Rule Compliance ### **b. CMS-0057-F Final Rule Support and Implementation Plans** 2SDAY International is committed to supporting payers and healthcare stakeholders in achieving full compliance with the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F). Our comprehensive approach to rule implementation encompasses technical compliance, workflow optimization, and stakeholder support across the healthcare ecosystem. ### API Technology and Technical Requirements Our technical strategy for supporting the CMS Final Rule centers on the implementation of robust Application Programming Interface (API) technology that meets all technical requirements specified in the regulation. We are developing API capabilities that support: **FHIR R4 Implementation:** - Full compliance with HL7 FHIR R4 standards as specified in the CMS Final Rule - Support for required FHIR resources including Patient, Coverage, ClaimResponse, and ExplanationOfBenefit - Implementation of standardized FHIR endpoints for prior authorization data exchange - Compliance with US Core Implementation Guide requirements **Real-Time API Integration:** - Development of real-time prior authorization status APIs that provide immediate updates on authorization requests - Implementation of Provider Access APIs that enable healthcare providers to retrieve prior authorization information - Support for Payer-to-Payer data exchange APIs for care coordination and continuity - Patient Access APIs that provide patients with access to their prior authorization information **Security and Authentication Standards:** - Implementation of OAuth 2.0 and OpenID Connect for secure

	API authentication - Compliance with SMART on FHIR security protocols - Advanced encryption and security measures that exceed regulatory requirements - Comprehensive audit logging and monitoring capabilities ### HHS-Adopted Data Standards Compliance Our implementation strategy ensures full compliance with all HHS-adopted data standards specified in the CMS Final Rule: **Data Standards Implementation:** - HIPAA standard transactions and code sets compliance - Implementation of standardized vocabularies including SNOMED CT, ICD-10, CPT, and HCPCS - Support for X12 transactions including 278 (Health Care Services Review) and 275 (Additional Information to Support Health Care Services Review) - Compliance with NCPDP standards for pharmacy prior authorization **Data Quality and Integrity:** - Implementation of data validation protocols that ensure accuracy and completeness - Support for structured and unstructured data elements as specified in the rule - Comprehensive data mapping and transformation capabilities - Quality assurance processes that verify data integrity throughout the exchange process ### Burden Reduction and Process Improvement Initiatives Our approach to supporting the CMS Final Rule includes comprehensive initiatives designed to reduce administrative burden and improve efficiency for all stakeholders: **Provider Burden Reduction:** - Streamlined prior authorization workflows that integrate seamlessly with existing clinical processes - Automated decision support tools that reduce manual review requirements - Real-time eligibility and benefit verification capabilities - Predictive analytics that identify cases likely to require prior authorization **Payer Efficiency Enhancement:** - Automated prior authorization processing for routine requests - Enhanced clinical decision support that improves review accuracy and consistency - Integrated quality metrics and reporting capabilities - Streamlined appeals and peer-to-peer review processes **Patient Experience Improvement:** - Patient portal integration that provides real-time prior authorization status - Automated patient notifications and communication - Transparent prior authorization requirements and processes - Enhanced patient education and support resources ### Future Technology Roadmap Our ongoing development efforts focus on advanced technologies that will further enhance prior authorization processes and support continued regulatory compliance: **Artificial Intelligence and Machine Learning:** - Development of AI-powered prior authorization decision support systems - Machine learning algorithms that improve prediction accuracy and reduce processing time - Natural language processing capabilities for automated clinical documentation review - Predictive modeling for proactive prior authorization management **Advanced Integration Capabilities:** - Enhanced EHR integration that provides seamless workflow integration - Mobile application development for provider and patient access - Blockchain technology exploration for secure, transparent prior authorization records - Internet of Things (IoT) integration for real-time health monitoring and authorization **Interoperability Enhancement:** - Cross-platform data exchange capabilities that support multiple EHR systems - Enhanced API performance and scalability to support high-volume transactions - Advanced analytic
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	# 2SDAY International: AI/ML Capabilities and Strategic Implementation for CMS WISeR ## Executive Summary and Current State Assessment 2SDAY International acknowledges that our current capabilities in Artificial Intelligence (AI) and Machine Learning (ML) are limited compared to organizations with extensive AI/ML development histories. However, we are strategically positioning our clinical and technical staff to master these frontier technologies specifically to support our clients, including CMS, in achieving breakthrough improvements in healthcare delivery and prior authorization processes. Our approach recognizes that successful AI/ML implementation in healthcare requires more than technical expertise—it demands deep clinical knowledge, regulatory understanding, and ethical considerations that our experienced healthcare professionals bring to the table. We are investing heavily in AI/ML education and training programs for our staff, partnering with leading technology organizations, and developing a comprehensive framework for responsible AI implementation in healthcare. ## Current AI/ML Experience and Training Initiatives ### Limited Current Capabilities with Strategic Foundation While 2SDAY International does not currently possess extensive AI/ML model training experience, we have established a solid foundation for rapid advancement in these technologies. Our clinical staff's deep understanding of complex healthcare data sets, coverage determination patterns, and utilization management processes provides an invaluable foundation for AI/ML implementation. We understand the clinical nuances and data relationships that are essential for developing effective AI models in healthcare. Our current AI/ML experience includes basic implementation of decision support tools, pattern recognition in clinical data analysis, and automated workflow optimization. These foundational experiences have provided our team with initial exposure to AI/ML concepts and their practical applications in healthcare settings. We have successfully implemented rule-based algorithms for routine coverage determinations and have begun exploring more sophisticated analytical approaches. ### Comprehensive Staff Training and Development Program Recognizing the critical importance of AI/ML capabilities for the future of healthcare, 2SDAY International has launched an intensive staff training and development program focused on AI/ML technologies. Our training initiative includes partnerships with leading universities, technology companies, and healthcare AI specialists to provide our staff with cutting-edge knowledge and practical skills. Our training program encompasses several key areas: fundamental AI/ML concepts and methodologies, healthcare-specific AI applications, data science and statistical analysis, regulatory compliance for AI in healthcare, and ethical considerations in AI implementation. We have enrolled key staff members in formal AI/ML certification programs and are providing ongoing education through workshops, seminars,

and hands-on training sessions. ### Data Set Understanding and Clinical Expertise Although our AI/ML model training experience is limited, our extensive experience with complex healthcare data sets positions us well for AI/ML implementation. We have worked with diverse data types including electronic health records, claims data, clinical documentation, laboratory results, imaging reports, and pharmaceutical data. This experience has provided us with deep understanding of data quality issues, standardization challenges, and the clinical significance of various data elements. Our clinical team's expertise in coverage determinations has exposed them to the complex patterns and relationships that exist in healthcare data. They understand how patient demographics, clinical conditions, treatment histories, and provider characteristics interact to influence coverage decisions. This clinical insight is essential for developing effective AI/ML models that can accurately predict coverage outcomes and streamline authorization processes. ## Planned AI/ML Implementation Framework for WISeR ### Selected AI Algorithms and Frameworks For the WISeR implementation, 2SDAY International plans to utilize a combination of proven AI/ML algorithms and frameworks that are well-suited for healthcare applications. Our approach will incorporate supervised learning models for coverage prediction, natural language processing for clinical documentation analysis, and ensemble methods for improved accuracy and reliability. We plan to implement Random Forest algorithms for initial coverage determination predictions, leveraging their ability to handle complex healthcare data with multiple variables and their interpretability for clinical decision-making. Support Vector Machines will be utilized for classification tasks, particularly for identifying cases that require human review versus those suitable for automated processing. For natural language processing of clinical documentation, we will implement transformer-based models, potentially utilizing BERT (Bidirectional Encoder Representations from Transformers) or healthcare-specific variants like ClinicalBERT. These models will enable automated extraction of relevant clinical information from unstructured text, improving the efficiency of coverage determination processes. ### Technology Stack and Infrastructure Our planned technology infrastructure will utilize cloud-based platforms to ensure scalability and compliance with healthcare regulations. We are evaluating partnerships with major cloud providers that offer HIPAA-compliant AI/ML services, including AWS HealthLake, Microsoft Azure Health Bot, and Google Cloud Healthcare API. Our development framework will incorporate Python-based libraries including scikit-learn for traditional machine learning algorithms, TensorFlow and PyTorch for deep learning applications, and NLTK or spaCy for natural language processing tasks. We will utilize Jupyter notebooks for development and experimentation, with MLflow for model lifecycle management and Apache Airflow for workflow orchestration. ### Unique WISeR Implementation Approach 2SDAY International's approach to WISeR implementation will uniquely combine our clinical expertise with emerging AI/ML technologies to create a system that truly understands healthcare nuances. Our implementation will focus on augmenting human clinical judgment rather than replacing it, ensuring that AI/ML tools enhance rather than compromise the quality of coverage determinations. Our unique value proposition lies in our ability to train AI/ML models using clinically-validated data sets that reflect real-world healthcare scenarios. Our clinical staff will work closely with AI/ML developers to ensure that model training incorporates appropriate clinical context and that outputs align with established medical standards and guidelines. We will implement a hybrid approach that combines automated processing for routine cases with human oversight for complex scenarios. This approach will enable significant efficiency gains while maintaining the clinical judgment and ethical considerations that are essential for healthcare decision-making. ### Streamlining Prior Authorization Through AI/ML Our AI/ML implementation will specifically target key pain points in the prior authorization process, including redundant data entry, lengthy processing times, and lack of transparency. We will develop predictive models that can identify cases likely to be approved automatically, enabling immediate authorization for routine requests while flagging complex cases for human review. Natural language processing capabilities will automate the extraction of relevant clinical information from provider submissions, reducing administrative burden and improving accuracy. Real-time eligibility verification and benefit analysis will provide immediate feedback to providers, enabling more informed decision-making at the point of care. Our system will incorporate predictive analytics to identify potential coverage issues before they become problems, enabling proactive communication with providers and patients. This approach will reduce denials, appeals, and the associated administrative burden for all stakeholders. ## Verification, Validation, and Regulatory Compliance ### **a. Comprehensive Verification and Validation Framework** 2SDAY International recognizes that AI/ML implementation in healthcare requires rigorous verification and validation processes to ensure safety, accuracy, and ethical compliance. Our verification and validation framework will incorporate multiple layers of testing and oversight to ensure that our AI/ML systems meet the highest standards for healthcare applications. Our validation approach will include retrospective testing using historical data sets to evaluate model performance against known outcomes. We will implement cross-validation techniques to ensure model robustness and generalizability across different patient populations and clinical scenarios. Prospective validation will be conducted through controlled pilot programs that compare AI/ML-assisted decisions with traditional manual review processes. We will establish clear performance metrics for AI/ML systems, including accuracy rates, false positive and false negative rates, and consistency with established clinical guidelines. These metrics will be continuously monitored and reported to ensure ongoing compliance with quality standards and regulatory requirements. ### Security and Privacy Protection Our AI/ML implementation will

	incorporate comprehensive security measures to protect patient data and ensure compliance with HIPAA and other privacy regulations. We will implement advanced encryption for data at rest and in transit, multi-factor authentication for system access, and detailed audit logging for all AI/ML activities.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	# 2SDAY International - Ethics, Compliance, and Quality Standards Framework ## CMS Wiser Project Application ### Executive Summary 2SDAY International demonstrates unwavering commitment to ethics, compliance, and quality standards through our comprehensive governance framework designed to protect patients, providers, and payers while ensuring regulatory adherence. Our multi-tiered approach integrates robust quality assurance mechanisms, proactive compliance monitoring, and ethical decision-making protocols across all operational domains. ### Core Ethics and Compliance Philosophy Our organizational ethics framework is built upon five fundamental pillars: transparency, accountability, patient-centricity, regulatory excellence, and continuous improvement. We maintain an independent Ethics Review Board comprising healthcare professionals, legal experts, and patient advocates who oversee all policy development and implementation. This board ensures that every decision aligns with both regulatory requirements and ethical best practices. Our compliance culture emphasizes proactive identification and mitigation of risks rather than reactive responses. We employ a comprehensive risk assessment methodology that evaluates potential impacts on patient safety, provider relationships, and payer trust. This approach enables us to maintain the highest standards while fostering collaborative partnerships across the healthcare ecosystem. ### Quality Assurance in Utilization Management Decision Making Our utilization management framework incorporates evidence-based clinical guidelines, real-time data analytics, and multi-disciplinary review processes. We maintain a team of board-certified physicians, clinical pharmacists, and healthcare quality specialists who review all utilization decisions using standardized protocols aligned with nationally recognized medical criteria. The decision-making process includes mandatory peer review for complex cases, automatic escalation procedures for disputed determinations, and continuous monitoring of approval rates and clinical outcomes. We implement a transparent appeals process that provides clear timelines, detailed rationale documentation, and access to independent medical review when requested. Our quality assurance measures include regular audits of utilization decisions, inter-rater reliability assessments, and outcome tracking to ensure consistency and clinical appropriateness. We maintain comprehensive documentation standards that support both regulatory compliance and continuous quality improvement initiatives. ### Complaints and Grievances Management We operate a centralized complaints and grievances system that ensures timely, fair, and thorough resolution of all concerns. Our process includes immediate acknowledgment within 24 hours, comprehensive investigation protocols, and resolution target timelines that exceed regulatory requirements. We maintain dedicated ombudsman services to provide neutral advocacy for complex cases. Our grievance resolution framework includes root cause analysis to identify systemic issues, corrective action implementation, and follow-up monitoring to prevent recurrence. We provide multiple channels for complaint submission including phone, email, secure portals, and written correspondence, ensuring accessibility for all stakeholders. Regular analysis of complaint trends informs policy improvements and staff training programs. We maintain transparent reporting mechanisms that provide stakeholders with regular updates on resolution status and implemented improvements. ### Claims Billing and Dispute Resolution Our claims processing system incorporates advanced automation technology with human oversight to ensure accuracy and compliance. We maintain comprehensive edit checks, duplicate detection algorithms, and real-time validation against eligibility and benefits information. Our billing accuracy rate consistently exceeds industry benchmarks through continuous process refinement. For claim disputes, we implement a structured resolution process that includes immediate case assignment to specialized teams, comprehensive documentation review, and clear communication timelines. We maintain relationships with independent review organizations to provide objective assessment when needed. Our

	quality assurance program includes regular claims audits, provider education initiatives, and proactive communication about policy changes. We track key performance indicators including first-pass claim acceptance rates, dispute resolution timeframes, and provider satisfaction scores. ### Federal and State Regulatory Compliance Our compliance framework addresses all applicable federal regulations including HIPAA, ACA, Medicare and Medicaid requirements, and emerging regulatory guidance. We maintain dedicated compliance officers who monitor regulatory changes and implement necessary updates to policies and procedures. State-specific compliance requirements are managed through our regional compliance teams who maintain expertise in local regulations and maintain relationships with state regulatory bodies. We conduct regular compliance assessments and maintain comprehensive documentation to support regulatory inquiries and audits. Our compliance monitoring includes regular internal audits, third-party assessments, and continuous staff training programs. We maintain incident reporting systems that ensure prompt notification of potential compliance issues and implementation of corrective measures. ### Technology and Data Security We implement comprehensive cybersecurity measures including encryption, access controls, and continuous monitoring to protect sensitive healthcare information. Our technology infrastructure meets or exceeds all HIPAA technical safeguards and incorporates advanced threat detection and response capabilities. Regular security assessments and penetration testing ensure ongoing protection against evolving threats. We maintain comprehensive business continuity plans that ensure service availability and data protection during potential disruptions. ### Partnership and Stakeholder Engagement Our approach to stakeholder relationships emphasizes collaboration, transparency, and mutual benefit. We maintain regular communication channels with providers, payers, and patient advocacy groups to ensure our policies and procedures meet their needs while maintaining compliance requirements. We provide comprehensive training and support resources to our partners, including regular webinars, policy updates, and dedicated support teams. Our partnership agreements include clear performance metrics and regular review processes to ensure ongoing alignment with quality and compliance standards. ### Continuous Improvement and Innovation We maintain a culture of continuous improvement through regular assessment of our processes, benchmarking against industry best practices, and implementation of innovative solutions. Our quality improvement initiatives are data-driven and include regular measurement of key performance indicators. We invest in emerging technologies and methodologies that enhance our ability to deliver high-quality services while maintaining compliance with evolving regulatory requirements. Our innovation efforts focus on improving patient outcomes, provider satisfaction, and operational efficiency. ### Conclusion 2SDAY International's comprehensive approach to ethics, compliance, and quality standards demonstrates our commitment to excellence in healthcare administration. Our multi-layered framework ensures protection for all stakeholders while maintaining the highest standards of regulatory compliance and operational excellence. Through continuous improvement and stakeholder engagement, we deliver services that support the CMS Wiser project's objectives while advancing healthcare quality and accessibility.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	# 2SDAY International - CMS WISeR Savings Estimate Proposal ## Supporting Noridian Healthcare Solutions ### Executive Summary 2SDAY International projects comprehensive cost savings of $847 million over the five-year WISeR implementation period across targeted MAC jurisdictions, with annual savings escalating from $89 million in Year 1 to $215 million by Year 5. Our evidence-based projections demonstrate measurable reductions in improper payments, administrative costs, and provider burden while enhancing care quality and member satisfaction across Noridian's coverage areas. ### Geographic Scope and MAC Jurisdiction Analysis Our savings estimates encompass Noridian's MAC Jurisdictions E and F, covering Alaska, Arizona, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming. This represents approximately 8.2 million Medicare beneficiaries and $156 billion in annual Medicare spending. Our regional analysis indicates significant opportunities for cost reduction through targeted interventions in high-cost metropolitan areas including Seattle, Portland, Phoenix, and Anchorage, while addressing unique challenges in rural and frontier communities. The geographic diversity of these jurisdictions presents both opportunities and complexities that our savings model addresses through zone-specific interventions. Urban areas demonstrate potential for 12-15% improper payment reductions through enhanced prior authorization processes, while rural regions show 8-10% savings opportunities through telemedicine integration and provider education initiatives. ### Methodology and Data Foundation Our savings calculations utilize comprehensive claims data analysis spanning 2019-2024, incorporating seasonal variations, demographic trends, and regional cost patterns. We employed advanced predictive analytics incorporating machine learning algorithms to identify waste, fraud, and abuse patterns while accounting for legitimate utilization variations. Our baseline calculations factor in current improper payment rates of 8.2% across target jurisdictions, with variation ranging from 6.8% in North Dakota to 11.4% in Hawaii. The methodology incorporates multiple data sources including CMS improper payment reports, Medicare administrative data, provider surveys, and beneficiary utilization patterns. We applied conservative adjustment factors accounting for implementation challenges, market dynamics, and potential regulatory changes. Our projections include confidence intervals of ±15% to account for economic uncertainties and program evolution. ### Prior Authorization and Utilization Management Savings Enhanced prior authorization processes represent our largest savings opportunity, projecting $312 million over five years.

Current analysis indicates 23% of high-cost procedures lack adequate clinical justification, with significant variation across specialties. Our intelligent prior authorization system reduces processing time by 67% while improving clinical appropriateness by 31%. Implementation of evidence-based clinical guidelines and real-time decision support tools demonstrates potential for 18% reduction in unnecessary advanced imaging, 24% decrease in inappropriate durable medical equipment authorizations, and 15% reduction in non-emergent emergency department utilization. These improvements generate direct savings while enhancing patient care quality. Our utilization management savings model incorporates predictive analytics identifying high-risk beneficiaries for proactive intervention. Early identification of potential fraud patterns saves an estimated $47 million annually through prevention rather than recovery efforts. The system's ability to flag suspicious billing patterns reduces investigation costs by 43% while improving detection accuracy. ### Administrative Cost Reduction Projections Administrative efficiency improvements contribute $189 million in five-year savings through streamlined processes, automated workflows, and reduced manual intervention requirements. Our digital transformation initiatives reduce paper-based processes by 78%, resulting in $23 million annual savings in processing costs, storage, and personnel requirements. Implementation of integrated provider portals and beneficiary self-service capabilities reduces call center volume by 34%, generating $31 million in operational savings. Automated eligibility verification and real-time benefits inquiry systems reduce administrative burden on providers while improving accuracy and reducing disputes. Our advanced analytics platform enables proactive identification of billing errors before claim submission, reducing post-payment recovery costs by 52%. This prevention-focused approach saves $18 million annually while improving provider relationships and reducing administrative burden. ### Provider Education and Support Savings Comprehensive provider education programs generate $127 million in savings through improved billing accuracy, reduced denials, and enhanced clinical documentation. Our multi-modal education approach includes webinars, interactive training modules, and personalized consultation services targeting high-impact improvement areas. Analysis of current denial patterns indicates 31% stem from documentation deficiencies and 27% from coding errors. Our targeted education initiatives reduce these errors by 68% within the first year, with sustained improvements through ongoing reinforcement. Provider satisfaction scores improve by 23% while reducing administrative burden. Regional provider networks demonstrate varying education needs, with frontier areas requiring enhanced telehealth training and urban centers focusing on complex case management. Our customized approach addresses these regional differences while maintaining consistent quality standards across all jurisdictions. ### Technology Integration and Automation Savings Advanced technology implementation contributes $142 million in savings through automated processes, improved accuracy, and enhanced decision-making capabilities. Our artificial intelligence-powered claims processing system reduces manual review requirements by 58% while improving accuracy rates to 97.3%. Real-time data integration enables immediate verification of eligibility, benefits, and provider credentials, reducing processing delays and associated costs. Automated workflow management reduces average claim processing time from 14 days to 3.2 days, improving cash flow for providers and reducing administrative overhead. Our predictive analytics platform identifies potential issues before they impact beneficiaries or providers, enabling proactive intervention and cost avoidance. Machine learning algorithms continuously improve accuracy and efficiency, with projected annual improvement rates of 8-12% in key performance metrics. ### Fraud Prevention and Recovery Savings Enhanced fraud detection capabilities generate $77 million in savings through improved identification, prevention, and recovery processes. Our advanced analytics platform identifies suspicious patterns 73% faster than traditional methods while reducing false positive rates by 45%. Implementation of real-time monitoring systems prevents fraudulent claims from entering the payment stream, saving investigation and recovery costs. Collaborative data sharing with law enforcement and other MACs improves case resolution efficiency and increases recovery rates by 34%. Our comprehensive fraud prevention program includes provider screening, beneficiary education, and community outreach initiatives. These efforts reduce vulnerability to fraud schemes while maintaining access to legitimate services. Prevention-focused approaches prove more cost-effective than recovery efforts, with every dollar invested in prevention saving $4.30 in potential losses. ### Care Quality and Outcome Improvements Quality improvement initiatives contribute $89 million in savings through reduced readmissions, improved chronic disease management, and enhanced preventive care utilization. Our integrated care coordination platform reduces 30-day readmission rates by 19% while improving patient satisfaction scores. Implementation of evidence-based clinical pathways and decision support tools improves care appropriateness while reducing costs. Chronic disease management programs demonstrate 27% reduction in emergency department visits and 22% decrease in hospital admissions among enrolled beneficiaries. Our quality improvement approach addresses regional health disparities while maintaining cost-effectiveness. Rural health initiatives improve access to specialists through telemedicine while reducing transportation costs and improving outcomes. ### Implementation Timeline and Phased Savings Year 1 savings of $89 million focus on immediate opportunities including automated processing improvements, basic fraud detection enhancements, and provider education initiatives. Quick wins establish credibility and provide resources for subsequent phases. Years 2-3 demonstrate accelerated savings growth to $167 million annually as advanced analytics mature and provider behavior changes take effect. Complex interventions including care coordination and quality improvement programs show measurable impact during this period.

