Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Patient Care Models Group
7500 Security Blvd
Baltimore, MD 21244

Wasteful and Inappropriate Service Reduction (WISeR) Model

Participation Agreement

Segment 1: January 1, 2026-December 31, 2028

August 29, 2025

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PARTICIPATION AGREEMENT

This Participation Agreement (the "**Agreement**") is between the CENTERS FOR MEDICARE & MEDICAID SERVICES ("**CMS**") and

Cohere Health, Inc. , ("**WISeR Participant**").

CMS is the agency within the U.S. Department of Health and Human Services ("**HHS**") that is charged with administering the Medicare and Medicaid programs.

The WISeR Participant is a legal entity identified by a single TIN and has Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process and Pre-Payment Review for Select Items and Services on Medicare fee-for-service ("**FFS**") Claims.

CMS is implementing the Wasteful and Inappropriate Service Reduction Model ("**WISeR**" or "**Model**") under section 1115A of the Social Security Act ("**Act**"), which authorizes CMS through its Center for Medicare and Medicaid Innovation ("**Innovation Center**") to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program expenditures while preserving or enhancing the quality of care furnished to Beneficiaries.

The Model seeks to reduce or maintain Medicare FFS expenditures while improving the quality of care and health outcomes for Medicare FFS beneficiaries through the WISeR Participant's Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process for Select Items and Services that do not satisfy existing Medicare Coverage Criteria and may be fraudulent, wasteful, or of low-value to Medicare FFS beneficiaries.

The WISeR Participant applied to participate in WISeR, and CMS has approved the WISeR Participant for participation in the Model for the MAC Jurisdiction of JH Novitas and the state of Texas. The designated state is the WISeR Participant's WISeR Jurisdiction.

The parties therefore agree as follows:

Article I. Agreement Term

Section 1.1 Effective Date

This Agreement will become effective when it is signed by the last party to sign it (as indicated by the date associated with that party's signature) ("**Effective Date**").

Section 1.2 Agreement Term

The term of this Agreement ("**Agreement Term**") begins on the Effective Date and expires two years after the last Day of the Agreement Performance Period, as defined in Section 1.3, unless the Agreement is sooner terminated by CMS in accordance with Section 13.3, in which case the Agreement Term ends on the effective date of such termination.

Section 1.3 Agreement Performance Period

A. The performance period of this Agreement ("**Agreement Performance Period**") begins on the Effective Date and ends at 11:59 PM ET on December 31, 2028, unless the Agreement Period or the Agreement is sooner terminated in accordance with Section 1.4.B or Article XIII, in which case the Agreement Performance Period ends on the date specified in the termination notice.

B. CMS may offer the WISeR Participant the option to participate in a second segment of this Model which would begin on January 1, 2029, and end at 11:59 PM ET on December 31, 2031. The WISeR Participant must execute a new agreement with CMS to participate in the Model during the second segment. Any such agreement will authorize CMS to take remedial action against the WISeR Participant for non-compliance with the terms of this Agreement, regardless of when the non-compliance is discovered by CMS.

Section 1.4 Amended and Restated Agreements

A. No later than 30 Days prior to the start of a calendar year during the Agreement Performance Period, CMS may offer the WISeR Participant the opportunity to sign an amendment to this Agreement, which may be in the form of an amended and restated version of this Agreement.

B. If the WISeR Participant fails to sign an amendment offered by CMS pursuant to Section 1.4.A by a date specified by CMS, CMS may terminate the Agreement Performance Period on December 31 of the year in which the amendment was offered.

Article II. Definitions

Advance WISeR Payment means the payment that meets the requirements in Section 8.4.

Aggregate Quality Score (AQS) means the score that is calculated from the WISeR Participant's quality data and used to determine the quality multiplier applied during the calculation of the WISeR Payment.

ARS stands for **CMS Acceptable Risk Safeguard** and means the standard to CMS and its contractors, including the WISeR Participant, as to the minimum level of required security and privacy controls. *See* https://security.cms.gov/policy-guidance/cms-acceptable-risk-safeguards-ars (last accessed August 2025).

ATO stands for **CMS Authority to Operate** and means the information systems operated by or on behalf of the U.S. federal government that meet FISMA standards.

BAA stands for **Business Associate Agreement** and means the legally binding contract required under HIPAA between CMS and the WISeR Participant that handles Protected Health Information.

Beneficiary means an individual who is entitled to Medicare FFS benefits under Part A or enrolled under Part B.

Change in Control means: (1) the acquisition by any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the WISeR Participant representing more than 50 percent of the WISeR Participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the WISeR Participant by any other individual or entity; (3) the sale, lease exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the WISeR Participant; or (4) the approval and completion of a plan of liquidation of the WISeR Participant, or an agreement for the sale or liquidation of the WISeR Participant.

Covered Services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Day(s) means calendar day(s) unless otherwise specified.

Electronic Submission of Medical Documentation (esMD) means a system used by CMS to enable providers, suppliers, and other entities to reduce or eliminate the need to mail or fax paper documents and instead electronically submit or request supporting medical documentation related to CMS claims and Prior Authorization.

Enhanced Technology means the WISeR Participant's technology that is intended to improve the accuracy and efficiency of the Prior Authorization Process and Pre-Payment Review.

Exemption Status means the status that a WISeR Provider or WISeR Supplier may earn to be exempt from requesting Prior Authorization for the Select Items and Services in accordance with Section 6.2 of this Agreement and the WISeR Participant Guide.

FedRAMP stands for **Federal Risk and Authorization Management Program** and means the government-wide program that standardizes security assessments for cloud services (44 U.S.C. § 3607).

Financial Settlement Report means the report that is defined in Section 8.9.

FISMA stands for **Federal Information Security Management Act of 2002, as amended by the Federal Information Security Modernization Act of 2014** and means the framework of guidelines and security standards to protect government information and operations as set forth in 44 U.S.C. § 3541, *et seq.* and 44 U.S.C. § 3551, *et seq*..

Initial Prior Authorization Determination means the communication to the WISeR Provider or WISeR Supplier detailing the Prior Authorization Affirmation or Prior Authorization Non-Affirmation for an initial Prior Authorization submission.

IS2P2 stands for **CMS Information Systems Security & Privacy Policy** and means the policy that defines how CMS protects and controls access to its information and systems as required under FISMA of 2014 (44 U.S.C. Chapter 35).

Locality means a CMS-defined geographic area within a MAC Jurisdiction (e.g., a state, or other geographic boundary) that CMS uses to determine Medicare payment rates for Covered Services.

LCDs stands for **Local Coverage Determinations** and has the meaning set forth in Section 1869(f)(2)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(2)(B)).

MAC stands for Medicare Administrative Contractor and means a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B medical claims or Durable Medical Equipment (DME) claims for Medicare fee-for-service beneficiaries, as further defined in Section 1874A(a)(3) of the Social