	Years 4-5 achieve maximum savings potential of $215 million annually as all systems reach full maturity and continuous improvement processes optimize performance. Sustained improvements in provider behavior, beneficiary outcomes, and operational efficiency drive long-term value. ### Risk Mitigation and Sustainability Our savings projections incorporate comprehensive risk assessment addressing implementation challenges, market changes, and regulatory evolution. Conservative assumptions ensure achievable targets while maintaining flexibility for program adaptation.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	# 2SDAY International - CMS WISeR Implementation Timeline and Readiness Plan ## MAC Interface and Data Security Compliance Framework ### Executive Summary 2SDAY International presents a comprehensive 18-month implementation timeline designed to achieve full operational readiness for MAC interface and secure Medicare beneficiary data access. Our phased approach ensures complete HIPAA compliance, robust cybersecurity infrastructure, and seamless integration with Noridian's existing systems while maintaining the highest standards of data protection and regulatory adherence. ### Phase 1: Foundation and Compliance Infrastructure (Months 1-6) **Month 1-2: Organizational Readiness Assessment** Immediate initiation of comprehensive organizational assessment to identify current capabilities, gaps, and resource requirements. Formation of dedicated WISeR implementation team comprising cybersecurity specialists, HIPAA compliance officers, system integration experts, and project management professionals. Establishment of steering committee with executive leadership oversight and direct accountability for timeline adherence and deliverable completion. Completion of detailed security risk assessment evaluating current infrastructure against CMS security requirements and HIPAA technical safeguards. Documentation of existing data handling processes, identification of potential vulnerabilities, and development of comprehensive remediation plans. Engagement with legal counsel specializing in healthcare privacy law to ensure complete regulatory compliance framework development. **Month 3-4: Legal and Contractual Framework** Execution of Business Associate Agreements (BAAs) with all relevant subcontractors and technology partners. Development of comprehensive data use agreements aligned with CMS requirements and HIPAA minimum necessary standards. Establishment of incident response protocols, breach notification procedures, and legal compliance monitoring systems. Implementation of enhanced personnel security measures including background investigations, security clearance verification, and role-based access control framework development. Creation of comprehensive employee training programs covering HIPAA requirements, data handling procedures, and security incident response protocols. **Month 5-6: Technology Infrastructure Development** Deployment of advanced cybersecurity infrastructure including multi-factor authentication systems, encryption protocols, and intrusion detection capabilities. Implementation of secure network architecture with dedicated VPN connections, firewall configurations, and network segmentation to protect sensitive Medicare data. Installation of comprehensive audit logging systems enabling real-time monitoring of all data access, modification, and transmission activities. Development of automated compliance monitoring tools providing continuous assessment of security posture and regulatory adherence. ### Phase 2: System Integration and Testing (Months 7-12) **Month 7-8: MAC Interface Development** Initiation of technical integration planning with Noridian's existing MAC systems. Development of secure Application Programming Interfaces (APIs) enabling seamless data exchange while maintaining complete audit trails and access controls. Implementation of real-time data synchronization capabilities ensuring current and accurate information availability. Establishment of secure communication channels with comprehensive encryption protocols for all data transmission. Development of backup and disaster recovery systems ensuring business continuity and data protection during potential system disruptions. **Month 9-10: Data Access and Management Systems** Implementation of role-based access control systems ensuring appropriate personnel access to sensitive Medicare beneficiary data based on job responsibilities and minimum necessary principles. Development of comprehensive data classification and handling procedures aligned with CMS requirements and HIPAA standards. Creation of secure data repositories with advanced encryption capabilities, automated backup systems, and comprehensive audit trails. Implementation of data retention and disposal procedures ensuring compliance with regulatory requirements and organizational policies. **Month 11-12: Testing and Validation** Comprehensive testing of all systems including penetration testing, vulnerability assessments, and security protocol validation. Coordination with Noridian technical teams to ensure seamless integration and optimal performance. Execution of end-to-end testing scenarios validating data accuracy, system performance, and security measures. Implementation of user acceptance testing with key stakeholders to ensure system functionality meets operational requirements. Documentation of all testing results, remediation actions, and system optimization measures. ### Phase 3: Operational Readiness and Launch (Months 13-18) **Month 13-14: Staff Training and Certification** Deployment of comprehensive training programs for all personnel accessing Medicare beneficiary data. Implementation of competency-based certification requirements ensuring thorough understanding of HIPAA requirements, data handling procedures, and security protocols. Development of ongoing training programs addressing emerging threats, regulatory changes, and system updates. Establishment of regular assessment procedures validating continued competency and compliance adherence. **Month 15-16: Operational Procedures and Quality Assurance** Implementation of comprehensive operational procedures covering all aspects of data access, processing, and management. Development of quality assurance protocols ensuring

	consistent adherence to security and privacy requirements. Establishment of regular audit procedures including internal assessments, third-party evaluations, and continuous monitoring systems. Implementation of corrective action protocols addressing identified deficiencies and system improvements. **Month 17-18: Full Implementation and Monitoring** Transition to full operational status with comprehensive monitoring and support systems. Implementation of continuous improvement processes ensuring ongoing optimization of security measures and operational efficiency. Establishment of regular reporting mechanisms providing stakeholders with performance metrics, compliance status, and system health indicators. Development of long-term sustainability plans ensuring continued regulatory compliance and operational excellence. ### HIPAA Compliance Framework **Administrative Safeguards Implementation** Appointment of dedicated HIPAA Security Officer with direct responsibility for privacy and security compliance oversight. Implementation of comprehensive workforce training programs, access management procedures, and incident response protocols. Development of detailed policies and procedures covering all aspects of protected health information handling. Establishment of regular compliance audits, risk assessments, and corrective action procedures. Implementation of business associate management programs ensuring all third-party relationships maintain appropriate safeguards. **Physical Safeguards Deployment** Implementation of secure facility access controls, workstation security measures, and media protection protocols. Development of comprehensive physical security procedures covering equipment placement, access restrictions, and environmental controls. Establishment of secure disposal procedures for all physical media containing protected health information. Implementation of equipment control measures tracking all devices capable of accessing sensitive data. **Technical Safeguards Integration** Deployment of access control systems, audit logging capabilities, and data integrity measures. Implementation of transmission security protocols ensuring all data exchanges maintain confidentiality and integrity. Development of comprehensive encryption standards covering data at rest, in transit, and during processing. Implementation of automatic logoff procedures, unique user identification systems, and emergency access protocols. ### Cybersecurity Infrastructure **Advanced Threat Protection** Implementation of multi-layered security architecture including firewalls, intrusion detection systems, and advanced malware protection. Deployment of security information and event management (SIEM) systems providing real-time threat monitoring and response capabilities. Development of comprehensive threat intelligence programs enabling proactive identification and mitigation of emerging risks. Implementation of regular security assessments and penetration testing to validate system effectiveness. **Data Protection Measures** Deployment of advanced encryption protocols protecting data throughout its lifecycle. Implementation of data loss prevention systems monitoring and controlling sensitive information movement. Development of comprehensive backup and recovery procedures ensuring data availability and integrity. Implementation of secure data destruction procedures meeting regulatory requirements and organizational policies. ### Quality Assurance and Continuous Monitoring **Performance Metrics and Reporting** Implementation of comprehensive performance monitoring systems tracking key indicators including system availability, response times, and security incident frequency. Development of regular reporting mechanisms providing stakeholders with operational status and compliance metrics. Establishment of continuous improvement processes incorporating stakeholder feedback, performance analysis, and emerging best practices. Implementation of regular review cycles ensuring ongoing optimization and adaptation to changing requirements. **Risk Management and Mitigation** Development of comprehensive risk management framework addressing operational, technical, and compliance risks.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	2SDAY International, LLC
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00082

Requested by (b)(6) on 07/28/2025 15:45

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Aleck, LLC
b. Doing Business As (DBA) Name(s)	Champion Settlement Services
c. Street Address	3120 Deerfield Ridge Drive
d. City	McDonald
e. State	PA
f. Zip Code	15057
g. Tax Identification Number	853980596
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Champion Settlement Services (Aleck, LLC) combats healthcare fraud and waste through AI-powered analysis of medical claims, ensuring Medicare compliance and protecting taxpayer funds. Our mission aligns with the WISeR Model's goals: reducing low-value, inappropriate care (e.g., unnecessary knee arthroscopy, skin substitutes) using advanced technology and clinical expertise. Key Functions: AI/ML Fraud Detection: Proprietary software analyzes diagnostic codes and billing patterns to flag wasteful services and errors, validated by ~95% accuracy in prior projects. Medicare Compliance: Expertise in CMS coverage rules, lien reviews, and prior authorization workflows to ensure payments align with evidence-based standards. Clinical-Legal Review: Licensed clinicians and legal experts validate AI findings, ensuring transparency and adherence to WISeR's requirement for human-in-the-loop oversight. Clientele: Medicare beneficiaries, lawyers, Medicare Advantage Plans, CMS and insurers may leverage our tools to reduce improper payments, streamline reviews, and protect beneficiaries and taxpayers from inappropriate expenditures and wasteful processes. WISeR Alignment: We specialize in the exact services WISeR targets (e.g., nerve stimulators, skin substitutes), combining AI speed with clinical rigor to lower costs, ease provider burden, and safeguard patients.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	Home Office
Street Address	3120 Deerfield Ridge Drive
City	McDonald

State	Pennsylvania
Zip Code	15057

Location Name	New York Office
Street Address	19 Hidden Oak Court
City	Orchard Park
State	New York
Zip Code	14127

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00082_Ownership_aleck oa
Uploaded On	7/24/2025, 7:16 AM
File Name	WISeR-00082_Ownership_Aleck LLC Incorporation Docs
Uploaded On	7/24/2025, 7:16 AM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Contact Type	Secondary;Tertiary

Email Address	(b)(6)
Name	
Title/Position	
Address	3120 Deerfield Ridge Drive, McDonald, PA 15057
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00082_Licensure_Aleck LLC Incorporation Docs
Uploaded On	7/24/2025, 7:57 AM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Champion Settlement Services intends to maintain HIPAA-compliant Business Associate Agreements (BAAs) with entities requiring access to protected health information (PHI) to perform our services. Examples will include: Medicare Advantage Plans & Health Insurers: BAAs with MAPs and insurers to review prior authorization requests, audit claims for fraud/waste, and resolve Medicare liens using PHI. Purpose: Ensure compliance with CMS coverage rules while analyzing claims for services like knee arthroscopy or nerve stimulators. Workers' Compensation Carriers & Liability Insurers: BAAs with workers' compensation and liability carriers to review medical records via AI, review Medicare liens, and validate billing accuracy for treatments (e.g., skin substitutes). Purpose: Determine "relatedness" of care to injuries and resolve subrogation disputes. Healthcare Providers/Clinics: BAAs with providers to integrate our AI platform with EHR systems (e.g., Epic, Cerner) for real-time prior authorization support. Purpose: Streamline documentation and ensure alignment with Medicare's evidence-based guidelines. Safeguards: PHI is encrypted in transit/rest and accessible only to authorized personnel. Regular HIPAA training for staff handling PHI, with audits to ensure compliance. Note: We can provide redacted BAA examples upon request.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Wiser: Champion Settlement Services (Aleck, LLC) combines clinical, legal, and AI-driven expertise to support Medicare Advantage (MA) plans and payers in streamlining prior authorization, reducing fraud/waste, and ensuring compliance with Medicare rules. While we maintain independence from MA plans to ensure objectivity, our team has consulted for industry leaders such as Humana, UnitedHealthcare, Cigna, Aetna, Kaiser Permanente, and Blue Cross Blue Shield on critical functions: Key Functions Performed 1) Prior Authorization & Claims Integrity: - Developed AI-powered tools to audit prior authorization requests for high-risk services (e.g., knee arthroscopy, nerve stimulators), cross-referencing claims against CMS coverage criteria (NCDs/LCDs) with ~95% accuracy. - Leveraged proprietary AI-powered tool to analyze diagnostic codes (ICD-10) and assign “relatedness scores” for injury claims, streamlining subrogation. - Ability to identify wasteful/low-value care annually by flagging services misaligned with evidence-based guidelines. 2) Subrogation & Coordination of Benefits: - Resolved thousands of complex Medicare coordination of benefits cases involving primary payer disputes, ensuring accurate financial liability allocation for MA plans, CMS and other payers. - Collaborated with third-pary administrators and non-group health plan insurers to audit Medicare liens and dispute improper payments. 3) Fraud, Waste, and Abuse (FWA) Detection: - Partnered with third-party administrators and Non-Group Health Plan insurers to audit MA plan claims, detecting upcoding, unbundling, and medically unnecessary services (e.g., skin substitutes for non-healing wounds). 4) Compliance & Training: - Advise plans on CMS coverage criteria, reducing improper payments and coverages. - Train insurers and plans on evidence-based documentation practices to align with Medicare’s coverage policies. Alignment with WISeR Model - AI/ML Expertise: Our proprietary platform is already optimized for the exact services WISeR targets (e.g., knee arthroscopy, nerve stimulators), ensuring rapid integration with MAC jurisdictions. - Clinical-Legal Validation: Licensed clinicians and attorneys review AI outputs, mirroring WISeR’s requirement for human oversight of non-payment recommendations. - Neutrality: With no financial ties to MA plans, we provide unbiased solutions that prioritize taxpayer savings and patient safety—critical for a government-led initiative. Why Choose Champion Settlement Services (Aleck, LLC) - Proven in Medicare Context: Successfully resolved $50M+ in contested MA and CMS liens, demonstrating mastery of Medicare’s regulatory landscape. - Technology + Human Expertise: Combines AI efficiency with clinical judgment to balance speed and accuracy.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	A) Champion Settlement Services (Aleck, LLC) leverages AI/ML-driven analytics and decades of Medicare expertise to ensure compliance with CMS coverage rules (NCDs/LCDs) and reduce wasteful care. Our work with Medicare Advantage plans, MACs, and CMS data directly aligns with WISeR’s focus on high-risk services like knee arthroscopy, nerve stimulators, and skin substitutes. Key Experience: - Prior Authorization & Pre-Payment Reviews: o Developed AI-powered tools to automate prior authorization workflows for MA plans, cross-referencing claims against LCDs/NCDs with ~95% accuracy. o Leveraged proprietary AI-powered tool to analyze diagnostic codes including ICD-9 and ICD-10, HCPCS, DRG and CPT codes and assign “relatedness scores” for injury claims, streamlining subrogation. o Flag $10M+ in non-compliant claims annually (e.g., skin substitutes billed without evidence of non-healing wounds). We are strategically aligned to partner with MACs (e.g., Noridian, Novitas) to resolve discrepancies in pre-payment reviews, ensuring alignment with CMS Pub. 100-03 guidelines. - Post-Payment Reviews: Developed AI-powered tools to automate review of Medicare Part A/B liens, MAP liens for inappropriate reimbursement requests with ~95% accuracy. - Coverage Determinations: Implemented NCD/LCD compliance frameworks that assist in reducing improper payments for services like knee arthroscopy (e.g., invalid ICD-10 codes for osteoarthritis). Our team has experienced clinicians that can train providers to reviewing evidence-based documentation to align with CMS standards, improving prior authorization approval rates. - Claims Data & MAC Collaboration: Analyze CMS administrative claims data to identify fraud/waste trends (e.g., unbundling of nerve stimulator billing codes, reimbursing Medicare for overpayments, etc.). Interfaced with MACs during Medicare Secondary Payer (MSP) appeals, securing $5M+ in corrected payment allocations through expertise in Medicare Secondary Payer (MSP) procedural requirements. WISeR Alignment: - AI/ML Precision: Our platform can be pre-trained on WISeR’s targeted services, ensuring rapid deployment in MAC jurisdictions. - MAC Expertise: Resolved claims disputes in all jurisdictions including New Jersey, Ohio, Oklahoma, Texas, Arizona and Washington, navigating MAC-specific workflows and regulatory nuances. B) Champion Settlement Services (Aleck, LLC) does not currently hold a FedRAMP authorization. However, our organization is fully committed to meeting and exceeding federal data security standards and has implemented robust internal protocols aligned with NIST SP 800-53 and HIPAA requirements. Our technical infrastructure is designed to support secure data handling, transmission, and storage in accordance with federal guidelines. While we have not pursued FedRAMP certification to date, we partner with FedRAMP-authorized cloud service providers and maintains readiness to operate within FedRAMP-compliant environments as required by federal contracts. Our team includes professionals with deep experience in federal data compliance, and we are prepared to undergo any necessary authorization processes to meet the specific requirements of this engagement. C) HIPAA Compliance, Data Incident Response & Risk Management for HHS Engagements Champion Settlement Services (Aleck, LLC) maintains a HIPAA-compliant, NIST-aligned security framework tailored for HHS engagements, ensuring data integrity and alignment with federal priorities like health equity and fraud prevention. Key Safeguards: 1. Technical Controls: o AES-256 Encryption: For data at rest and in transit. o

	FedRAMP-Ready Infrastructure: Partner with AWS GovCloud for secure hosting. o Real-Time Monitoring: AI-driven anomaly detection to prevent breaches. 2. Incident Response: o 24/7 SOC Team: Immediate containment, forensic analysis, and HHS-coordinated notifications within 72 hours. 3. HHS Strategic Alignment: o Health Equity: Identified disparities in prior authorization denials using CMS data, enabling targeted provider training. o Fraud Prevention: Reduced improper payments via AI-audited claims. Business Continuity: • Disaster Recovery: 99.9% uptime via geo-redundant backups. • Annual Penetration Testing: Conducted by third-party cybersecurity firms. In sum, our multidisciplinary team ensures that privacy, security, and strategic alignment are embedded into every aspect of our service delivery, making Champion Settlement Services (Aleck, LLC) a trusted and capable partner for HHS initiatives.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Champion Settlement Services (Aleck, LLC) delivers rigorous, clinically grounded medical review services through a multidisciplinary team of licensed clinicians, legal experts, and technology specialists. Our work ensures coverage determinations align with CMS guidelines, evidence-based standards, and the WISeR Model's mission to reduce wasteful care. Clinical Experience in Coverage Determinations & Peer-to-Peer Reviews 1. Medicare Advantage & CMS Expertise: o Conducted medical necessity reviews for high-risk services including knee arthroscopy, nerve stimulators, and skin/tissue substitutes, applying Local and National Coverage Determinations (LCDs/NCDs) to ensure compliance. o Ability to resolve prior authorization appeals through peer-to-peer consultations, leveraging clinician expertise to align disputed cases with CMS coverage criteria. 2. Specialized Clinical Team: o Licensed Clinicians: Board-certified physicians, nurse practitioners, physician assistants, registered nurses, and specialists in orthopedics, neurology, and wound care will directly perform reviews, ensuring decisions reflect clinical evidence and Medicare policies. o Legal Integration: Attorneys validate compliance with federal regulations (e.g., Anti-Kickback Statute, Stark Law) and CMS documentation requirements for defensible determinations. Staffing Structure & Workflow Scalable, Technology-Driven Model: 1. Dedicated Clinical Reviewers: o A core team of clinicians, coders and attorneys with Medicare Advantage and MAC jurisdiction experience conducts real-time reviews, supported by specialists for complex cases (e.g., conflicting LCDs). 2. Proprietary Technology Platform: o Intelligent Triage: AI-driven tools prioritize cases requiring urgent review (e.g., skin substitutes for non-healing wounds) and flag discrepancies in coding or documentation. o Decision-Support Tools: Integrate CMS guidelines (e.g., NCD 100-03) into clinician workflows, ensuring consistency with Medicare rules. 3. Escalation Protocols: o Ambiguous or high-risk cases (e.g., experimental nerve stimulator implants) are escalated to senior clinicians for peer consultation, ensuring alignment with evidence-based standards. 4. Collaboration with MACs: o Experience resolving coverage disputes in coordination with Medicare Administrative Contractors (MACs), including pre-payment review workflows and appeals processes. Alignment with WISeR & HHS Priorities • Fraud/Waste Reduction: Rigorous reviews of services prone to abuse (e.g., knee arthroscopy for osteoarthritis without clinical indication). • Transparency & Compliance: All determinations include clear citations of CMS policies, LCDs/NCDs, and clinical evidence. • Provider Engagement: Peer-to-peer consultations resolve disputes efficiently, reducing administrative burden and fostering trust. Why Champion Settlement Services (Aleck, LLC)? • Independence: No financial ties to MA plans ensure unbiased, patient-centered determinations. • Integrated Expertise: Clinicians, attorneys, and technologists collaborate to balance clinical integrity, legal compliance, and operational efficiency. • WISeR-Ready: Proven experience with the model's targeted services and MAC workflows ensures rapid, seamless implementation.

4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Champion Settlement Services (Aleck, LLC), in collaboration with our exclusive teaming partner FordHall Technology, delivers secure, interoperable prior authorization solutions honed through federal health IT initiatives like the VA's Electronic Health Record Modernization (EHRM). Our joint expertise ensures seamless EHR integration, compliance with CMS-0057-F, and reduced administrative burden for patients, providers, and payers. a. EHR Integration & Compatibility Integrations: Epic, Cerner, Meditech, Athenahealth, eClinicalWorks, Allscripts, and VA's Federal EHR System. Federal Health IT Experience: VA EHR Modernization (EHRM): Supported deployment of electronic prior authorization (ePA) within the Veterans Health Information Exchange (VHIE), enabling seamless care coordination between VA, DoD, USCG, and community providers. Key Features: Auto-Populated Authorizations: EHR-integrated tools reduce manual paperwork by 80% (validated in VA pilot programs). Real-Time Tracking: Providers and veterans monitor authorization statuses via portals, mirroring WISeR's transparency goals. Interoperability: FHIR APIs align with CMS-0057-F standards, enabling data exchange across 65+ EHR platforms. b. Support for CMS-0057-F & Future Plans Proven Compliance: FHIR APIs: Deployed HL7 FHIR R4 standards in VA's EHRM to share prior authorization data with community providers, ensuring compliance with CMS-0057-F's technical requirements. Patient Access: Veterans view/approve authorizations via VA.gov, a model adaptable to Medicare beneficiaries under WISeR. Ongoing Initiatives: Federal Interoperability: Expanding APIs to align MAC workflows with VA/DoD systems (e.g., auto-apply Noridian LCDs for DME). Burden Reduction: VA-Inspired Automation: "Gold card" high-compliance providers for services like knee arthroscopy, reducing repeat reviews. AI-Driven Validation: Flag incomplete documentation (e.g., missing nerve conduction studies for stimulators) within EHR workflows. Future Roadmap: Da Vinci CRD/DTR Integration: Leverage FordHall's expertise in CMS data standards to automate coverage rule discovery. Cross-Agency Analytics: Replicate VA's success in reducing community care delays (e.g., 30% faster approvals for veterans) in Medicare. Why Champion Settlement Services (Aleck, LLC) & FordHall? 1) Federal Provenance: Successfully modernized prior authorization for VA's 9M+ veterans, demonstrating mastery of complex government systems. 2) CMS-0057-F Ready: Already operationalize FHIR APIs, patient access tools, and denial transparency protocols in federal EHRs. WISeR Alignment: 1) Streamlined Workflows: Eliminate manual processes for WISeR's targeted services (e.g., skin substitutes). 2) Secure Interoperability: FedRAMP-authorized infrastructure ensures data security across MACs and providers. Differentiators 1) VA EHRM Experience: Directly applicable to WISeR's goals of reducing delays and improving data sharing. 2) Dual Compliance Expertise: FordHall's technical mastery (FHIR, NIST) + Champion Settlement Services' clinical-legal review ensures end-to-end compliance. 3) Scalability: Solutions tested in VA's nationwide system ready for MAC jurisdictions. Conclusion: Champion Settlement Services (Aleck, LLC) & FordHall Technology bring unmatched federal health IT expertise to WISeR, combining VA-proven interoperability with CMS-focused compliance.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	AI/ML Capabilities to Support WISeR Implementation Champion Settlement Services (Aleck, LLC) brings a robust and ethically grounded approach to in health care, with proven experience AI/ML training models on complex datasets to support coverage determinations, prior authorization workflows, and utilization management. Our AI strategy is designed to align with the goals of the WISeR initiative, particularly in streamlining processes for patients, providers, and payers while maintaining compliance with CMS and HHS standards. AI/ML Training Experience Champion Settlement Services (Aleck, LLC) has trained AI/ML models using diverse and high-integrity data sources, including: • Claims Data: Historical medical claims, CPT/HCPCS codes, DRG codes, ICD-9 and ICD-10 code diagnosis patterns • Clinical Data: EHR-derived records, lab results, imaging data, physician notes • Administrative Data: Prior authorization histories, appeals, and coverage determination outcomes • Regulatory Data: CMS coverage policies, MAC-specific guidelines, FDA approvals These datasets are de-identified and securely managed in compliance with HIPAA and federal privacy laws. Algorithms and Technical Frameworks for WISeR To support WISeR's selected items and services, we deploy a combination of: • Natural Language Processing (NLP): To extract and interpret clinical documentation and medical literature • Decision Trees and Ensemble Methods: For rule-based coverage logic and robust decision-making • Deep Learning Networks: For pattern recognition in complex clinical scenarios • FHIR API Integration: To enable seamless data exchange with MACs and EHR platforms Our models are built using TensorFlow, PyTorch, and scikit-learn, and deployed on secure, scalable cloud infrastructure (AWS) with full auditability. Unique Value for WISeR Goals Champion Settlement Services (Aleck, LLC) AI tools are designed to reduce administrative burden and accelerate access to medically necessary care: • For Medicare Beneficiaries: o Real-time eligibility checks o Automated documentation assembly o Transparent status tracking with predictive timelines • For Providers: o Intelligent form pre-population o Predictive analytics for approval likelihood o Automated evidence gathering and formatting • For Payers: o Consistent, evidence-based decision frameworks o Accelerated preliminary reviews o Enhanced fraud detection and utilization oversight a. Technology Verification, Validation, and Ethical Oversight We maintain a rigorous framework to ensure ethical, secure, and high-quality AI deployment: • Bias Detection & Fairness Metrics: Continuous monitoring for demographic and clinical bias • Explainable AI: Transparent decision logic with human-readable rationale • Clinical Validation: Physician review of AI-generated recommendations • Regulatory Compliance: Full alignment with HIPAA, CMS, and FDA standards • Security Protocols: End-to-end encryption, role-based

	access, and advanced de-identification b. Managing Adverse Effects of Automation We proactively mitigate risks associated with AI automation: • Human Oversight: Mandatory clinician review • Safety Alerts: Automated flags for high-risk scenarios • Override Capabilities: Clinicians retain full authority to override AI decisions • Gradual Implementation: Pilot programs and change management support • Continuous Learning: Feedback loops and model retraining based on real-world outcomes We also maintain real-time dashboards, incident reporting systems, and stakeholder communication plans to ensure transparency and responsiveness across all user groups. Our AI strategy is not just technically advanced—it's ethically sound, clinically validated, and fully aligned with HHS's goals for modernization, equity, and efficiency. This makes us a uniquely qualified partner for WISeR and other federal initiatives seeking to transform prior authorization through intelligent automation. Executive Summary: Champion Settlement Services (Aleck, LLC)'s AI/ML Strategy for WISeR We offer a secure, scalable, and ethically governed AI/ML framework designed to streamline prior authorization processes and support coverage determinations under the WISeR initiative. Our approach leverages advanced algorithms, regulatory-aligned data sources, and human oversight to reduce administrative burden, accelerate care access, and improve program integrity. Key Differentiators: • Trained on claims, clinical, and regulatory data • Built with explainable, bias-monitored AI models • Fully aligned with CMS-0057-F interoperability standards • Designed to support beneficiaries, providers, and payers equally • Includes safeguards to prevent over-automation and ensure clinical safety Our AI tools are not just innovative—they're purpose-built to meet the operational, ethical, and compliance demands of HHS programs. Diagram: AI/ML Framework for WISeR plaintext +----------+ | Data Sources | +----------+ | - Claims Data | | - EHR Records | | - Prior Auth Histories | | - CMS Coverage Policies | +----------+ +----------+ | AI/ML Algorithms | +----------+ | - NLP for Clinical Notes | | - Decision Trees | | - Deep Learning Models | | - Ensemble Methods | +----------+ +----------+ | Technical Framework | +----------+ | - TensorFlow / PyTorch | | - scikit-learn | | - FHIR API Integration | | - Secure Cloud Hosting | +----------+ +----------+ | WISeR Outcomes | +----------+ | Patients: Faster Access | | Providers: Less Burden | | Payers: Better Oversight | +----------+ +----------+ | Governance & Safeguards | +----------+ | - Bias Monitoring | | - Human Oversight | | - HIPAA Compliance | | - Real-Time Dashboards | +----------+
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Champion Settlement Services (Aleck, LLC) operates under a robust ethical framework that prioritizes patient safety, regulatory compliance, and equitable outcomes. Our multidisciplinary team of clinicians, legal experts, and technologists ensures alignment with federal standards while streamlining processes for patients, providers, and payers. a. Quality Assurance in Utilization Management, Complaints, and Claims Resolution 1. Utilization Management Decision-Making: • Evidence-Based Reviews: Board-certified clinicians evaluate prior authorization requests against CMS NCDs/LCDs, ICD-9 and ICD-10, DRGs, HCPCS, CPT codes and evidence-based guidelines (e.g., knee arthroscopy for documented osteoarthritis, nerve stimulators for refractory conditions). • Peer-to-Peer Escalation: Disputed cases undergo direct provider consultation to resolve conflicts and ensure clinical accuracy. 2. Complaints and Grievances: • Formal Resolution Protocol: o Complaints documented, tracked, and resolved within 30 days. o Cross-functional review by legal, clinical, and compliance teams to ensure impartiality. • Transparency: Providers/patients receive detailed rationales for denials, citing specific CMS policies. 3. Claims Billing and Dispute Resolution: • Settlement Expertise: Through Champion Settlement Services, we resolve complex claims involving Medicare liens, workers' compensation, and liability disputes, ensuring compliance with Medicare Secondary Payer (MSP) rules and have extensive experience resolving payment disputes between providers and payers. • Appeals Support: Legal team guides providers through CMS appeals processes, reducing administrative burden. 4. Patient and Provider Advocacy: • Timely Care

	Access: Expedited reviews for urgent cases (e.g., non-healing wounds requiring skin substitutes). • Fair Billing Practices: Audit claims for coding accuracy (e.g., nerve stimulator HCPCS codes) to prevent overpayment/underpayment. b. Compliance with State and Federal Regulations 1. Federal Compliance: • HIPAA & Data Security: o FedRAMP-Ready Infrastructure: Partner with AWS GovCloud for encrypted data storage/transit. o NIST SP 800-53 Controls: Role-based access, audit trails, and SOC 2-certified monitoring. • CMS Alignment: o Claims processing adheres to Medicare Administrative Contractor (MAC) jurisdiction rules (e.g., Noridian LCDs for DME). o Regular updates to AI models with revised NCDs/LCDs. 2. State-Specific Compliance: • Tailored Workflows: Adapt prior authorization processes to meet state Medicaid requirements (e.g., prior approval timelines for elective surgeries). • Licensing: Clinicians and legal staff maintain state-specific certifications (e.g., wound care specialists in CA, TX, FL). 3. Internal Oversight: • Monthly Audits: Review utilization decisions for consistency with CMS guidelines and demographic fairness. • Staff Training: Quarterly sessions on Anti-Kickback Statute, Stark Law, and evolving state/federal regulations. Commitment to Partnership and Safety • Ethical AI Use: Clinicians may override AI recommendations, ensuring human accountability. • VA-Proven Interoperability: Leverage experience from VA EHR Modernization to securely share data across providers, payers, and MACs. • Transparency Tools: Real-time dashboards for providers to track claims status and compliance metrics. In sum, Champion Settlement Services (Aleck, LLC), in partnership with FordHall Technology, combines federal health IT expertise with clinical-legal rigor to deliver ethical, compliant solutions for HHS initiatives like WISeR. Our commitment to transparency and patient safety is unmatched.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Champion Settlement Services (Aleck, LLC) presents a savings estimate that is firmly anchored in a thorough analysis of historical performance, trends in claims data, and targeted enhancements in prior authorization and coverage determination processes. Leveraging our advanced AI tool, we anticipate achieving greater than 20% in annual medical cost savings across the selected items, services, and geographic regions/MAC jurisdictions included in WISeR. Key Drivers of Projected Savings Our estimates reflect anticipated cost reductions in several critical areas: • AI-Enhanced Care Coordination: Our AI tool streamlines prior authorization and coverage determinations, ensuring timely access to necessary care while effectively reducing delays and eliminating duplicative services. • Fraud, Waste, and Abuse Mitigation: Utilizing our integrated clinical-legal review model alongside our AI tool, we identify instances of improper billing, prevent overutilization, and ensure precise primary payer identification. • Geographic-Specific Strategies: Our interventions are tailored to address the unique utilization patterns and provider behaviors within each MAC jurisdiction, enabling precise targeting and localized impact. • Skin Substitute Overspending: Our clinical review and prior authorization protocols are strategically designed to identify inappropriate or excessive use of skin graft procedures. By applying evidence-based coverage determinations and escalating questionable cases to peer review, we can mitigate unnecessary procedures and confirm compliance with CMS billing guidelines. • Practice Expense Optimization: Our legal and technical teams assist providers in navigating the complexities of CMS's revised practice expense calculations, mitigating overbilling risks related to costly office equipment, and ensuring accurate reimbursement. • Chronic Disease Care Coordination: Enhanced coverage determinations and formulary management lead to better care alignment for patients with chronic conditions, significantly reducing avoidable hospitalizations and improving medication adherence. Data-Driven Methodology We employ an iterative, evidence-based approach to savings estimation. Our methodology includes: • Retrospective Claims Analysis: Identifying historical cost drivers and patterns to inform future interventions. • Predictive Modeling: Our AI tool forecasts potential savings opportunities based on various intervention scenarios. • Benchmarking: Comparing our findings against CMS and industry standards to validate our assumptions. This initial savings estimate is provisional and will be refined through collaborative implementation planning and comprehensive data review with HHS stakeholders. Champion Settlement Services (Aleck, LLC) is dedicated to maintaining transparency and accountability in all financial projections and will provide ongoing reporting to validate savings and performance outcomes.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Champion Settlement Services (Aleck, LLC) is fully committed to meeting all technical, operational, and regulatory requirements necessary to interface with Medicare Administrative Contractors (MACs) and access sensitive Medicare beneficiary data in full compliance with HIPAA, CMS guidelines, and other applicable federal privacy and security laws. While a formal implementation plan will be finalized in collaboration with HHS and MAC stakeholders, we have developed a standardized readiness framework based on prior government healthcare engagements. This framework ensures rapid mobilization, secure data integration, and regulatory alignment. Typical Implementation Timeline (Post-Award) Phase Timeframe Key Activities Phase 1: Contract Initiation & Compliance Review Weeks 1–4 Finalize data use agreements (DUAs), conduct HIPAA risk assessment, align with CMS and MAC protocols Phase 2: Infrastructure Configuration Weeks 5–8 Configure secure environments, validate SOC 2 controls, integrate FedRAMP-authorized cloud services Phase 3: Staff Onboarding & Training Weeks 6–10 Train staff on MAC-specific workflows, HIPAA compliance, and CMS data handling procedures Phase 4: Interface Testing & Validation Weeks 9–12 Conduct end-to-end testing with MAC systems, validate encryption, access controls, and audit logging Phase 5: Go-Live & Monitoring Weeks 13+ Launch operations, initiate real-time monitoring, begin reporting and performance tracking Internal

	Readiness Actions Champion Settlement Services (Aleck, LLC)'s internal teams—including legal, compliance, IT, and clinical operations—will coordinate to: 1) Finalize all required documentation (DUAs, BAAs, security attestations) 2) Configure secure data environments with role-based access and encryption 3) Conduct internal audits and penetration testing to validate safeguards 4) Ensure all personnel complete HIPAA and CMS-specific training 5) Establish escalation protocols for data incidents and MAC coordination In sum, our readiness framework is designed to be modular and scalable, allowing for rapid adaptation to specific MAC jurisdictions and HHS program requirements. We are prepared to work closely with HHS to tailor the final implementation plan to the scope and complexity of the awarded contract.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Aleck, LLC
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00096

Requested by (b)(6) on 07/28/2025 15:46

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	CASTLESTONE ADVISORS LLC
b. Doing Business As (DBA) Name(s)	CASTLESTONE ADVISORS LLC
c. Street Address	7 Ginger Creek Drive
d. City	Glen Carbon
e. State	IL
f. Zip Code	62034
g. Tax Identification Number	562412446
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Castlestone operates a service that uses the in-place payment networks to deliver real-time data from the point of care. Our mission has been and continues to be to deliver services that improve the efficiency of claims and administrative processes, reduce fraud and abuse in health insurance, and apply financial industry innovations into healthcare. To our knowledge, Castlestone is the only company that can verify that orders or authorization requests come from the point of care in a face-to-face visit. This is part of Section 6407 of the PPACA, and modified by CMS for 46 categories of Durable Medical Equipment. No claim systems can determine whether services or authorizations / orders were created at the point of care. This leads to unauthorized, wasteful and fraudulent claims. The recent Operation Gold Rush demonstrates how physicians' identities are misused to authorize, among other things, urinary catheters that were unneeded. Castlestone has previously demonstrated to CMS how to prevent misuse of physician and beneficiary identities to prevent waste and fraud. Castlestone has also employed AI for years to help determine the legitimacy of claims, orders and authorization requests. Based on conditions of the card network transaction we receive and historical data, we can route the information to reviewers, Inspectors General and others in rea time.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	J15 CGS; JL Novitas
5. Provide street address, city and state for all locations.	

Location Name	Castlestone HQ
Street Address	7 Ginger Creek Drive
City	Glen Carbon

State	Illinois
Zip Code	62034

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00096_Ownership_WiSER Ownership declaration
Uploaded On	7/21/2025, 12:53 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	7 Ginger Creek Drive,, Glen Carbon, IL 62034
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00096_Licensure_Castlestone Cert. of Good Standing (2)
Uploaded On	7/21/2025, 12:57 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.	
N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	• CVS/Aetna • Mutual of Omaha • Palmetto GBA • National Government Services • Bankers Life • Centers for Medicare and Medicaid United Healthcare

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Castlestone created and implemented programs to deliver real-time information from the point of care to health insurers The function also included using the payment networks to capture orders, diagnostic codes, and CPT codes. We have worked with private insurers, Medicare MACs, Medicare Supplement insurers and CMS. Our technology addresses multiple issues in the ordering or referring of goods and services. First, we have addressed the problem of verifying that orders or request for authorization actually originate in a physician office. Our services use the payment networks to facilitate real-time healthcare communications. Our primary role was to provide authentication that the patient was at the authorizing physician's office, and that orders or prior authorization originated in that office, and not from a fraudulent use of the physician's identity or NPI. Our architecture also enables entries in a payment network terminal to initiate other actions. An example is below: In this example, substitute "authorization request" for "order" if Power Mobility Equipment is requested.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	a.Castlestone created and implemented interfaces with National Government Services and Palmetto GBA. The interfaces were to keep active beneficiary and provider information synchronized in both systems, and to communicate real-time information from the point of care to NGS. Coverage determinations b. Castlestone received authorizations and certifications that we comply with data security requirements from both National Government Services and Palmetto GBA. Documents are attached. c. First, all data on Castlestone servers is encrypted. Second, UserIDs and passwords are stored on separate servers to reduce the chances of using credentials to access data. As a service provider offering services on the payment networks, Castlestone is also subject to Payment Card Industry Data Security Standard (PCI DSS) and systems are routinely audited. Depending upon the client, Castlestone has rules where data are removed based on agreed-to criteria. We also meet all standards in the payment industry for back up and availability, as well as performance. The industry has existing protocols to address stolen identities and prevent fraud.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program	

(FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Castlestone does not, nor do we engage, clinicians to conduct medical reviews. Our services are limited to capture, perform fraud risk analysis, and communicate encounter data.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	a. As long as EHR platforms can be accessed via web services queries, Castlestone will be compatible with them. b. Castlestone's platform enables multiple processes with a single entry in the point-of-sale system. Those can include capture of encounter, initiate a medical records request, alert reviewers that a prior authorization request will be forthcoming. All of that takes place in real time. That will ease the administrative burden on providers as well as protect Medicare, the providers and beneficiaries from misuse of identities to request authorization. Writing to an API is a common practice and readily implemented.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met.	Jeff Leston, founder of Castlestone, implemented the first AI-based fraud detection system for health insurance in 1991. Our approach to AI focuses on enhancing the existing Rules Engine which has been part of our services for 15 years. The addition of AI will be smooth since our Rules Engine is designed to enhance knowledge. The Rules Engine is positioned to take data on file and analyze them against incoming card network data.

b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	a) Castlestone has demonstrated that we adhere to privacy, data protection and compliance standards. Not only have we met standards for CMS, but we are required to meet Payment Card Industry (PCI) standards.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	It is important to note that Castlestone's focus is on verifying, transporting and analyzing data that is not otherwise available. Misuse of identities for claims and for authorization of anything requiring physician assent is the leading cause of fraud. This is because no claim system can verify that the clinician and the beneficiary were in the same place at the same time that the encounter claims.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Castlestone has already demonstrated, with National Government Services (NGS) and Palmetto GBA (PGBA) the ability to exchange data to operate our services. The interface/integration of our services with a MAC has been operational in under 65 days from project start

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any	✓

information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	
Company/Organization Name:	CASTLESTONE ADVISORS LLC
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00125

Requested by (b)(6) on 07/28/2025 15:50

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Rogue Management Consulting LLC.
b. Doing Business As (DBA) Name(s)	Rogue Management Consulting LLC.
c. Street Address	1724 S. Brahma Blvd #106
d. City	Kingsville
e. State	TX
f. Zip Code	78343
g. Tax Identification Number	99-202365
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Currently provide specialzed patient benefit verification and predeterminations for several manufacturers in the wound care industry. Have extensive knowledge in LCD, NCD requirements and ability to conduct accurate prior authorizations on advanced modalitites listed in the WISeR Model. Our mission is to provide medically necessary patient access to the most vulnerable of the patient populations while ensuring compliant clinician utilization preserving federal resources.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	Rogue Management Consultants LLC
Street Address	1724 Brahma Blvd
City	Kingsville
State	Texas
Zip Code	78363

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00125_Ownership_LLC Articles OR Certificate of Organization
Uploaded On	7/24/2025, 10:43 AM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	1724 S. Brahma Blvd #106, Kingsville, TX 78343
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00125_Licensure_LLC Articles OR Certificate of Organization
Uploaded On	7/24/2025, 10:45 AM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five

years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.	
N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	Rogue Management Consulting LLC

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Currently have experience requesting prior authorizations on behalf of clinicans and manufacturers ensuring the documentation supports the medical necessity to include all required LCD, NCD requirements, utilization is approriate based on the services requested and products are FDA complaint in the request. Have experience working with UHC, Wellmed, Molina, Cigna, Humana, BCBS and several indepenedent contracted Medicare advantage payers. Also work with small payers in developing policies surrounding documentation guidelines to protect the integrity of plans.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Experience working with clinicans through RAC and UPIC navigation and as expert witness when requested in support of medical necessity with extensive experience with compliance and documentation requirements with FDA approved products and indications. Extensive experience building compliance programs while rehabilitating clinicans surrounding LCD, NCD guidelines and requirements. Our organization's data security system has been vetted with multiple Hospital IDN's to ensure transfer of HIPPA complaint patient information thorugh the works of our IT department as well the hospital systems Quality and IT departments. We ensure compliance with secure servers, enforcement of BAA and continous education as a company completing annual CEU and conference attendence to ensure we are always up to date with the most recent guidelines and requirements.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Have experienced clinicians on contract to conduct peer to peer reviews and coverage determinations that acutally specialize in the field and falls within the scope of the clinicans in need of peer to peer. Where we have an advantage, specifically in skin substitutes is the experienced clinican performing peer to peers rather than a physician that has no understanding of the space or the medical necessity of utilization.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Right now availity is utilized but would add on any additional resources needed to ensure a streamline response to support CMS. Currently utilize Fax and encrypted email platforms to provide patient benefit results.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	Have access to AI models that can scrub claims and ensure all required LCD, NCD requirements are met. More importantly, the extensive knowledge the Rogue Management team consists of has the ability to manually review claims and ensure medical necessity and complaince in reponse to overutilization, misapproriate utilization and product knowlege to include FDA guidelines and indications to support the integrity of the WISeR model.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be*	No

sure the expiration or renewal date is included in this documentation.	

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Our company has educated and implemented compliance programs before the abuse and overutilization gained oversight. Our mission has always been to ensure the appropriate patients have access while educating clinicans the importance of proper utilzation and complaince in accordance to LCD, NCD guidelines. Claims disputes are handeled appropraitely in a timely manner and until resolution is completed. All State and federal laws and regulations will be followed by ensuring each claim is reviewed and authorized in accordance of CMS guidelines per the LCD and NCD.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	There is an overambundance of wasteful spending specifically in the skin substitute catagory as this is our specialty. Sites of service where services are being rendered, lack of documented conservative care, elevated markers will all be caught. Difficult to pin point an estimate, but on experience in the industry and claims reviewed can safely saw minimum of 50% reduction in Federal payments within Novitas and Noridian alone. Minimum.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	If awarded contract, we will have full implementation completed within 60 days of award. HIPPA and provacy laws are secure, would just have to adjust our AI models with awarded contracts to ensure NCD, LCD requirements are set up.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	Rogue Management Consulting LLC.
Certifying Individual: **Title:**	(b)(6)

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00138

Requested by (b)(6) on 07/28/2025 15:51

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	WiserAuth, LLC
b. Doing Business As (DBA) Name(s)	WiserAuth
c. Street Address	4338 Grey Spencer Dr.
d. City	Las Vegas
e. State	NV
f. Zip Code	89141
g. Tax Identification Number	393364748
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	WiserAuth, LLC is a newly founded, MWBE physician-led healthcare technology company purpose-built to support Medicare Fee-for-Service (FFS) prior authorization reform. Our flagship platform, WiserAuth.ai, was developed from the ground up to address the complexity, fragmentation, and inefficiencies in utilization management for high-cost, high-variation services—precisely the focus of the CMS WISeR model. Mission and Values Our mission is to simplify and accelerate healthcare decision-making by equipping providers, payers, and patients with intelligent, transparent, and compliant prior authorization tools. We are guided by the following values: • Clinical integrity through evidence-based decisions • Transparency in AI outputs and coverage determinations • Efficiency to reduce administrative burden and provider friction • Equity by building systems that identify and mitigate bias • Compliance with CMS, HIPAA, and NCQA utilization standards Core Services • AI-powered prior authorization platform (WiserAuth.ai) that supports: o Real-time coverage determinations aligned with NCDs, LCDs, InterQual®, and MCG® o FHIR-based clinical data integration from EHRs o Explainable AI (XAI) for MAC and provider auditability • Clinical review and peer-to-peer escalation services conducted by board-certified physicians with over a decade of utilization management experience • Real-time claims intelligence and CMS-aligned pathway guidance for Medicare payers and providers Leadership and Advisory Team WiserAuth is led by a multidisciplinary team of experts in Medicare policy, AI development, and clinical decision-making: Co-Founders: • Dr. Heidi Fischer – Board-certified physician and former Senior Medical Director for national Medicare Advantage plans • Vik Mehta – CEO of Vast Edge, with extensive experience in secure, compliant cloud infrastructure, AI and analytics • Jim Pospychala – Healthcare operations leader with expertise in payer/provider contracting, Medicare compliance, and digital health transformation Advisory

	Board Members: • Tom Lutzow – Principal, Health Management Associates; former Medicaid Director • Tony Mollica – CEO, iCare (a subsidiary of Humana) • Dr. Barry Rosen – Surgical Oncologist and CMO at SimBioSys; former Advocate Health Medical Director • Vikas Anand – Director of Product at Google; past VP of Product Management at Oracle • Don Calcagno – SVP, Chief Population Health Officer at Advocate Health Differentiation and Alignment with WISeR • WiserAuth is not a retrofitted commercial tool, but a purpose-built solution engineered to support Medicare FFS, the most complex and underserved payer segment. • Our AI/ML tools are designed to enhance authorization accuracy, minimize inappropriate utilization, and maintain CMS-aligned transparency and fairness. • We offer real-time interoperability with EHRs, MACs, and payer systems using FHIR R4, HL7, and SMART on FHIR standards.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	WiserAuth
Street Address	4338 Grey Spencer Dr.
City	Las Vegas
State	Nevada
Zip Code	89141

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00138_Ownership_WiserAuth_Ownership_Disclosure
Uploaded On	7/25/2025, 2:49 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Contact Type	Secondary
Email Address	(b)(6)

Name Title/Position Address Business Phone Number	(b)(6)

Contact Type	Primary
Email Address Name Title/Position	(b)(6)
Address	4338 Grey Spencer Dr., Las Vegas, NV 89141
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00138_Licensure_WiserAuth LLC document
Uploaded On	7/25/2025, 3:03 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	WiserAuth is a newly formed company and does not currently hold active Business Associate Agreements (BAAs) with HIPAA-covered entities under its own name. However, our leadership and clinical team have extensive prior experience operating under BAAs through prior roles with Medicare Advantage plans, provider groups, and delegated utilization management organizations. We have fully developed, BAA-compliant infrastructure and workflows in place, including: • A HIPAA-compliant cloud environment (e.g., Google Cloud with FedRAMP Moderate authorization) • Standard BAA templates aligned with HHS guidance • Internal policies and procedures governing PHI access, breach notification, and role-based access control WiserAuth is prepared to execute BAAs with

	CMS, MACs, and any covered entities as required under the WISeR model, and can provide compliance documentation upon request.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	WiserAuth Experience with Medicare Advantage Plans and Prior Authorization WiserAuth is a physician-led clinical review organization with deep expertise in prior authorization, medical necessity review, and peer-level adjudication designed specifically for the WISeR program. Our team has vast experience across Medicare Advantage (MA), Medicaid, and commercial populations. While WiserAuth is a newly formed entity, our leadership and clinical review panel bring decades of direct payer-side experience in utilization management and policy-aligned decision-making. Clinical Leadership and Plan Experience Our Chief Medical Officer, Dr. Heidi Fischer, brings over 20 years of clinical and health plan leadership experience. She has served as Senior Executive Medical Director for national and regional plans including UnitedHealth Group, Empower Health, Premera, IUH, MoreCare, MedStar, and CountyCare. In these roles, she oversaw: • Utilization management and prior authorization operations • Development of medical necessity review protocols • Policy alignment across Medicare Advantage and Medicaid populations • Interrater reliability frameworks and audit-ready documentation standards Dr. Fischer also played a central role in building scalable, defensible prior authorization programs and leading enterprise-level clinical teams. She also has AI Healthcare certification from Stanford University. Physician Panel Expertise WiserAuth's physician reviewers are all board-certified, with over 10 years of experience each in clinical review, coverage determination, and delegated UM programs. Collectively, our panel: • Conducts 10,000+ reviews per physician annually, including PA determinations, peer-to-peer reviews, and appeals • Applies NCDs, LCDs, InterQual, and MCG guidelines with high fidelity • Maintains proven consistency across initial reviews, escalations, and audit tracks Our panel covers a full spectrum of medical and surgical specialties, enabling high-quality review across diverse service categories. Experience with CMS-Linked Policies and Payers While WiserAuth has not yet contracted directly with CMS, our medical directors and reviewers have applied CMS-aligned policies and guidelines in delegated UM arrangements with multiple MA plans. We are fully versed in: • CMS coverage policy interpretation and application • NCQA and URAC compliance • Integration with plan-side PA systems and workflows WISeR Readiness WiserAuth's payer-side experience, clinical rigor, and volume-ready infrastructure position us to support the goals of the WISeR model through high-throughput, policy-aligned, and equitable utilization management. Our team is equipped to deliver scalable, defensible prior authorization support in partnership with CMS and MACs.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Answer to Q2a: While WiserAuth has not yet engaged directly with Medicare Administrative Contractors (MACs) in a contracted or delegated role, our leadership team—including Chief Medical Officer Dr. Heidi Fischer and our senior physician advisors—bring extensive, hands-on experience interfacing with MACs from both the provider and payer perspectives. From the provider side, our board-certified physicians have: • Responded to MAC audits • Submitted clinical appeals aligned with Local Coverage Determinations (LCDs) • Participated in peer-to-peer reviews to justify coverage and support reimbursement for complex services From the payer side, our leadership has worked within Medicare Advantage organizations where MAC guidance, NCDs, and LCDs were routinely referenced and operationalized as part of: • Utilization management protocols • Claims adjudication frameworks • Internal medical policy development This dual vantage point enables WiserAuth to interpret and apply MAC guidance with accuracy, ensuring our AI-driven utilization review platform aligns with evolving CMS expectations and regional coverage standards. We are fully prepared to interface with MACs in the WISeR model, offering a clinically grounded, policy-aware, and technology-enabled approach to collaborative decision-making. Answer to Q2b: Yes, WiserAuth maintains strong data security, privacy, and compliance practices aligned with federal standards. While we are not yet directly FedRAMP-authorized as a company, we leverage secure cloud infrastructure and hold certifications that demonstrate our commitment to robust security governance. Security Certifications and Controls • ISO/IEC 27001:2013 – Our organization is certified for this internationally recognized standard for information security management. • SOC 2 Type II – We maintain this attestation, which validates the effectiveness of our internal controls related to security, availability, and confidentiality. FedRAMP Hosting and Authorization Status • Our applications are deployed within FedRAMP-Authorized cloud environments, including: o Google Cloud Platform (FedRAMP Moderate) o Microsoft Azure o Amazon Web Services (AWS) o Oracle Cloud Infrastructure • We are currently in the process of pursuing FedRAMP Moderate authorization as an independent SaaS provider and expect to be listed as "In Process" on the FedRAMP Marketplace in the near term. Marketplace Deployment • WiserAuth applications are live and certified on both the Google Cloud Marketplace and Microsoft Azure Marketplace, confirming our compatibility with enterprise-grade cloud standards and deployment practices. Documentation We are happy to provide ISO, SOC 2, and FedRAMP hosting documentation upon request and will submit our FedRAMP authorization documentation to CMS once our "In Process" designation is finalized. Answer to Q2c: WiserAuth HIPAA Privacy, Security, and Breach Rule Compliance & Incident Response Plan WiserAuth maintains a comprehensive and documented HIPAA compliance

	program aligned with the Privacy, Security, and Breach Notification Rules, as well as other applicable federal and state data protection laws. Our framework includes formal policies, continuous monitoring, regular assessments, and a robust incident response plan. 1. Workforce Training and Access Management • All employees complete mandatory HIPAA and security training upon hire and annually thereafter, including attestations of completion. Additional training is required when policies are updated or new risk factors are introduced. • Role-based access controls (RBAC), multi-factor authentication (MFA), and the principle of least privilege are enforced across systems handling PHI. 2. Policy Governance and Risk Management • WiserAuth's Information Security and Compliance Team reviews and updates privacy and security policies annually, or more frequently if required by regulatory changes, client needs, or audit findings. • A formal Risk Analysis and Risk Management Plan is conducted regularly to assess threats to ePHI and implement mitigation strategies. • Business Associate Agreements (BAAs) are required for all downstream partners and vendors handling PHI. All PHI data exchanges conform to FHIR-based interoperability standards. 3. Technical Safeguards and Monitoring • We utilize automated security tools and AI-based user behavior analytics to monitor system activity in real time. Key indicators include: o Failed login thresholds o Anomalous data access patterns o Unusual resource consumption or user click behavior • System audits and vulnerability assessments are conducted monthly, quarterly, and annually to identify and patch potential security gaps. • Data is encrypted in transit and at rest. We enforce periodic encryption key rotation, password complexity validation, and system hardening protocols. 4. Data Handling and Protection • All data movement is logged, including the originator, destination, dataset accessed, access method, and timestamp. • PHI is subject to automatic redaction, encryption, or blocking, based on destination and content sensitivity, in accordance with HIPAA minimum necessary standards. 5. Security Incident Response Plan WiserAuth maintains a detailed incident response plan designed to ensure prompt containment, investigation, and resolution of any data breach or security incident: • Detection & Containment – Automated tools and manual reviews flag suspicious activity; immediate isolation of affected systems follows. • Notification & Communication – Internal escalation and, if necessary, notification to covered entities, affected individuals, and regulatory bodies per HIPAA timelines. • Investigation & Remediation – Root cause analysis and corrective action plans are initiated immediately after containment. • Post-Incident Review – Documentation, policy updates, and system improvements are made to prevent recurrence. Conclusion WiserAuth's HIPAA compliance and data protection program reflects industry best practices and regulatory standards, ensuring secure and ethical handling of PHI throughout our AI-driven utilization management processes.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	Yes

Authorizations or Certifications Document

File Name	WISeR-00138_Authorizations_Vast Edge_SOC 2 Type 2 Report 2024
Uploaded On	7/25/2025, 3:30 PM

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Clinical Expertise and Staffing Model for Medical Reviews and Peer-to-Peer Engagement At the core of WiserAuth's approach is a highly experienced team of board-certified physician reviewers who specialize in medical necessity determinations, peer-to-peer reviews, and appeals across all Medicare service categories. Our physicians bring deep clinical knowledge and operational experience from both payer and provider environments, ensuring reviews are consistent with CMS coverage criteria, NCD/LCD guidelines, and evidence-based standards such as InterQual® and MCG®. Medical Review Experience WiserAuth's clinical team has collectively performed hundreds of thousands of utilization management (UM) reviews for Medicare Advantage and commercial plans. These reviews span: • Initial coverage determinations • Resubmissions and appeals • Peer-to-peer

	physician discussions • Second-level and complex case adjudications Our reviewers have supported delegated UM arrangements and served in medical director roles for large national and regional health plans. Many reviewers handle 10,000+ cases per year, with established track records for quality, consistency, and defensibility. Peer-to-Peer Review Expertise Our physicians are extensively trained in peer-to-peer (P2P) engagement, facilitating respectful, evidence-based conversations with treating providers to: • Clarify documentation • Align on clinical guidelines • Resolve discrepancies in real time WiserAuth reviewers routinely handle high-cost, high-denial areas such as spine procedures, DME, and biologics. Several also serve as escalation reviewers for appeals, ensuring appropriate care is not delayed or denied without clear justification. Clinical Staffing Structure and Specialties WiserAuth maintains a national panel of board-certified physicians across all major specialties, allowing us to assign cases based on service type and clinical complexity. All reviewers are immediately available and meet CMS-aligned turnaround standards. Specialties include (but are not limited to): • Interventional Pain, Spine, and PM&R • Orthopedic and Neurosurgery • Interventional Radiology and Cardiology • Sleep Medicine and DME • Wound care, Dermatology, Urology, Psychiatry, General Surgery Each reviewer has over a decade of experience in medical review and is supported by clinical QA leadership to ensure continuous performance oversight. Quality Assurance and Reviewer Oversight To maintain consistency and clinical integrity, WiserAuth implements: • Annual CMS policy and guideline training • Ongoing continuing medical education (CME) for UM • Quarterly interrater reliability (IRR) testing • Routine internal audits and documentation reviews These processes ensure alignment with Medicare criteria, minimize reviewer variation, and promote defensible, high-quality decision-making. Conclusion WiserAuth's physician-led model, specialty-based reviewer alignment, and rigorous QA framework ensure that every coverage determination reflects clinical expertise, policy compliance, and timely patient-centered decision-making—in full alignment with the goals of the WISeR model.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Integration with Electronic Health Record (EHR) Platforms for Prior Authorization WiserAuth is built to integrate seamlessly with leading Electronic Health Record (EHR) systems to automate, accelerate, and simplify the prior authorization process. Our interoperability framework is grounded in HL7® FHIR® R4 standards, allowing us to extract relevant clinical data and streamline end-to-end authorization workflows. FHIR-Based API Integration WiserAuth utilizes secure, standards-based APIs to: • Extract structured and unstructured clinical data directly from the EHR, including patient demographics, problem lists, medications, lab results, imaging, procedures, and prior treatments • Auto-generate prior authorization requests using AI-driven clinical rules and payer-specific policies • Reduce manual data entry and eliminate unnecessary back-and-forth between providers and health plans Our solution is compliant with the ONC's interoperability and information blocking rules, and supports real-time data exchange while maintaining full HIPAA compliance. EHR Compatibility Our platform is currently integrated with Epic and readily supports integration with other major EHR vendors including: • Cerner (Oracle Health) • Athenahealth • Allscripts (Veradigm) • Meditech We can interface directly via FHIR APIs, SMART on FHIR apps, or through secure HL7 messaging, depending on the capabilities of the provider organization. Deployment Options WiserAuth offers flexible deployment models based on provider preference: • In-EHR integration via embedded apps or launch buttons for real-time decision support • Standalone secure web portal with document upload and EHR-to-portal data bridging • Batch submission APIs for high-volume providers and delegated entities These options are designed to minimize provider disruption, increase submission accuracy, and accelerate time to decision—in full alignment with the WISeR model's goals. Q4a: EHR Platform Compatibility WiserAuth is designed to integrate seamlessly with both cloud-based and on-premises Electronic Health Record (EHR) platforms, using HL7® FHIR® R4 and SMART on FHIR standards to ensure compliance with CMS interoperability requirements. Our system supports automated clinical data exchange and real-time prior authorization submission without requiring disruptive changes to provider infrastructure. Compatible EHR Platforms WiserAuth is currently compatible with the following widely used EHR systems: • Epic – Fully integrated using FHIR APIs and OAuth2 for real-time data extraction and submission • Cerner (Oracle Health) – Supports SMART on FHIR applications for clinical data access and action • Athenahealth – Integrated via published FHIR endpoints and custom connectors • Allscripts (Veradigm) – Supports both FHIR APIs and legacy HL7 integration for structured data retrieval • Meditech – Customizable workflows using HL7 messaging and FHIR modules • eClinicalWorks – Integrated using field mapping and RESTful APIs • Greenway Health – Connected via standardized FHIR-based modules Deployment Flexibility Our solution allows providers to: • Integrate directly within their existing EHR interfaces • Use WiserAuth as a standalone portal with secure EHR data upload • Implement batch submission APIs for high-volume operations This flexibility ensures rapid deployment, minimal IT burden, and high compatibility with existing clinical workflows—aligning directly with WISeR's objectives of efficiency, interoperability, and provider enablement. Q4b: WiserAuth's Commitment to Supporting CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) WiserAuth is fully aligned with the goals and technical requirements outlined in CMS-0057-F, and we are actively enhancing our platform to support payers, providers, and patients through improved interoperability, API adoption, and prior authorization reform. Our platform is built on HL7® FHIR® R4 standards and is designed to reduce administrative burden, increase transparency, and accelerate access to medically necessary care. Current Capabilities Supporting CMS-0057-F WiserAuth offers

	production-ready components aligned with the final rule's API requirements: • Prior Authorization API Enables real-time submission and tracking of authorization requests, reducing delays and increasing transparency for providers and patients. • Patient Access API Supports secure retrieval of patient clinical and claims data in standardized FHIR format. • Payer-to-Payer Data Exchange API Facilitates seamless transfer of prior authorization and clinical decision data when a beneficiary transitions between payers, minimizing redundant documentation. • Consent Management Our ConsentAuth API allows granular capture and verification of patient consent preferences in accordance with HIPAA and CMS guidelines. • Data Format Converters WiserAuth includes tools to normalize disparate data sources into FHIR R4, including: o HL7v2 to FHIR R4 conversion o JSON/CSV to FHIR R4 transformation These tools ensure interoperability with legacy EHRs and payer systems while meeting CMS technical standards. Ongoing and Future Enhancements • Full integration with Da Vinci and CARIN implementation guides for prior authorization and data sharing • Expansion of SMART on FHIR app capabilities for in-EHR deployment • Enhanced clinical decision support (CDS) hooks to pre-check requirements and guide providers at the point of care • Support for automated prior authorization adjudication with audit logs and XAI-based explainability Burden Reduction Goals WiserAuth is committed to: • Reducing provider time spent on documentation through automation and intelligent form pre-fill • Improving patient access to timely care by decreasing PA turnaround time • Lowering payer workload by improving the accuracy, consistency, and speed of medical necessity reviews Conclusion WiserAuth is fully prepared to support payers and CMS in implementing the CMS-0057-F Final Rule through standards-based APIs, interoperable workflows, and automation that enhances efficiency, compliance, and patient outcomes.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	AI/ML Experience and Approach to Implementing WISeR Overview of AI/ML Experience WiserAuth has deep experience building and training AI and machine learning (ML) models for prior authorization, coverage determination, and clinical decision support across Medicare Advantage and Medicaid programs. Our models are specifically designed to improve appropriateness of care, reduce administrative burden, and align with CMS policy frameworks. Training Data Sources Our AI models are trained using a diverse, de-identified dataset drawn from: • Prior authorization outcomes across multiple payer types, including approval, denial, and appeal histories • Structured EHR data, including ICD/CPT codes, medications, lab results, imaging, and procedure history • Unstructured clinical notes, parsed using NLP to extract rationale, symptoms, and medical necessity indicators • Coverage determination guidelines, including: o CMS National and Local Coverage Determinations (NCDs/LCDs) o InterQual® and MCG® criteria o Commercial payer policy sets We follow strict HIPAA de-identification protocols and implement PHI protections throughout the ML pipeline. AI Algorithms and Frameworks Used Our approach blends predictive modeling, NLP, and decision support using the following technologies: • BERT and ClinicalBERT – Transformer-based NLP models to extract clinical meaning from free-text notes and identify language that supports or undermines medical necessity. • XGBoost and Random Forest – Gradient-boosted and tree-based models trained to predict authorization outcomes, flag documentation gaps, and recommend next steps. • spaCy and Hugging Face Transformers – For real-time text parsing and named entity recognition in physician notes. • TensorFlow and PyTorch – Model training and orchestration frameworks, used for scalable AI deployment in secure cloud environments. • FHIR-Compatible Outputs – All decision artifacts and AI-generated recommendations are structured in FHIR R4 format for seamless integration with CMS systems and MAC workflows. Unique Advantages for WISeR Implementation WiserAuth's AI engine is purpose-built to support the WISeR model's goals of reducing waste, improving appropriateness, and streamlining the prior authorization process. Our approach includes: • Real-time documentation validation – Instantly identifies missing elements needed to support coverage, reducing provider rework and denials. • Auto-decisioning with confidence scores – High-confidence approvals/denials are executed automatically, while ambiguous cases are escalated to physician reviewers. • Explainability and auditability – Each decision includes rationale references (e.g., LCD #, clinical finding), improving transparency for MACs, providers, and CMS. • Adaptive learning – Our models incorporate MAC-level patterns and region-specific utilization data to support continuous improvement and regional customization. • Workflow integration – Smart form-fill and real-time prompts guide providers at the point of care, reducing manual entry and administrative burden. Compliance and Validation We ensure all models are: • Continuously validated for accuracy, fairness, and interpretability • Audited for bias across demographic groups • Reviewed under a governance framework that includes clinical oversight and CMS-aligned policy experts Conclusion WiserAuth's AI platform is designed to support scalable, explainable, and compliant prior authorization automation in partnership with MACs and CMS. Our tools reduce friction for providers, accelerate appropriate care for patients, and enable smarter decision-making across the Medicare ecosystem. Q5a: Approach to Verifying, Validating, Securing, and Regulating Enhanced Technology Software At WiserAuth, we recognize that ethical, high-quality utilization management (UM) depends on trustworthy AI, secure infrastructure, and transparent oversight. Our approach combines technical rigor, clinical governance, and ethical AI practices to ensure our platform consistently meets or exceeds CMS standards. 1. Verification and Validation Framework • Clinical Ground-Truth Benchmarking: All AI-driven decisions are validated against manually adjudicated prior authorization cases by board-certified physicians to ensure clinical appropriateness and accuracy. • Rule and Model Testing in Simulated Environments: New

	or updated logic is deployed in sandbox environments with synthetic or de-identified data to test safety, precision, and recall before go-live. • Continuous Model Monitoring: We employ real-time feedback loops and performance dashboards that track false positives, false negatives, and approval accuracy over time. Drift detection triggers alerts and retraining as needed. • Auditability and Explainability: Every automated decision includes a confidence score, clinical rationale, and full audit trail, enabling MACs and providers to understand and contest outcomes as needed. 2. Security and Compliance Protocols • FedRAMP-Equivalent Hosting: Our cloud infrastructure (Google Cloud Platform) complies with FedRAMP Moderate and HIPAA requirements, ensuring secure storage and transmission of PHI and CMS data. • Zero-Trust Access Control: Role-based access, multifactor authentication, and endpoint security are enforced across all environments. • Data Encryption: All sensitive data is encrypted in transit (TLS 1.2+) and at rest (AES-256). • Third-Party Penetration Testing & Risk Assessments: Annual independent security audits and vulnerability scans will be conducted to maintain a high-security posture. 3. Ethical AI and Governance • Ethical Oversight Committee: WiserAuth will convene an internal committee of clinicians, ethicists, and technologists to review AI use cases, monitor potential bias, and ensure equitable outcomes. • Bias Mitigation & Fairness Audits: We apply fairness testing frameworks (e.g., disparate impact analysis) to detect and correct algorithmic bias across race, gender, age, and geography. • Human-in-the-Loop Review for Complex Cases: Our system is designed for hybrid review—automating routine decisions while flagging ambiguous cases for clinical adjudication. • Regulatory Alignment: Our utilization management policies align with CMS NCDs/LCDs, state-level Medicaid guidelines, and NCQA UM standards. 4. Quality and Metrics Assurance • Key Quality Metrics Monitored Include: o Timeliness of PA decisions o Approval/denial consistency by indication o Overturn rates upon appeal o Provider satisfaction with PA process o Equity of access outcomes • CMS-Ready Reporting: WiserAuth generates structured reports for CMS and MACs to evaluate utilization trends, systemic outliers, and UM policy effectiveness over time. Conclusion WiserAuth's approach integrates clinical expertise, secure engineering, ethical AI governance, and real-time monitoring to ensure our technology delivers high-integrity, compliant, and equitable utilization management—in full alignment with WISeR's goals. Q5b: Managing Potential Adverse Effects of Automation and AI At WiserAuth, we understand that while AI and automation can streamline the prior authorization process, they must be applied ethically, transparently, and safely to avoid unintended harm. Our platform includes multiple layers of safeguards to manage the potential adverse effects of automation, in full alignment with CMS and WISeR objectives. 1. Human-in-the-Loop Oversight • All AI-generated decisions are subject to confidence thresholds. Requests with lower certainty are automatically escalated to physician reviewers rather than processed autonomously. • Clinicians remain central to our workflow—especially for complex, high-cost, or ambiguous cases. 2. Explainability and Auditability • Every automated determination includes a clear rationale, referencing specific NCD/LCD criteria or clinical indicators. • All actions are logged and traceable, ensuring full auditability by MACs, CMS, or provider organizations. • Our AI engine uses explainable AI (XAI) techniques, including SHAP-based interpretations, to provide visibility into how decisions were made. 3. Bias Monitoring and Fairness Safeguards • We actively monitor for bias in AI outputs across demographics such as race, age, gender, and geography. • Our training data excludes sensitive features unless clinically justified, and we will regularly conduct fairness audits to ensure equitable outcomes. • Disparity metrics are reviewed as part of our ongoing QA process and model tuning. 4. Safe Default Handling • In the event of missing, conflicting, or incomplete data, the system is configured to default to human review rather than force an automated decision. • Any edge case or system anomaly triggers a graceful degradation pathway to manual review and escalation. 5. Ongoing Governance and Quality Control • WiserAuth maintains a multidisciplinary AI Governance Committee, including physicians, data scientists, and compliance experts, to oversee model behavior and incident review. • We will perform regular interrater reliability testing, policy alignment reviews, and CMS compliance validations to maintain quality and consistency. Conclusion WiserAuth's AI solutions are designed not only for efficiency but for clinical accountability, transparency, and patient safety. Our approach to managing automation risks ensures that prior authorization decisions are appropriate, fair, and aligned with WISeR's goals of reducing waste while protecting care access.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	Yes

Accreditations or Certifications Document

File Name	WISeR-00138_Accreditations_WISeR Accreditation Response
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7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	WiserAuth's Approach to Ethics, Compliance, and Quality Standards WiserAuth is committed to upholding the highest standards of ethics, regulatory compliance, and clinical quality to ensure the safety, trust, and alignment of our operations with the interests of patients, providers, payers, and CMS. 1. Ethical Governance • We have established a formal Code of Ethics grounded in transparency, respect, non-discrimination, and responsible innovation. • Ongoing ethics training is mandatory for all employees and includes case-based modules on topics such as AI fairness, informed consent, and data transparency. • Our product and policy decisions are guided by a patient-first philosophy and will be regularly reviewed by our multi-stakeholder advisory board. 2. Regulatory Compliance Program WiserAuth is building a comprehensive Corporate Compliance Program aligned with CMS, OIG, and HIPAA requirements. Key elements include: • Adherence to HIPAA Privacy and Security Rules, GDPR, and CMS-specific mandates (e.g., WISeR model parameters) • Cybersecurity protocols aligned with NIST and/or HITRUST CSF, including annual risk assessments, vulnerability scanning, and access audits • Maintenance of SOC 2 Type II and ISO/IEC 27001:2013 certifications to ensure system integrity, traceability, and data protection 3. Quality Management and Standards Alignment WiserAuth's clinical and operational practices are built to meet or exceed nationally recognized quality benchmarks: • Utilization of HEDIS®, STARS, and CAHPS® measures to track service quality and member experience • Implementation of a Continuous Quality Improvement (CQI) framework using PDSA (Plan-Do-Study-Act) cycles to drive iterative improvement • Support for interoperability standards such as FHIR®, HL7®, C-CDA, and ONC-certified workflows to ensure seamless and secure data exchange 4. Partnership Transparency and Stakeholder Trust • Development of plain-language dashboards and decision summaries for providers and patients, increasing clarity and trust • Formation of Clinical and Payer Advisory Councils to inform product design, governance policies, and ethical safeguards • Deployment of formal grievance, appeals, and issue resolution protocols, including audit trails and tracking metrics to identify trends and prevent recurrence 5. AI-Specific Quality and Controls • All AI-driven determinations include version-controlled logic, auditability, and human override pathways • Fairness monitoring tools assess model outputs by race, gender, age, and geography to detect and mitigate bias • AI decisions are explainable and traceable back to clinical criteria and policy sources, ensuring defensibility for MACs and CMS review Conclusion WiserAuth's ethics, compliance, and quality framework is not just regulatory—it is foundational to how we build trusted partnerships, protect patients, and support providers in alignment with CMS's evolving expectations under the WISeR model and beyond. Q7a: Approaches and Quality Assurance for UM, Complaints & Grievances, Claims Billing, and Dispute Resolution WiserAuth has developed detailed policies and procedures across the utilization management (UM) lifecycle, including complaints, grievances, claims billing, and dispute resolution. These processes are aligned with CMS, NCQA, and URAC standards and are designed to ensure clinical integrity, member protection, and operational accountability. 1. Utilization Management Decision-Making • Evidence-Based Reviews: All UM decisions will be made using nationally recognized clinical guidelines (e.g., InterQual®, MCG®), CMS coverage criteria (NCDs/LCDs), and plan-specific policies. • Timeliness Compliance: We adhere to CMS-mandated decision timeframes, including 72-hour turnaround for expedited requests and 14-day standards for standard determinations. • Clinical Peer Review: Denials involving medical necessity will be reviewed by same-specialty, board-certified physicians, ensuring appropriate clinical context. • Clear Communication: Denial notices include specific clinical rationale, appeal rights, and instructions for reconsideration or expedited appeal. 2. UM Quality Assurance • Quarterly UM Audits: Retrospective reviews assess decision accuracy, documentation quality, and guideline alignment. • Real-Time Dashboards: Internal dashboards monitor key metrics such as turnaround times, approval/denial ratios, and reviewer performance. • Denial Trends Monitoring: High-volume and high-overturn categories are flagged for additional review, and protocols are updated accordingly. • Interrater Reliability (IRR): Routine IRR testing ensures consistency across reviewers and identifies training needs. 3. Complaints and Grievances • Accessible Reporting Channels: Members and providers can submit complaints via phone, portal, or email. All complaints are logged and categorized. • Resolution Timelines: We adhere to CMS grievance resolution timeframes (e.g., within 30 calendar days) and conduct internal tracking to prevent recurrence. • Root Cause Analysis: All grievances are analyzed for systemic issues (e.g., communication gaps, policy misalignment), with findings reported to compliance leadership. • Transparency: Complainants receive clear summaries of investigation findings and actions taken. 4. Claims Billing and Dispute Resolution • Clean Claim Support: WiserAuth ensures that prior authorization decisions are documented and structured to facilitate accurate downstream claims billing. • Appeals Process: A tiered clinical appeals workflow is in place, with same-specialty physicians reviewing resubmissions and providing evidence-based justifications. • Standardized Templates: Appeal responses include clearly documented rationales, linked policies, and audit-traceable versions. • AI-Powered Analytics: We use AI

	and machine learning to: o Analyze denial and appeal trends o Identify upstream documentation issues o Predict high-risk dispute categories for proactive intervention Conclusion WiserAuth's approach ensures that utilization decisions are clinically sound, procedurally fair, and quality assured—while enabling transparency and responsiveness across the prior authorization and claims continuum. These systems help reduce unnecessary denials, support accurate billing, and enhance satisfaction for patients, providers, and payers alike. Q7b: Compliance with State and Federal Regulations WiserAuth is committed to full compliance with all applicable state and federal regulations, including those outlined by CMS, HHS, OIG, OCR, and state Medicaid agencies. Our compliance infrastructure is designed to ensure legal adherence, operational transparency, and patient data protection across all service lines. 1. Governance and Oversight • We will appoint a designated Compliance Officer and establish a multidisciplinary Compliance Committee responsible for policy oversight, risk management, and regulatory alignment. • Our compliance framework is structured according to the OIG's Seven Elements of an Effective Compliance Program, ensuring robust monitoring, enforcement, and reporting systems. • A centralized regulatory registry will track all applicable federal and state regulations, including variations across jurisdictions where services are delivered. 2. Policies, Training, and Culture • WiserAuth maintains documented policies addressing HIPAA Privacy and Security, Fraud, Waste & Abuse (FWA), Breach Notification, Anti-Kickback Statute (AKS), and applicable CMS program integrity rules. • Mandatory annual compliance training and new-hire onboarding are conducted for all employees, with role-specific modules as required. • We promote a "speak-up" culture through anonymous reporting channels, whistleblower protections, and non-retaliation policies. 3. Technical Safeguards and Interoperability Standards • Our platform is built with modern data protection features, including: o End-to-end encryption (at rest and in transit) o Audit logging o Role-based access controls (RBAC) • We ensure interoperability and data exchange compliance through implementation of: o FHIR® R4, HL7®, and C-CDA o ONC Cures Act mandates for data access, exchange, and use 4. Auditing, Risk Assessment, and Remediation • We will conduct regular internal audits, including: o Annual HIPAA Security Risk Assessments o Quarterly internal compliance reviews o Real-time monitoring of regulatory KPIs • Compliance checklists and remediation tracking tools are used to ensure timely resolution of identified gaps. • Our Incident Response Plan includes: o Formal incident logging and escalation protocols o Root cause analysis o Implementation of Corrective Action Plans (CAPs) as needed 5. Vendor Compliance and Risk Management • All vendors handling PHI will be required to sign Business Associate Agreements (BAAs) and undergo annual compliance and risk assessments, which may include: o SOC 2 Type II o HITRUST certification o Proprietary risk scoring models based on service type and data access level 6. Documentation and Retention • All compliance-related records—including training logs, audits, incident reports, policy attestations, and CAP documentation—will be retained for a minimum of seven years, in accordance with federal and state requirements. Conclusion WiserAuth's compliance program is structured to ensure proactive, accountable, and transparent adherence to all relevant laws and CMS expectations, including those associated with WISeR model participation. Our infrastructure supports ongoing monitoring, rapid response, and alignment with industry best practices.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Projected Savings Estimate in WISeR Jurisdictions Overview WiserAuth proposes an AI-enabled prior authorization and clinical oversight solution tailored to the goals of the CMS WISeR pilot. By targeting high-cost, high-variation procedures across the WISeR states—New Jersey, Ohio, Oklahoma, Texas, Arizona, and Washington—we project substantial Medicare savings, increased care appropriateness, and reduced beneficiary exposure to unnecessary interventions. _____ Targeted Services: National Baseline Cost Using CMS Fee-for-Service (FFS) utilization data and peer-reviewed cost estimates, WiserAuth has identified a national baseline of $7B–$10B in annual Medicare spending for the following high-variation services: Service Category Volume Avg. Cost Est. CMS Spend Epidural Steroid Injections 1.5–2M $400 $600M–$800M Spinal Fusions 100,000+ $40K–$60K $4B–$6B Implantable Nerve Stim 50,000+ $20K–$30K $1.5B–$2B Vertebral Augmentation 50K–75K $6K $300M–$500M Arthroscopic Lavage (Knee OA) 30,000+ $5K $150M Hypoglossal Nerve Stimulators 2.5K–5K $30K $75M–$125M Incontinence/ED Implants 20,000+ $10K–$20K $250M–$400M Skin/Tissue Substitutes 50,000+ ~$10K $600M–$1B Total National Spend (Baseline): $7B–$10B annually These procedures are not currently subject to structured prior authorization under Medicare FFS, despite exhibiting significant clinical variation and questionable appropriateness in many cases. _____ Estimated Avoidable Spend via WISeR (Scaled to WISeR States) Based on Medicare Advantage benchmarks and OIG data, WiserAuth conservatively estimates that 10–30% of these services could be avoided or modified through structured, evidence-based authorization processes. Applying this to WISeR's six pilot states, which account for approximately 18–20% of national Medicare FFS spending, projected savings are: Avoidance Rate National Estimate WISeR-State Estimate (20%) 10% $700M–$1B $140M–$200M 15% $1.05B–$1.5B $210M–$300M 20% $1.4B–$2B $280M–$400M 30% $2.1B–$3B $420M–$600M These savings are achievable without denying medically necessary care, but rather by reducing unnecessary procedures, identifying missing documentation, and supporting evidence-based clinical decisions. _____ Clinical Oversight and Readiness WiserAuth's platform is guided by licensed, board-certified physicians in all 50 states,

	including specialists in: • Pain Management • Orthopedics • Neurosurgery • PM&R • Wound Care • Sleep Medicine • Urology Each specialist contributes to same-specialty medical reviews, ensuring all decisions are clinically defensible, guideline-aligned, and appeal-ready. Our AI platform supports: • Automated documentation checks • Real-time policy enforcement (NCD/LCD, InterQual, MCG) • Full audit traceability • MAC-aligned escalation protocols _____ Conclusion WiserAuth is uniquely positioned to help CMS achieve the WISeR model's goals of reducing waste, improving clinical appropriateness, and lowering FFS spending. Our hybrid clinical-AI solution delivers measurable savings, while protecting patient access and maintaining full regulatory compliance.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Timeline & Implementation Plan for Interfacing with MACs and Securely Accessing Medicare Beneficiary Data Overview WiserAuth is fully committed to ensuring readiness for secure data exchange with Medicare Administrative Contractors (MACs), in strict compliance with HIPAA, CMS guidelines, and all applicable federal privacy and security standards. Our AI-powered platform is designed for real-time prior authorization processing, electronic medical record parsing, and regional pattern learning, and we have foundational capabilities in place to support secure interfaces with MACs. Implementation Timeline & Key Milestones Phase Timeframe Activities 1. Gap Assessment & Planning Weeks 1–2 Finalize security risk assessment, identify specific MAC interface requirements (e.g., APIs, EDI), and align internal workflows 2. Infrastructure & Security Enhancements Weeks 3–6 Harden infrastructure using FedRAMP-equivalent cloud controls (e.g., GCP or AWS); enable audit logging, encryption at rest/in transit, and access controls 3. Staff Training & Role-Based Access Config Weeks 5–7 Train personnel on HIPAA privacy/security protocols and CMS data use policies; restrict PHI access based on least privilege 4. Secure Interface Development & Testing Weeks 6–10 Configure APIs, authentication, and data exchange methods in alignment with MAC requirements and CMS-approved specs 5. Compliance Validation & Legal Review Weeks 8–10 Conduct internal HIPAA compliance audit and finalize Data Use Agreements (DUAs) as needed 6. Go-Live & Continuous Monitoring Week 11 onward Begin live integration with MACs under CMS approval; implement real-time monitoring, incident response protocols, and quarterly reviews Internal Actions for Privacy and Security Readiness • Security Architecture: Utilize cloud-native, HIPAA-compliant infrastructure (e.g., Google Cloud Platform with FedRAMP Moderate authorization). • Access Management: Implement MFA, role-based access control, and audit logging for all personnel accessing Medicare data. • Policies and SOPs: Maintain internal SOPs for data access, breach notification, PHI redaction, and endpoint protection. • Data Governance: Apply metadata tagging and activity tracking to ensure proper handling of Medicare beneficiary information. • Business Associate Agreements (BAAs): Ensure all vendors or contractors with data access execute CMS-compliant BAAs. Conclusion WiserAuth is prepared to meet CMS WISeR data-sharing expectations securely and efficiently. Our AI-driven solution and experienced team are well-positioned to integrate with MACs while upholding the highest standards of data privacy, compliance, and operational readiness.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	WiserAuth, LLC
Certifying Individual:	(b)(6)
Title:	

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00140

Requested by (b)(6) on 07/28/2025 15:52

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	Accenture Federal Services
b. Doing Business As (DBA) Name(s)	N/A
c. Street Address	800 N. Glebe Road, Suite 300
d. City	Arlington
e. State	VA
f. Zip Code	22203
g. Tax Identification Number	412048319
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Accenture Federal Services (AFS),a wholly owned subsidiary of Accenture LLP, is a U.S. company headquartered in Arlington, Virginia. We empower the federal government to solve challenges, achieve greater outcomes and build a digital core that is agile, smart, and secure. We draw on the best of Accenture's global network in every industry including health, bringing proven commercial innovation to solutions built with advanced R&D, emerging technologies, and human-centered design at speed and scale. Accenture is a recognized market leader with 15k+ global health professionals including 2k+ licensed clinicians, serving 140 million+ health plan members (45%+ of insured Americans). Accenture serves 200+ health customers, including almost all the top 20 largest health payers including Medicare Advantage payers and pharmacy benefit managers, over 70% of the largest health systems in North America including Cigna, Kaiser Permanente, WellCare, Aetna, BCBS of CA, and others, and all ten of the largest managed care plans. Accenture is the world's largest EHR integrator, processing 170M+ health claim transactions annually with strategic relationships with EHR systems including Epic and Cerner. We work with EHRs that directly integrate with MACs in all regions. Accenture is recognized as a top leader in Healthcare Provider Digital Services, driven in part by 160+ awarded health patents in advanced analytics, AI, virtual agents, cybersecurity and cloud-based platforms. We team with a variety of technology vendors, such as GenHealth and Salesforce, with relevant, specialized capabilities to provide our clients with best-fit solutions to achieve their desired outcomes. Accenture offers a broad spectrum of services designed to meet the diverse needs of federal healthcare agencies, including: Fraud, Waste and Abuse (FWA) Reduction: Using AI and ML, predictive modeling and algorithmic decision logic to streamline and enhance detection of FWA Prior Authorization: Combining technology and services to automate and streamline prior authorization between providers and payers

	Artificial Intelligence and Machine Learning: Implementing AI and ML solutions to automate processes, enhance decision-making, and improve service delivery Data Analytics: Leveraging advanced analytics to turn data into actionable insights, enabling informed decision-making and improved outcomes Cloud Services: Assisting agencies in migrating to the cloud to increase scalability, flexibility, and cost-efficiency Digital Transformation and Technology Integration: Helping agencies modernize their IT infrastructure and applications to improve efficiency, enhance security, deliver better services, and reduce administrative burden Cybersecurity and Compliance: Providing comprehensive solutions to protect sensitive data and systems from evolving threats. Ensuring adherence to regulations such as HIPAA, FedRAMP, and other federal data protection laws
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas; J15 CGS; JL Novitas; JF Noridian

5. Provide street address, city and state for all locations.

Location Name	AFS Headquarters
Street Address	800 N Glebe Road, Suite 300
City	Arlington
State	Virginia
Zip Code	22203

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00140_Ownership_Ownership Interest Document
Uploaded On	7/25/2025, 2:28 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address Name Title/Position	(b)(6)
Address	800 N Glebe Road, Suite 300, Arlington, VA 22203
Business Phone Number	(b)(6)

Contact Type	Secondary
Email Address	(b)(6)

Name Title/Position	(b)(6)
Address	800 N Glebe Road, Suite 300, Arlington, VA 22203
Business Phone Number	(b)(6)

Contact Type	Tertiary
Email Address Name Title/Position	(b)(6)
Address	800 N Glebe Road, Suite 300, Arlington, VA 22203
Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00140_Licensure_Certificate of Formation 2002-06-03
Uploaded On	7/25/2025, 2:30 PM
File Name	WISeR-00140_Licensure_Amended Certificate of Formation 2005-06-20
Uploaded On	7/25/2025, 2:30 PM
File Name	WISeR-00140_Licensure_Amended Certificate of Formation 2010-07-19
Uploaded On	7/25/2025, 2:30 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any	Department of Veterans Affairs - VA118-16-D-1001 Department of Veterans Affairs -

HIPAA covered entities with which your company or organization has a business associate agreement.	36C10B24D0018 Department of Veterans Affairs - VA118-16-D-1001/36C10B23N10010013 Department of Veterans Affairs - VA118-16-D-1001/36C10B21N10010010 Department of Veterans Affairs - VA118-16-D-1001/36C10B21N10010009 Department of Veterans Affairs - VA118-16-D-1001/36C10B22N10010011 Department of Veterans Affairs - VA118-16-D-1001/36C10B22N10010012 Department of Veterans Affairs - 36C79122D0007 Department of Veterans Affairs - 36C79123D0002 Department of Veterans Affairs/Ironbow - Subcontract VA-CCIN_20240805 Department of Veterans Affairs/Oracle - Subcontract Cerner 8-6-2018 Centers for Medicare & Medicaid Services/Sparksoft - SUBK_SSOFT-AFS-HUB2-0-004 Centers for Medicare & Medicaid Services/Sparksoft - Subcontract SSOFT-ACC-EAOS-001 Centers for Medicare & Medicaid Services/Sparksoft - SUBK_SSOFT-AFS-ICITS-003 Centers for Medicare & Medicaid Services/Sparksoft - Subcontract SSOFT-ACC-MOMOT-001 Department of the Navy - N0018925F3030 Centers for Medicare & Medicaid Services - HHSM-500-2016-00003I_75FCMC21F0002

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	Accenture serves almost all the top 20 largest health payers including Medicare Advantage payers and pharmacy benefit managers, over 70% of the largest health systems in North America, and all ten of the largest managed care plans, bringing significant Medicare and prior authorization expertise on both the payer and provider side. We have successfully implemented innovative solutions to automate and streamline the prior authorization (PA) process for our clients, significantly reducing administrative burdens, improving accuracy and turnaround times. By leveraging data analytics, we enhance decision-making processes and ensure that PA criteria are met efficiently. To do this at scale, we utilize advanced technologies such as AI and machine learning to predict authorization needs, improve accuracy and optimize the prior authorization process. Accenture supports many of our healthcare clients with innovation in utilization management (UM) engagements, particularly the prior authorization lifecycle. We partner with our clients to provide embedded operational support, strategy assessments, including data-driven analysis for assessing costs & operational efficiency, reporting modernization, and technology advisement & implementation. Our experience spans the spectrum of commercial payer operations with Medicare Advantage and commercial contracts. In working with these clients and across engagement types, our expertise touches the entire lifecycle of utilization management, including intake and clinical review operations for prior authorization. Our expertise extends to concurrent clinical review, post-service clinical claims review, and appeals & grievances operations. Our health payer experts implement a variety of solutions across both member and provider engagement and experience, enrollment and billing, provider network, appeals, claims and benefits, quality and risk and utilization management including prior authorization solutions. We work closely with our payer customers on vendor selection and implementation and have successfully launched and optimized over ten UM solutions including prior authorization solutions that leverage GenAI capabilities. Accenture has provided strategy, technical and consulting services related to utilization management and prior authorization to large commercial payers with Medicare Advantage operations such as SCAN Health Plan, Cigna, Health Care Service Corporation, Kaiser Permanente, Premera, WellCare, Aetna, Clover Health, Blue Cross Blue Shield of California, Independence Health Group, Horizon, Centene, Blue Cross of Idaho, Cambia Health Solutions and more. Accenture partners with clinical, technology, data, and business leadership to define initiatives to improve the utilization management processes. Some examples of our Medicare prior authorization and utilization management work are below: Accenture partners with a large regional Blues plan with 4.5 million members in utilization management and prior authorization. Recently, Accenture worked with this client on a UM Modernization program to re-imagine the prior authorization process and to develop plans to comply with CMS-0057-F mandate. Interoperability and compliance during the prior authorization submission process is a focal point of the transformation, with a goal of delivering intake automation and improving outdated manual business processes. Accenture explored several potential solutions with this client, leveraging Accenture's strong industry partnerships, and we were able to offer the client a variety of technology solutions, including Accenture-developed assets to augment other commercial products and services. For this client, we are introducing Salesforce to work alongside the client's existing UM platform in support of coverage requirements discovery (CRD), documentation templates and rules (DTR), and prior authorization support (PAS). For another regional Blues plan with 2M+ million members, Accenture partnered with the client to deliver multiple successful releases for UM and case management (CM) that allowed for quick wins and served as the basis for future-state business optimizations. Accenture led overall project delivery of a fully integrated implementation across client, vendor, and Accenture teams. Accenture supported the client's early achievement of multiple corporate goals including integration with a third-party provider portal resulting in a ~200% increase in electronic prior authorization submissions (vs. non-electronic submissions). Accenture migrated the Case Management team from their legacy platform onto a cloud-based SaaS platform to automate case prioritization and routing. This is expected to reduce manual work by 15-25% and provides the client with new, innovative capabilities. Additionally, Accenture drove organizational change management, training activities, and provided go-live and production support to ensure successful production releases for the UM and CM teams. For a large national payer

	client, Accenture co-developed a three-year plan and value case for a portfolio of initiatives which eliminated unnecessary UM volume and reduced UM transaction review time to give providers and members faster and more consistent decisions about their coverage requests. Following our partnership on the initial planning phase, we focused on two vital areas. First, within UM Transformation, we simplified the process for doctors to obtain precertification for specific medical procedures. This involved reducing the list of procedures requiring precertification and improving the speed at which we assess the medical necessity of these procedures through automation tools. Secondly, we assessed initial inpatient review volume and identified types of admissions based on diagnosis and facility details which could be automated through technical capabilities. Overall, this effort alleviated the cost and burden associated with UM reviews without leaking medical cost. Through Radiant Services (a wholly owned Accenture subsidiary) Accenture provides utilization management operations services, including clinical review processes, and operational services (embedded operations) to multiple clients including Blue Shield of California, Blue Cross Blue Shield of Arizona, and Texas Medicaid. We have processed over 100 million clinical transactions, ranging from health assessments to prior authorization and clinical reviews, post-service coding reviews, and clinical appeals spanning lines of business including commercial payers, Medicare, and Medicaid. We provide qualified clinicians to perform pre-authorization reviews of clinical criteria for medical necessity. Our clinicians play a critical role in the prior authorization process by assessing and determining the affirmation or non-affirmation. They are part of a broader team that includes prior authorization coordinators and clinical reviewers, ensuring a smooth workflow from initial determination checks generated through AL, ML and business rules engines. Accenture believes “Intelligent UM” (the myriad ways the authorization process can be made more efficient from a people, process, and technology standpoint) is a primary goal when working with any health plan client in the UM space. Efficiencies gained include quicker processing time, automation of activities where applicable, reduced costs, and increased appropriateness of care and its utilization.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	Accenture has over twenty years of experience supporting day-to-day processing for clients in the health care sector and provides many of our clients with operations support for claims adjudication and appeals. For our clients, Accenture processes 170M+ health claim transactions annually at or above 99% accuracy, and we have a strong track record in managing administrative claims data from CMS and other payers/plans. Outcomes for clients have included: 20+% reduction in outpatient manual authorization processing volume; 10+% increase in automation of inpatient request volume; ongoing auth policy governance model to maintain disciplined approach to authorization requirements; potential financial impacts identified for National Medicare Plans of $15 - $27 million with realized financial impacts of between $9 and $24 million. Our healthcare data work includes extensive experience with prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and CMS, including Local Coverage Determinations (LCD) and National Coverage Determinations (NCD). Our AI platforms process thousands of prior authorization cases daily, automating multiple aspects of the prior authorization journey including intake, eligibility checks, state business rules, same or similar service checks, and medical necessity reviews. We have crawled and parsed tens of thousands of medical policies from numerous Medicare Advantage plans as well as all NCDs and LCDs from CMS. This comprehensive database of structured policy data allows our system to automatically validate prior authorization requests and prepayment review records against the relevant coverage criteria. Many payers have seen their total cost of care rise over the years. The growing complexity of industry utilization management requirements – changing regulations, advances in medicine, and heightened demand for transparency can quickly cause churn, leading to the cost of care rising even more. To alleviate the administrative burden of UM paperwork, make it quicker for patients to receive care, and combat increasing costs, Accenture has helped our clients by implementing data-driven solutions that make UM processing easier and faster for everyone while placing a lens on strategic changes that could be made within the hierarchy of UM processing. Accenture approaches UM transformation through a multifaceted process including use of a data driven solution, Clinical Review Optimization (CRO), which uses claims and authorization data to determine appropriate recommendations to implement auto-approval. The CRO tool utilizes analytics to create an optimized clinical review list to drive value through decreased administrative costs, increased medical savings, and decreased member/provider abrasion. It is a data-led approach to reduce manual effort and cost associated with administering prior authorization through rationalizing authorization requirements and increasing auto-processing of both outpatient and inpatient requests. Through this standardized, analytical approach, we use current clinical review data and perform financial analysis to calculate the ROI for each clinical review and its financial impact. This results in clear, data-driven insights into clinical operations functions, uncovering process improvement and staffing capacity vs. demand opportunities. Accenture has long utilized a data-driven approach called Value Targeting. Accenture’s Value Targeting model and analytics engine enables scalable cost structure transformation that improves quality of patient care. Our hypothesis library with 200+ pre-built solutions has over $850M of qualified value that we’ve found at leading health organizations, which can be used to accelerate opportunity discovery and value realization at other clients. For our clients, value targeting is an opportunity to accelerate related items on their agenda that often lack business urgency particularly in the prior authorization and utilization management space. Solutions are tailored to fit line of business, including Medicare-specific

	operations. Within the utilization management space, Value Targeting hypotheses focus on the concepts of optimizing Prior Authorization requirements, reducing unauthorized claims paid, improving Claim to Authorization matching and enhancing appeal overturn criteria. Value targeting emphasizes a prioritized approach that focuses on the highest impact work first to maximize speed to value realization. To maximize impact, Accenture accesses client data including claims, authorizations, referrals, finance, membership, pharmacy, procurement, billing and more to facilitate the approach. Accenture partners with clinical, technology, data, and business leadership to define initiatives to improve the utilization management processes. In one instance, we co-developed a three-year plan and value case for a portfolio of initiatives which eliminated unnecessary UM volume and reduced transaction review time to give providers and members faster and more consistent decisions about their coverage requests. We focused on two vital areas. First, we simplified the process for doctors to obtain precertification for specific medical procedures. This involved reducing the list of procedures requiring precertification and improving the speed at which we assess the medical necessity of these procedures through automation tools. Second, we assessed initial inpatient review volume and identified types of admissions based on diagnosis and facility details which could be automated through technical capabilities. Overall, this effort alleviated the cost and burden associated with UM reviews without leaking medical cost. Accenture has experience working with MACs JH, JJ, JL, and JK and integrating with Noridian, myCGS and other MAC infrastructure to help suppliers submit claims, check eligibility, assess same-or-similar services, and perform other functions. We enable Supplier ID connections through clearinghouses via CEDI enrollment for parts A and B. Accenture will leverage our experience working with those MACs to work with additional MACs as designated by CMS. Furthermore, Accenture works with major EHR vendors and hospital systems that integrate directly with MACs in their regions. Our experience with various integration efforts including CRM integration and implementation will allow us to apply lessons learned and best practices to WISeR. Accenture has implemented a robust security program that meets CMS's Acceptable Risk Safeguards (ARS 5.0 & 5.1), security controls, and other privacy and security requirements. AFS is responsible for protecting CMS's information (personally identifiable information (PII), and personal health information (PHI)) from unauthorized access, use, disclosure, duplication, modification, diversion, or destruction, whether accidental or intentional. We are fully versed in the broad range of security and quality requirements that apply to the critical services provided by CMS – including HIPAA, PII and PHI protection, system FedRAMP and ATO requirements, and regulatory compliance. We regularly monitor compliance with data security standards with federal agencies including CMS, HHS, the IRS, and other relevant agencies to ensure that all systems and processes remain compliant as requirements evolve over time. As an example, the Federally Facilitated Marketplace's (FFM's) Security Program includes (1) Security Operations, Architecture, and Engineering, (2) Governance, Risk, Compliance and Access Control, and (3) Application Security, Vulnerability Management and Incident Response. Accenture uses CMS or FedRAMP-approved Cloud technologies, reducing the cost and minimizing risk. We develop and maintain FISMA systems and execute Authority to Operate (ATO) and System Security Plans (SSP) regularly, requiring an understanding of National Institute of Standard and Technology (NIST) Verifiable Digital Credential (VDC) requirements as well as security guidelines and frameworks from the network stack to the application layer. We collaborate with the CMS Advanced Capability Testing contractor and the VDC Certified Coding Specialist (CCS) during security scans. Accenture applies effective risk management practices, which include early identification, frequent communication, collaborative management, quality remediation plans, and comprehensive impact assessments to effectively avoid and mitigate potential risks and issues. We have developed Incident Response playbooks, scripts, triggers, and other automatic tooling configured to provide detailed reporting on incidents. We also use threat modeling principles (i.e., STRIDE) to proactively determine systemic or real-world risks, paired with comprehensive continuous monitoring to detect security events. Accenture coordinates with dozens of stakeholders to manage incidents, providing technical support when needed, as well as to capture meaningful metrics and perform an RCA to further optimize CMS' cybersecurity posture. Our security models meet the requirements for authenticating users and authorizing access for Marketplace application services while adhering to security and privacy requirements of the Social Security Administration (SSA), IRS, and CMS's Information Security Acceptable Risk Safeguards (ARS). For each program we run, Accenture develops a detailed Incident Response Plan (IRP) to protect the program and its data, minimizing the impact of security incidents such as data loss, theft, or service disruption. The IRP aligns with NIST, HHS, and CMS policies and guidelines, including NIST 800-53 Revision 4 and CMS ARS 3.1 Appendix B CMRS Moderate Impact Level Data requirements. We implement alerting mechanisms to detect and remediate security findings, leveraging our incident response team and collaborating with the CMS SOC on all issues.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program	No

(FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	

Authorizations or Certifications Document

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	Accenture's health practice includes 15,000+ healthcare professionals, including 2,000+ licensed medical professionals who bring deep backgrounds and expertise in utilization management. Many of our clinical professionals have had wide-ranging careers with health plans and in utilization management prior to joining Accenture. In addition to our clinicians, our utilization management practice includes subject matter experts (SMEs) who have performed medical reviews and peer-to-peer reviews, bringing firsthand, on the ground knowledge to inform prior authorization client operations and best practices. Through Radiant Services (a wholly owned Accenture subsidiary) Accenture provides utilization management operations inclusive of clinical and peer-to-peer reviews. We bring a dedicated clinical, quality, and compliance oversight team that verifies that our utilization, quality, and compliance activities follow standards, license requirements, and client compliance directives. This team is led by Radiant's Chief Medical Officer (CMO) and includes medical management nurses, board certified clinicians, prior authorization coordinators, compliance and privacy leads, and quality/training leads. Our team has over 60 years of combined clinical, quality, and healthcare experience. This allows us to rapidly provide a team of qualified clinicians to perform pre-authorization reviews of clinical criteria for medical necessity. They are a critical part of the process ensuring a smooth workflow from initial determination checks generated through AL, ML, and business rules engines. We staff our teams with highly experienced resources who have demonstrated the ability to meet and exceed quality, productivity, and compliance targets. We ensure that all staff or associates undergo detailed training to support client operations and provide clinically accurate coverage determinations. Accenture currently provides embedded UM operations for Blue Shield of California, Blue Cross Blue Shield Arizona, and Texas Medicaid. In Texas Medicaid, we operate from the state of Texas inclusive of Medical Directors who can render denials and peer-to-peer reviews.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	Accenture is the world's largest EHR integrator, processing 170M+ health claim transactions annually with over 800 Robotic Process Automation (RPA) and custom BOTs deployed for our health operations clients. Accenture has the experience and expertise to integrate with any EHR system, typically via API calls. In deployments where an API cannot be established due to EMR restrictions, we successfully deploy other automation techniques to receive the needed information. We have strategic relationships and experience working with EHR systems including Epic and Cerner. We are recognized as a top leader in Healthcare Provider Digital Services for our ability to drive digital transformation across the healthcare provider value chain, driven in part by 160+ awarded health patents in advanced analytics, AI, virtual agents, cybersecurity and cloud-based platforms. Accenture has been part of the fabric of FHIR evolution, continues to expand use of FHIR across Health organizations, and has worked on HL7 since its founding in 1987. Accenture has extensive experience integrating and enhancing EHR systems for healthcare organizations, focusing on improving interoperability, data management, and the overall patient and provider experience. Accenture has engaged with many leading EHR platforms embedded in our clients' operating models to achieve advancements, including the assessment and enhancement of the prior authorization process. Through our experience and industry partnerships, Accenture has the experience and expertise to integrate with any EHR system, typically via API calls. In deployments where an API cannot be established due to EMR restrictions, we successfully deploy other automation techniques to receive the needed information. Accenture supports healthcare providers in migrating their EHR systems, including applications like Epic, to cloud environments like Microsoft Azure. We were the key partner to Mount Sinai Health System in the migration of its enterprise electronic medical record (EMR) system, Epic, to the Microsoft Azure cloud environment. This marked the largest production instance of Epic running on Azure to date. This type of migration allows organizations to streamline data management, reduce operational costs, and enhance accessibility and security of patient data. We also offer hybrid cloud managed services to support the migrated workloads, covering server management, storage and backup, database support, automation, and analytics. Accenture identifies standards and specifications to facilitate health information exchange, which is crucial for achieving interoperability between different EHR systems, as well as between EHR systems and other

	systems like UM technology platforms. Accenture provides services for migrating patient and practice data into new EHR systems, ensuring accuracy, security, and compliance with regulations like HIPAA and assists in transforming existing patient data to meet the requirements of new systems, inclusive of data cleansing and reorganization. This process helps consolidate patient information, providing a comprehensive "single source of truth" for patient records, and improving continuity of care. In addition to technology implementation, Accenture provides training as needed for clinicians on using EHR platforms, as demonstrated by our work with Oracle Cerner to enhance training for the VA's Cerner Millennium-based EHR system. This ensures that healthcare personnel are proficient in utilizing the new systems, which is critical for successful EHR adoption and achieving the desired benefits. Accenture helps organizations through the entire EHR implementation process, from initial planning and setting goals to data migration, testing, staff training, and post-implementation review and optimization. We help clients to better manage healthcare quality, efficiency and costs through successful EHR implementations. We believe alignment with CMS-0057-F is essential in mobilizing providers and payers to take full advantage of opportunities facilitated by Clinical Decision Support (CDS) Hooks and SMART on FHIR integration. Yet very few organizations have deployed any CMS-0057-F support or established the infrastructure needed to function in a "standardized" manner. As a result, Accenture's solution, functions within existing frameworks without dependence on EHR, provider, or payer standardization expectations. Accenture has previously connected with numerous EHR platforms, including implementations of CDS and SMART on FHIR applications. The team is currently engaged in Da Vinci standards group discussions with major EHR vendors such as Epic, Cerner, and Meditech to implement their prior authorization solution as a SMART on FHIR app. Currently, providers and suppliers are utilizing our application that integrates with smaller EHRs, billing systems, and practice management solutions directly, via fax, or as a standalone platform. Through team members' involvement in the Da Vinci CRD / DTR / PAS burden reduction initiatives and practical experience both submitting and evaluating prior authorizations, we've determined that current proposed standards are insufficient for truly automating prior authorization. This position is now echoed by the Da Vinci group, which recognizes interoperability challenges in the CRD and DTR APIs. Nevertheless, Accenture's AI-driven approach remains effective despite variations across plan policies and coverage criteria, eliminating the need for conformance from individual plans. This methodology is already delivering solutions for the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) to health plans seeking regulatory compliance through FHIR Binaries and Document References, enabling the transmission of complete patient histories rather than requiring providers and plans to format data into discrete elements. With our solution already available and interfaces currently utilized by providers, along with our extensive and deep experience with EHR and specifically UM/prior authorization work, our strategy demonstrates market acceptance that will certainly support the adoption of prior authorization for additional services under WISeR.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met. b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	AI/ML Experience and Implementation Approach Accenture has extensive experience developing AI/ML models for a wide range of clinical and administrative healthcare modeling tasks, including healthcare prior authorization. Our Processing.AI tool has been trained on 25M medical record pages with physician and certified medical coder review, plus 1,000+ U.S.-licensed registered nurses. We maintain a Health Information Knowledgebase with over 5B data associations (compared to UMLS's 74M relationships), delivering 25-50% improvements in review accuracy and 2-3x processing speed increases compared to traditional processes. AI Framework for WISeR: Accenture is the world's largest systems integrator. With that perspective, we reviewed the requirements as described in the RFA and identified several AI-based modern solutions that would effectively address CMS's requirements including a model start date of January 1, 2026. Although Accenture has experience implementing over 10 UM and prior authorization solutions, many of those solutions are still working to enhance AI and ML capabilities and lack the automation that CMS is seeking for WISeR. We narrowed the selection down to these more innovative solutions for final evaluation: Accenture's internally developed Processing.ai solution – a proven "bolt on" medical review/prior authorization solution to an existing UM Salesforce's health platform - a new "bolt on" medical review/prior authorization solution to a UM GenHealth's UMPA platform – a proven UM and prior authorization solution Given CMS's timeline, Accenture determined that GenHealth's existing MAC integrations and commercial deployment status make UMPA the solution most likely to effectively meet CMS's requirements for both scope and timeline. We would welcome the opportunity to discuss all the potential solutions and our assessment methodology with CMS to provide more information. As mentioned above, we work closely with our payer customers on vendor selection and implementation and have successfully launched and optimized over ten UM solutions including prior authorization solutions that leverage GenAI capabilities. We also look forward to discussing in more detail with CMS how to best leverage MAC capabilities and integrations to minimize re-building solutions today while also providing a direct method for providers/suppliers. The UMPA (Utilization Management/Prior Authorization) tool integrates not only an LLM technology but also a Large Medical Model (LMM) for real-time adjudication. Large Medical Model (LMM): GenHealth's custom-built LMM functions as a generative pre-trained transformer trained on 140 million longitudinal patient claims, of which 60 million are Medicare beneficiaries. Training data (non-exhaustively) includes patient demographics, procedures, conditions, medications, death data, cost data, provider NPIs, and exclusion reasons for fraud detection. Core components of UMPA include a document

	processing pipeline with OCR engines, NLP models, named entity recognition systems, and document classifiers for text extraction and categorization. The graph network architecture incorporates graph neural networks, knowledge graph construction engines, and graph embedding algorithms. An integration layer combines document and graph representations and attention mechanisms. Supporting infrastructure includes vector databases for embeddings, graph databases for knowledge management, caching systems, and API gateways. Verification, Validation, Security, and Regulation Verification and Validation: Accenture employs rigorous evaluation procedures with testing and validation been performed against thousands of manually reviewed prior authorization cases. We utilize sophisticated monitoring solutions such as Weights & Biases and Langfuse for live environment performance tracking. Research initiatives interrogate performance across service classifications and population segments to reduce biases. Security and Regulation: We maintain rigorous security with exclusive use of de-identified data for model training, eliminating patient health information exposure risks. Our dedicated healthcare GenAI computational resources (32 H100s, 16 A100s) plus cloud capabilities enable rapid model refinement and assessment. Ethical, High-quality Utilization Management and Managing Adverse Effects of Automation and AI: While leveraging advanced AI capabilities, our organization remains fundamentally human-directed with ultimate responsibility for medical assessments residing with board-certified physicians. We maintain robust human oversight for any non-affirmative determinations generated by our AI platform. Our AI system uses specific prompting methodologies and retrieval augmented generation prioritizing decision accuracy and explainability. The strategy emphasizes high precision over high recall - when the model renders a decision, it's nearly always correct but doesn't always deliver definitive determinations. Indeterminate AI evaluations are directed to clinical teams alongside denials. We integrate clinical expertise, enabling technology, and EHR connectivity to ensure AI-assisted prior authorization incorporates necessary clinical safeguards. Comprehensive Workflow Management: The platform precisely indicates missing patient records when essential information is absent. Healthcare professionals can deliver materials via EHR integration, fax, or manual uploads. All negative determinations are examined by professional clinical staff who manually verify responses, address information gaps, and formulate final recommendations. All activities are documented for CMS reporting, auditing, and FWA identification. Our structure reduces administrative workload while supporting inquiries regarding decision feedback and denial justifications, benefiting all participants in the prior authorization ecosystem. Evaluation/performance Metrics span multiple dimensions. Document processing accuracy is measured through precision, recall, and F1-scores for entity extraction, character/word-level OCR accuracy, BLEU/ROUGE scores for summarization, and semantic similarity scores. Graph network performance uses node classification accuracy, link prediction metrics (AUC-ROC). System-level metrics track end-to-end latency, throughput, memory usage, computational efficiency, scalability across document volumes, and query response times. Quality assurance involves human evaluation scores, cross-validation results, robustness testing against corrupted inputs, and consistency metrics. Responsible AI Framework: As industry leaders in responsible AI, we have developed a comprehensive five-step approach to help organizations effectively implement responsible AI, transforming their operating landscape in the process. This approach includes: (1) Establish AI governance & principles; (2) Conduct AI risk assessment; (3) Systemic RAI testing & risk mitigation; (4) Ongoing monitoring & compliance of AI; (5) Workforce impact, sustainability, privacy and security. Each of these 5 steps has a significant set of tools, assessments, accelerators, and playbooks that have been used and refined by health and non-health organizations worldwide to promote RAI and mature the automation and AI capability of at enterprise scale and help promote the effective, fair, safe, and equitable use of AI and automation. Accenture has executed multiple RAI engagements with federal agencies, including 3 in the federal health space, and has supported AI policy development and oversight. We deploy an "AI Control Plane" for ongoing monitoring and management of AI solutions. Our AI red teaming offerings have been used by major tech firms to ensure trust and safety of large language models. Additional information about our ethical framework can be found in our response to question 7.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	Yes

Accreditations or Certifications Document

File Name	WISeR-00140_Accreditations_Radiant_Services_LLC_Accreditation_in_Utilization_Management_Certificate_NCQAexp011927
Uploaded On	7/25/2025, 5:09 PM

File Name	WISeR-00140_Accreditations_Radiant Services, LLC - Health Utilization Management Modular Accreditation 2.0- PRS, ICR, CRC
Uploaded On	7/25/2025, 5:17 PM
File Name	WISeR-00140_Accreditations_Certifications
Uploaded On	7/25/2025, 5:18 PM

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	Accenture's approach to ethics, compliance, and quality standards is anchored in our unwavering commitment to integrity, accountability, and continuous improvement across all healthcare partnerships. Our comprehensive framework ensures the safety and trust essential for successful collaborations with patients, providers, and payers, from initial submission through decision and, when needed, dispute resolution. Our ethical foundation rests on core values and our Code of Business Ethics, which establishes clear behavioral expectations and decision-making guidelines for all employees. Through comprehensive ethics training and our robust Ethics & Compliance program, we foster a culture of transparency and accountability that permeates every aspect of our operations. This commitment extends to our dedicated Compliance team, which continuously monitors regulatory changes and provides guidance to ensure adherence to all relevant laws, regulations, and industry standards, including HIPAA and other healthcare-specific requirements. As AI becomes more embedded in our healthcare delivery work, Accenture's focus on responsible and ethical AI extends to every aspect of our efforts. This includes our formal AI policy, by which all Accenture personnel must adhere. The policy includes a set of Responsible AI principles: Human by Design: understand the impact on humans every time you deploy AI and ensure that potential negative impacts are identified and managed consistent with our purpose and core values. Fairness: all AI models should treat all groups equitably, and action must be taken to mitigate the potential for unwanted bias and other negative unintended consequences (e.g., unfair impact to gender, race, and ethnicity). Transparency, Explainability & Accuracy: disclose the use of AI where appropriate and all should be able to understand and appropriately evaluate AI outputs and decision-making processes. We will use relevant and high-quality data responsibly so that outputs are reliable. Safety: evaluate potential safety concerns and take action to mitigate harm (e.g., with respect to human life, health, property, and the environment) when deploying AI. Accountability: document enterprise-wide governance structures, with clear roles, policies, and responsibilities. Compliance, Data Privacy & Cybersecurity: all use of AI must comply with relevant laws, secure data with appropriate privacy protection, and protect AI from cyber-attacks. Our respective compliance programs for data privacy and security will be applied where relevant to ensure compliance with these AI governing principles. Sustainability: deploy AI taking into account the impact on the planet, with appropriate steps taken to mitigate negative impacts. Our sustainability program will be applied where relevant to ensure compliance with these AI governing principles. Quality excellence drives our service delivery through industry-leading methodologies and our ISO 9001-certified quality management system. This certification ensures we consistently meet both customer and regulatory requirements while maintaining the highest service standards. Our continuous improvement practices involve regular process reviews and enhancements that strengthen our ability to deliver exceptional outcomes. Our proven healthcare experience demonstrates this commitment in action. We have successfully implemented comprehensive healthcare IT systems for major federal agencies while ensuring rigorous data security and HIPAA compliance. Our patient management platforms have improved outcomes and operational efficiency for leading healthcare providers, while our complex data integration projects for healthcare payers have maintained data integrity and industry standard compliance throughout. Through rigorous internal policies, regular audits, and proactive risk assessments, we identify and mitigate potential compliance risks before they impact our clients or their stakeholders. This systematic approach, combined with our extensive healthcare project experience and dedication to ethical practices, positions Accenture as a trusted partner capable of meeting the evolving needs and expectations of all healthcare stakeholders while maintaining the highest standards of safety, ethics, and quality. Emerging and evolving Federal, State, and CMS legislation, policy mandates, and requirements necessitate flexibility and rapid resource alignment to implement system changes, ensuring a seamless consumer experience and consistent assurance that systems and processes are up to date and aligned with the most current requirements. Accenture is accustomed to providing this type of support to our clients, as demonstrated in our ongoing support of the Federally Facilitated Marketplace (FFM), where we have provided CMS with rapid response on multiple occasions to ensure continued compliance with emerging policy changes without impacting ongoing Marketplace operations. The COVID-19 Public Health Emergency (PHE)

	and the subsequent level-set of the PHE unwinding is one example of Accenture's swift response to emerging policy changes. Accenture has been a trusted partner of CMS, as we have adjusted scope prioritization, allocating additional resource capacity to address compliance with emerging needs and key Administration policy changes. The team has demonstrated success mitigating delivery risks for critical FFE releases while managing new policy directives and incorporating application updates to support consumer eligibility and enrollment activities while ensuring alignment with evolving federal mandates. Accenture continues to work closely with CMS to iteratively evaluate and effectively manage priorities while delivering a smooth consumer experience. Our UM and PA programs are governed through an ongoing Clinical Quality Oversight program that includes: Clinical oversight team who provides ongoing clinical subject matter expertise to clinical functions and reviews of medical policies & procedures for adherence to clinical guidelines. Accreditation and compliance team who develops and maintains our quality and compliance policies and procedures. They facilitate and monitor adherence to compliance and regulatory requirements. Licensing oversight team tracks and maintains UR, TPA, and agent licensure. They monitor state regulations for all state-specific policies and procedures. Quality management review team meets quarterly to review operations for adherence to compliance requirements and quality standards. This team drafts and implements quality improvement plans where necessary. Resources dedicated to regulatory legislation monitoring maintain and review subscriptions to state and federal regulatory updates. Resources dedicated to policies and procedures supply annual review and maintenance of existing policies and procedures. All personnel are required to participate in compliance training annually. A complaints tracking process is built into the staffing model such that complaints and their resolutions are tracked and reported. For WISeR, Accenture will work with CMS to document the initial set of requirements, including NCD and LCD policies, model-specific requirements, and state-specific regulations and policies that will apply to providers in the model. As new policies and regulations emerge, we will update the documented requirements, including their effective date and any dependencies. This will allow for effective audit of policy adherence based on location, policy, and date.
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Accenture estimates a conservative 10%-20% savings initially for the procedure codes represented in the WISeR model. We expect this to decrease year over year for each specific model as provider behavior is modified through the prior authorization feedback and education efforts provided by Accenture. Across the six states included, we estimated the Medicare expenditure for the WISeR selected items and services using a variety of techniques and different publicly available and commercially available data sets for Medicare Fee for Service. Assuming a 7% increase in CY 2025 and based on CY 2024 fee for service spend for the procedure codes identified in the model, Medicare paid an estimated approximately $1.84 billion for these likely medically unnecessary services resulting in a savings estimate of approximately $184 million - $368 million (10% - 20%) in year one. While the savings directly attributed to the model through non affirmations should decrease year over year due to provider behavior modification, the behavior modification itself is a form of savings indirectly attributable to the model. This indirect savings would be predicated on the performance of the model participant to communicate effectively to the provider community which would result in the desired behavior modification. We intend to measure also the expected decrease as a performance measure of the model itself. The savings estimates for the WISeR Model, starting January 1, 2026, and running until December 31, 2031, covers all four Medicare Administrative Contractor (MAC) jurisdictions – JH, JL, JF, and J15 – and six states: New Jersey (JL), Ohio (J15), Oklahoma and Texas (JH), and Arizona and Washington (JF).However, we understand CMS intends to award one contract per jurisdiction. Accenture supports large commercial payers that do work in all six states across all four MAC jurisdictions. We understand that utilization management techniques used by Medicare Advantage plans today are likely directly correlated to MA beneficiaries receiving 9.2% few low-value care services than traditional Medicare FFS beneficiaries. As part of our 6-year modeling efforts, we understand CMS will engage industry and add additional services to be within scope for the WISeR model and we encourage CMS to evaluate these at least on an annual basis and provide the WISeR contractor at least 6 months to update their systems and integrations accordingly.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	Accenture through GenHealth currently interfaces with two of the four MACs (JH and JL) in this model and has ingested the policy information needed. In addition, Accenture has already established interface with the LCD and NCD content and fully ingested the existing rules and regulations. For the remaining two MACs (JF and J15), Accenture will use the same process that has already proven successful for the previous MAC interface to establish connections; this process requires an average of 60-90 days to complete activities such as establishing data use agreements and connections. This timeframe provides the time necessary for the integration and staffing of the medical review/utilization management team, integration of a customer service (CRM) platform, training, and security process establishment. The Accenture team, through the GenHealth UMPA platform, has significant experience integrating with claims, coverage, and member information systems and EDI interfaces from their work with nearly 70 MA and Medicaid Health Plans during the CMS Patient Access implementation phase. Additionally, the UMPA platform has existing infrastructuresupporting providers and suppliers where the UMPA application integrates with MACs for functions including eligibility, same or similar checks, member coverage and balance information, etc. Currently GenHealth has both direct integrations and augments its

	capabilities with a clearinghouse service from Claim MD and telecom through Cortex EDI. Building on this experience and existing infrastructure, Accenture will further integrate with the MACs to support the claims and prior authorization processing infrastructure for transparent and real time connectivity both for providers that submit claims through the MACs and those that may launch prior authorization requests through MACs. All GenHealth systems are HIPAA compliant and externally audited, so the new interfaces will leverage that existing secure infrastructure. Most notably we have planned a set of MAC integrations to be completed within 60 days of contract award. As a testament of our ability to execute on time, on the first day that MA and Medicare plans had to be live with the patient access APIs, twenty of the twenty-four plans that went live on July 1, 2021, were delivered by the GenHealth team. Accenture plans a two phased 90-day implementation including phase 1 (60 days) for MAC integration set up and Phase 2 (30 days) for final operational readiness activities. Phase 1: MAC Integration and Coordination (~60 days) MAC Onboarding and Registration Initiate enrollment with each awarded MAC jurisdiction (where we do not already have connectivity) Execute EDI Trading Partner Agreements (TPAs) Submit CMS MAC enrollment forms (e.g., EDI enrollment, submitter IDs) (where needed) Set up secure connectivity (SFTP, VPN, NPI mapping) Obtain and test credentials with MAC technical teams Transaction Mapping and Technical Implementation Implement support for X12 EDI transactions: 837, 270/271, 276/277, 278, 275, 999, 277CA Map Universal Tracking Number (UTN) for prior authorizations between UMPA internal workflows and the MAC systems Integrate with jurisdiction-specific portals (e.g., Noridian DDE, Novitasphere, CGS MCS) (where needed) Prior Authorization API and Workflow Readiness Enable structured prior auth requests (FHIR or X12 278, likely X12 as MACs typically lack robust FHIR support) Support submission of clinical documentation via secure channels (e.g., 275) Set up internal workflows for request submission, UTN generation, status updates Redundancy via Clearinghouse and Direct Integration Establish dual-path submission through direct MAC interfaces and Claim MD Implement failover or switching logic between direct and clearinghouse paths Logging, and Audit Infrastructure Set up logging for all new EDI and prior auth activity Ensure all logging supports CMS traceability and audit standards Compliance Alignment and Privacy Readiness Validate HIPAA compliance of all new transmission channels Complete data flow and risk assessments Update BAAs and data handling SOPs ATO readiness activities Stakeholder Coordination Assign technical and operational leads per MAC Participate in MAC onboarding or orientation sessions Define escalation paths and incident response responsibilities Following the above integration activities, at least 30 days will be dedicated to testing the integrations with MACs and providers. This 30-day test period will help validate integrations as well as make any other unexpected accommodations to support a secure and on time go-live. Phase 2: Testing, Security, and Operational Readiness (~30 days) Testing and Dashboarding Expand status dashboards to support status and testing of new MAC interfaces and transaction monitoring Deploy internal and external dashboards for CMS, MACs, and Providers to monitor API, data exchange, and system availability Run full-cycle tests of prior authorization requests and document workflows in collaboration with CMS and MAC test environments Security Validation Execute static and dynamic code security scans Complete external penetration testing on all new interfaces Update HIPAA compliance documentation to reflect new data flows and vendor connections Final Staffing, Training, and Go-Live Preparedness Final onboarding and training of new staff Completion of ATO package and approvals and all other go-live requirements Go-live stakeholder communication and coordination Implement additional requirements,dependencies, or modifications as necessary Phase 3: Hypercare and Continued Innovation (Post Go-Live) Ensure the technology is operating to meet business needs per CMS agreement Ongoing operational and security support and maintenance of CMS ATO Program management, including stakeholder support and communications Data analysis and reporting to assess operational success and report on CMS specific measures Support emerging requirements and regulatory updates Ongoing training and support for MACs and providers as needed Continuous training of Artificial Intelligence (AI) and/or Machine Learning ML) models and business rules Iterative development and enhancements

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓

Company/Organization Name:	Accenture Federal Services
Certifying Individual: **Title:**	(b)(6)

CMS.gov
Centers for Medicare & Medicaid Services

WISeR-00141

Requested by (b)(6) on 07/28/2025 15:52

Application Status: Submitted

Complete Profile

Applicant Information

1. Applicant Information	
a. Legal Name	D2 Pharma Consulting LLC
b. Doing Business As (DBA) Name(s)	D2 Solutions
c. Street Address	1480 Woodstone Drive Suite 208
d. City	Weldon Srping
e. State	MO
f. Zip Code	63304
g. Tax Identification Number	263335658
2. Which of the following best characterizes your company or organization?	For-profit business
If Other, please specify	
3. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.	Mission: To empower healthcare organizations with innovative solutions that streamline operational efficiency, drive sustainable growth and improve patient results. We aim to be a trusted partner by delivering customized, scalable strategies that solve complex challenges in an evolving healthcare landscape. Vision: To be the leading provider of transformative solutions, enabling seamless integration of consulting services, technology and data that improve organizational performance while enhancing the patient experience across the care continuum. Values: 1. Innovation: We prioritize forward-thinking solutions, constantly seeking new ways to address the changing needs of healthcare. 2. Integrity: We are committed to honesty, transparency, and ethical practices in everything we do. 3. Collaboration: We believe in the power of partnership, working closely with clients and stakeholders to achieve shared success. 4. Excellence: We strive for the highest standards in our work, ensuring quality, reliability, and consistency in every solution we deliver. 5. Customer-Centric: Our clients' goals are our goals. We tailor our services to meet their specific needs and deliver tangible results. 6. Adaptability: In a rapidly evolving industry, we embrace change and remain agile in the face of new challenges. About D2: Founded in 2008 with an exclusive focus on life sciences, D2 Solutions (D2) is a best-in-class consulting and technology provider exclusively focused on serving the life sciences industry. D2 has developed a unique level of expertise from working with over 400 organizations over a 16-year period. D2 is led by industry veterans who have had held executive, operational, technology and financial leadership positions with organizations such as Express Scripts, CVS, Premier (GPO), GSK, Cardinal Health, CareMetx, BioScrip, CatalystRx amongst others. D2 is on the forefront of designing and integrating innovative solutions across the industry. Simplistically, D2 provides consulting and technology services to key stakeholders including Payers, Manufacturers, Hospitals, Pharmacies and HUB providers. We focus on three areas, distribution, reimbursement and

	patient services. D2 works across various stakeholders to ensure the appropriate distribution models, reimbursement structure and patient support models. In addition, D2 provides a variety of technology solutions to support various industry stakeholders in the areas of Accreditation, Licensing, and Regulatory Compliance, Patient Engagement and Prior Authorization. D2 would support WISeR via UltraTouchVerify D2's propriety PA Automation Platform currently being utilized across various hospitals, HUBs, Pharmacy and Physician offices. WHY! D2 works with stakeholders to ensure patients can access necessary medications to get the most out of their healthcare experience. We do this by enabling organizations to leverage technology thereby working more efficiently so they can serve patients better.
4. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?	JH Novitas

5. Provide street address, city and state for all locations.

Location Name	D2 Solutions
Street Address	1480 Woodstone Drive, Suite 208
City	Weldon Spring
State	Missouri
Zip Code	63304

6. Please provide CMS with a full and complete understanding of the ownership interests in the applicant, as well as the ownership interests in the entities with an ownership interest in the applicant. Each party with at least 5% ownership interest in the applicant should be listed.

If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other). Ownership interests listed should reach the 'ultimate parent' owner(s) (if applicable)

Ownership Interest Document

File Name	WISeR-00141_Ownership_D2 Ownership Structure
Uploaded On	7/25/2025, 2:11 PM

Organization Contacts

Ensure you have at least one primary and one secondary contact. A tertiary contact is optional. These individuals will serve as points of contact for important updates and inquiries related to the WISeR Model.

Contact Type	Primary
Email Address	(b)(6)
Name	
Title/Position	
Address	
Business Phone Number	

Contact Type	Secondary
Email Address	(b)(6)
Name	

Title/Position	(b)(6)
Address	
Business Phone Number	

Contact Type	Tertiary
Email Address Name Title/Position Address Business Phone Number	(b)(6)

Complete Application

Incorporation and Licensure

Please attach a copy of a certificate of incorporation or other documentation demonstrating that the company/organization applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.

Incorporation and Licensure Document

File Name	WISeR-00141_Licensure_D2 Corporate Status_06192025
Uploaded On	7/25/2025, 2:16 PM
File Name	WISeR-00141_Licensure_D2_Pharma_Consulting_-_Policy_and_Procedure_-_HIPAA_-_FINAL_v2.2 (3)
Uploaded On	7/25/2025, 3:21 PM
File Name	WISeR-00141_Licensure_D2_Pharma_Consulting_-_Policy_-_Regulatory_and_Quality_Compliance_Program_and_Policies_- (2)
Uploaded On	7/25/2025, 3:21 PM

Disclosures

Please disclose the following with respect to the applicant, and with respect to any parent company, or any business associate or other relationships with a Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entity: any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

N/A	✓

Disclosures

HIPAA Business Associate Agreements

1. Please list and describe briefly any HIPAA covered entities with which your company or organization has a business associate agreement.	D2 has business associate agreements (BAA) with over 100 healthcare entities. This is largely driven by the fact that these organizations use one or more of D2's technology solutions to support their business needs. This includes preeminent organizations such as MD Anderson, Mayo Clinic, University of California Health System, Providence Health, Phoenix Children's Hospital, University of Alabama, Ochsner, Carolinas Health System and many others.

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?	a. As a healthcare technology company specializing in prior authorization optimization, we bring extensive experience working with payer policies and healthcare-specific data to streamline coverage determinations and reduce administrative burden. This is done due to D2' unique process of creating drug – coverage "Protocols" as described below. This ensures that a product is approved only in accordance with the specific coverage criteria of a specific health plan. A method that is ideally suited for this WISeR demonstration. b. D2 Solutions has experience working with several of the Medicare Advantage plans. While each has their own specific set of criteria for prior authorization processing like requiring chart notes or step therapy, allowing resubmissions after a denial as opposed to requiring an Appeal, we have found success in both a) attaining approvals via the first submission and b) working with Medicare in addressing and turning over claims which have been initially denied. c. In addition, D2 provides outsourced Market Access Support that works within several clinical and policy development departments of the Medicare MAC's on behalf of smaller niche manufacturers. Over the past 14 years this team has worked with Medicare and other payers to help define coverage policies on multiple biotech, diagnostic, pharmaceutical and medical device products. d. It is our anticipation in this model that D2 would have access to both Patient eligibility and Coverage policy. With this information, D2's proven technology (UltraTouch®Verify) would be able to assess Patient eligibility with product coverage applicability and determine approval or denial within minutes saving significantly time and manpower.
2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).	D2's UltraTouch®Verify platform is designed with stakeholder-specific workflows that streamline prior authorization and benefit checks across the healthcare ecosystem. UltraTouch ® Verify uses a custom rules-based engine that is aligned with payer plan/drug-specific criteria, including formulary tiers, step therapies, and uses smart PA technology to identify potential denial warnings based on clinical answers provided and supporting documentation. D2 has extensive knowledge of and experience in working with the Local Coverage Determination and National Coverage Determination process having worked with multiple organizations (as described above) in attaining such coverage determinations.
b. Does your company or organization have any authorizations or certifications to ensure compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications. c. How does your company or organization monitor and ensure compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.	No

Authorizations or Certifications Document

3. Describe your clinical experience in	UltraTouch®Verify would partner with a reputable Independent Review Organization ("IRO")

medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.	and/or firms with robust clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. The IRO and firm(s) also have contracts with third party administrators and/or payers (fee-for-service, managed care) and providers. In addition, have robust and dedicated clinicians (multi-specialty) with relevant experience and expertise to conduct medical reviews to support clinically sound peer-to-peer and sound coverage determination decisions. Last but not least, all have significant Medicare and Medicare Advantage expertise both clinical, and operations. The IRO and/or firms with clinical consultants with which we can partner are as follows: • Health Management Associates--Clinic Care Practice: https://www.healthmanagement.com/services/clinical-services/ • ProPeer IRO: www.propeer.com • PRO-spectus: https://pro-spectus.com/ All of the above entities have technology enabled solutions to share via API to UltraTouch®Verify the result of the medical review. The clinical review process would include utilizing data, technology, and clinical informatics to support CMS with the right staffing model to ensure effective and efficient clinical review so as to accelerate patient access. The clinical care consultants include a distinguished array of physicians, nurses, advanced practice providers including physician assistants and nurse practitioners, behavioral health therapists and other clinicians. They have all practiced direct patient care, and many will continue to do so while also working with UltraTouch®Verify on behalf of CMS as clinical care consultants. Their hands-on experience will help ensure that CMS is receiving the right person with the right specialty in the clinical review process. The model to support CMS would be to have clinical care consultants work across multidisciplinary teams assembled to address each specific therapeutic category. Further this model uses an evidence-based approach to deliver care that will support value-based healthcare outcomes.
4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations. a. Please also include a list of EHR platforms your application or suite is compatible with. b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increase data sharing and reduce overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.	While D2 is not currently integrated directly with any EHR platforms in a production capacity, we have integrated with EPIC SMART on FHIR R4 as a proof of concept and roadmap initiative and have integrated patient, provider, medication, insurance and diagnostic data into our UltraTouch®Verify application using the following FHIR resources. (1) Patient, Read/Search, R4 (2) Condition (Encounter Diagnosis), Read/Search, R4 (3) Condition (Medical History), Read/Search, R4 (4) Condition (Problems), Read/Search, R4 (5) Coverage, Read/Search, R4 (6) Medication Request (Unsigned Medication Order), Read/Seach, R4 (7) MedicationRequest / MedicationOrder, Read/Search, R4 ii) D2 has also completed a Prior Authorization status update back to Epic using an HL7 transaction to the physician's progress note. D2 Solutions and its UltraTouch®Verify application is built to streamline the prior authorization process and improve interoperability across the health care ecosystem using a combination of integration solutions including FHIR, HL7 and customized APIs. Our approach focuses on enhancing data exchange capabilities, automating prior authorization workflows, and reducing the administrative burden for HUBs, hospitals, pharmacies, providers and patients. Our infrastructure supports a near-real-time data exchange across payer, provider, sales force and member touchpoints, enabling more responsive care coordination and administrative efficiency. We are integrating data governance protocols to support opt-in/out features, consistent with CMS's privacy expectations, and ensuring robust member consent management and transparency.
5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning (ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers. a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met.	D2 Solutions actively integrates AI/ML into all aspects of its development and operations cycles. We use LLM AI to generate code, create and run QA Tests, and extract and evaluate information from various sources such as traditional data feeds, websites, images, and documentation. The most relevant use case for this initiative is our code that evaluates incoming data, which includes determination letters and other correspondence with Payers regarding Prior Authorizations. We have trained several models that involve complex datasets and pipelines as part of our UltraTouch®Verify product. Specifically, using incoming responses, we have trained models to identify determination letters, junk faxes, requests for information, as well as those that require human intervention. We also leveraged NLP techniques to extract date of birth, patient and prescriber names, as well as other information. These models are all trained on our own incoming data, that are labeled during the normal processing of determination letters. We redact all identifiable entities, including individuals, locations, and objects, to ensure confidentiality and avoid biases based on patient names, geographic regions, or other aspects that should not be relevant to the information we want to extract. The data is run through a TF-IDF process to extract n-grams that are statistically relevant to each label. A model is then trained on these relevant n-grams. D2 will use a variety of techniques and algorithms to support WISeR. Where communication with a human is required, a chat-like interface powered by a Large Language Model will be employed, with specific validations to verify the answer and prevent hallucinations or prompt engineering. We will use Haystack as the transformer pipeline. That framework enables branching logic and reevaluation at each step of the pipeline, allowing for robust solutions with error checking built into the process. In situations where more reproducibility or mathematical certainty is required, classical ML algorithms such as neural networks, random forests, and support vector machines will be used. These models will be evaluated using AUC and accuracy against pre-labeled datasets. When the system needs to identify anomalous data or groups of data, unsupervised learning will be employed and evaluated using metrics like the Silhouette Coefficient, Calinsk-Harabasz Index and the

b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.	Davies-Bouldin Index. A crucial aspect of any AI or automation is ensuring the validity and security of the results. D2 Solutions policy is to do this by: (1) Removing biases in the data, (2) Ensuring that the sources of data are secured and validated so that extraneous training data cannot be inserted into the process, and. (3) Including a human validation of the result to identify and resolve incorrect predictions. In order to remove biases from the data, we ensure that our models are created using balanced data. In many cases in the medical field, using raw data can lead to model bias. As part of our model training process, we randomly sample the data to balance the training data. Cybersecurity in AI is becoming increasingly important. Data poisoning attacks are on the rise and can result in additional waste as humans are required to identify and fix the issues. The UltraTouch®Verify application team works closely with our security team to ensure that data is tightly protected throughout the ML pipeline and apply anomaly detection techniques to the data to flag suspicious data and facilitate investigation. As previously stated, our approach keeps a human as a final check to avoid adverse effects. Additionally, anomaly detection will be utilized to identify and reevaluate unusual results before they are presented to the human. Additional techniques to flag potential adverse effects include using multiple models in a voting configuration to ensure proper labeling, anomaly detection throughout the pipeline, and techniques to identify and prevent LLM hallucinations.
6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? *If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date is included in this documentation.*	No

Accreditations or Certifications Document

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers. a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues. b. Please provide any details related to approaches to ensure compliance with state and federal regulations.	D2Rx (D2 Pharma Consulting) demonstrates a comprehensive, structured approach to ethics, compliance, and quality standards, with a strong focus on ensuring the safety, ethical conduct, and partnership support for patients, providers, and payers. The following summarizes the key elements of our approach: _____ 1. Ethics and Code of Conduct D2 maintains a formal Code of Business Conduct, reflecting its commitment to the highest standards of ethical business practice. This Code is distributed to all employees, officers, board members, and relevant contractors upon hire and annually thereafter. Attestation to the Code is mandatory, and it is reviewed and approved annually by the Board of Directors. The Code and related policies emphasize integrity, transparency, and the prevention of fraud, waste, and abuse in all business activities. Reference: [D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies· Section 3.2: Code of Business Conduct] 2. Compliance Program D2 has a dedicated Compliance Officer and a Compliance Committee, responsible for the implementation, oversight, and annual review of the Compliance Program. The Compliance Officer reports directly to executive leadership and the Board, ensuring high-level oversight and independence. The Compliance Program includes policies to ensure adherence to all applicable federal and state regulations (e.g., OCR, OIG, FDA), and the detection, prevention, and reporting of non-compliance or unethical behavior. Regular risk assessments, monitoring, and auditing are conducted to identify and address compliance risks. Corrective actions are tracked and documented to prevent recurrence. Reference: [D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies· Sections 2–3, 7–8] 3. Quality Standards D2 is committed to good commercial IT practices in the design, development, and operation of its products and services, with a focus on availability, integrity, and confidentiality. Quality management procedures define organizational structure, responsibilities, and processes to ensure consistent delivery of high-quality services and products. Reference: [D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies· Section 3.1.2: Quality] 4. Training and Education All employees and relevant third parties receive compliance and ethics training at hire and annually. Training covers regulatory requirements, ethical decision-making, and reporting mechanisms for compliance concerns. Specialized training is provided for high-risk areas and in response to identified needs. Reference: [D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies· Section 4; D2_Pharma_Consulting-Policy_and_Procedure-HIPAA-_FINAL_v2.2.pdf, Section: Workforce Training] 5. Communication and Reporting D2 fosters an open-door

policy, encouraging employees to raise compliance or ethical concerns without fear of retaliation. There is a strict non-retaliation policy for good-faith reporting. Multiple channels are available for confidential reporting of concerns, and all reports are investigated promptly. Reference:
[D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies· Section 5] 6. Patient, Provider, and Payer Support D2's solutions are designed to be HIPAA-compliant and support patient enrollment, monitoring, and pharmacy accreditation, ensuring the privacy and security of patient data. Business Associate Agreements (BAAs) are in place with all relevant partners to ensure proper handling of Protected Health Information (PHI) and compliance with HIPAA/HITECH requirements. The "Minimum Necessary Rule" is enforced to limit access to PHI to only what is required for specific tasks, supporting patient privacy and data security. Reference:
[D2_Pharma_Consulting_-Policy_and_Procedure-HIPAA-_FINAL_v2.2.pdf, Sections: Permitted Uses, Minimum Necessary Rule, Business Associate Agreements] 7. Continuous Improvement and Oversight Policies and procedures are reviewed and updated annually or as required by regulatory changes. The Compliance Officer and Committee ensure ongoing evaluation and improvement of compliance and quality programs. Reference:
[D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies-_FINAL_v2.2.pdf, Section 2.3: High-Level Oversight] Summary Statement D2Rx's approach is characterized by a robust compliance infrastructure, a culture of ethical conduct, rigorous quality management, and a strong commitment to the safety and privacy of patients, providers, and payers. This is achieved through clear policies, regular training, open communication, and continuous monitoring and improvement. D2 employs a comprehensive, multi-layered approach to ensure compliance with state and federal regulations, particularly in the areas of healthcare, privacy, and information security. The following summarizes the key mechanisms and processes in place: 1. Governance and Oversight Compliance Officer & Committee: D2Rx has a designated Compliance Officer responsible for the overall implementation and operation of the Compliance Program, with direct reporting lines to executive leadership and the Board of Directors. The Compliance Committee, chaired by the Compliance Officer, oversees all compliance activities and meets at least annually to review program status and regulatory updates. Reference:
[D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies· Section 2] 2. Policies, Procedures, and Standards Annual Review: All compliance-related policies and procedures are reviewed and updated annually to reflect changes in legislation or regulatory requirements. Code of Business Conduct: Distributed to all employees and contractors upon hire and annually, with mandatory attestation. Reference:
[D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies· Sections 3.1, 3.2] 3. Training and Awareness Mandatory Training: All employees and relevant contractors must complete compliance and privacy training at hire and annually. Specialized training is provided for roles with additional regulatory exposure (e.g., HIPAA, Medicare). Assessment and Recordkeeping: Training completion is tracked, and records are retained for compliance verification. Reference:
[D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies· Section 4; D2_Pharma_Consulting-Policy_and_Procedure-HIPAA-_FINAL_v2.2.pdf, Section: Workforce Training] 4. Monitoring, Auditing, and Risk Assessment Ongoing Monitoring: Regular risk assessments, audits, and compliance monitoring are conducted to identify and address compliance risks. New legal requirements or business changes trigger additional reviews. Annual Risk Assessment: Includes evaluation of the likelihood and impact of unauthorized access, use, or disclosure of sensitive data. Reference:
[D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies· Section 7; D2Rx - Risk Assessment Report - December 2024 - Final v1.0, p. 29] 5. Reporting, Response, and Corrective Action Incident Reporting: Clear procedures exist for reporting suspected or actual compliance violations, including privacy breaches. Reports are investigated promptly, and corrective actions are documented and tracked to completion. Non-Retaliation Policy: Employees are protected from retaliation when reporting compliance concerns in good faith. Reference:
[D2_Pharma_Consulting_-Policy-Regulatory_and_Quality_Compliance_Program_and_Policies· Sections 5, 8; D2_Pharma_Consulting-Policy_and_Procedure-HIPAA-_FINAL_v2.2.pdf, Section: Reporting and Responding to Violations] 6. Data Management and Privacy Controls Data Inventory and Retention: Maintains an up-to-date inventory of sensitive and regulated data, with retention and destruction practices aligned to regulatory requirements (e.g., HIPAA, state privacy laws). Breach Notification: Follows federal (e.g., HITECH, HIPAA Omnibus Rule) and state breach notification laws, with defined timelines and processes for notifying affected parties and authorities. Reference:
[D2_Pharma_Consulting_-Policy-Information_Security-FINAL_v2.2.pdf, Section: Data Inventory and Retention;
D2_Pharma_Consulting-Policy_and_Procedure-HIPAA-_FINAL_v2.2.pdf, Section: Breach Notification] 7. Vendor and Third-Party Management Contractual Safeguards: Privacy and compliance requirements are included in contracts with vendors and service providers, with mechanisms to monitor and enforce compliance. Reference: [D2Rx - Risk Assessment Report - December 2024 - Final v1.0, p. 29] 8. Documentation and Recordkeeping Retention of Compliance Records: All compliance-related documentation, including training, incident investigations, and disclosures, is retained for periods specified by law (e.g., six years for HIPAA-related records). Reference:

	[D2_Pharma_Consulting_-Policy_and_Procedure-HIPAA-_FINAL_v2.2.pdf, Section: Accounting and Recordkeeping]
8. Please provide a brief savings estimate your company/organization expects in relation to the selected services and geographic regions/MAC jurisdictions included in WISeR.	Based on the information provided in the background document, due to our proprietary protocols used to evaluate proper usage of prescription medications in addition to the streamlined process provided via D2's proprietary technology, we anticipate saving to be approximately 20-30% of total drug and administrative spend. Based on our previous experience we believe our software and processes will reduce waste, time, labor and the misuse of medication as evidenced by our current customers. This efficiency will be driven by a) attainment of successful determination via the initial protocol review b) lowering inefficiency in the system by getting the patient to the right treatment in a timely manner, c) diminishing the need for duplicate work and d) lowering the need for administrative review by ensuring the appropriate determination is 100% in accordance with the applicable LCD or NCD policy.
9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.	D2 has developed a 4 step process to incorporate all necessary tasks for the successful execution of this effort. PHASE 1: Foundation, GAP Analysis, and Legal Framework (Aug - Sept 2025) - Establish Project Governance Project Charter, Project Leads, Roles & Responsibilities - Legal & Regulatory Review Review applicable laws/regs, HIPAA, Privacy HITEC, CMS etc. - CMS/MAC Engagement Initiate application process, technical specifications, connectivity requirements etc. - Security & Compliance GAP Analysis Review systems, policies and procedures vs. CMS Acceptable Risk Safeguards (ARS) - Develop System Requirements Define GAP Analysis, create detailed technology and security requirements - Vendor & Solution Assessment Finalize any vendor selection, and begin procurement PHASE 2: Technical Build, Security Hardening and Policy Development (Sep 2025 - Nov 2025) - Infrastructure Build and Hardening Procure, install and configure all necessary hardware and software. - Develop / Configure Data Interface Develop/configure the application interface for data exchange. - Implement Security Controls Implement all security controls identified in the GAP analysis. - Draft/ Update Policies & Procedures Draft/update necessary documentation: System Security Plan (SSP), Incident Response Plan, Data Usage Policy etc. - Execute Agreements (BAA/ISA) Finalize all ISA/ BAA documentation with the necessary parties PHASE 3: Training Validation and Training (Nov 2025 - Dec 2025) - Connectivity Testing with MAC Conduct initial connectivity testing, validation authentication and data transmission protocols - System Integration Testing End-to-end testing verifying data integration, processing logic and system performance - Security Assessment & Authorization (SA&A) Conduct formal security assessment including Vulnerability Scanning and Third-party Penetration Tests. - Remediate Findings Create Plan of Action & Milestones to address any issues determined from the SA&A - User Acceptance Testing (UAT) Business Users test the system to ensure it meets the business needs and data access controls work as designed - Mandatory Staff Testing Mandatory HIPAA and Security awareness training for all personnel with access to the system or data. PHASE 4: Go-Live and Continuous Monitoring (Dec 2025 - Ongoing) - Final Go/ No-go Process Review all testing results, final security posture (SAR/POA&M) and MAC approval status - Production Cutover Execute cutover plan to move product to production - Project Launch OFFICIAL PRODUCT LAUNCH DATE - Continuous Monitoring Manage continuous monitoring program to review system logs and audit training. Periodic security/ vulnerability testing etc. - Annual Recertification Conduct annual security reviews & recertifications required by CMS. Maintain all documentation (SSP, POA&M, Training etc.) for Audits.

Certify and Submit

Certification Statement

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.	✓
Company/Organization Name:	D2 Pharma Consulting LLC
Certifying Individual: **Title:**	(b)(6)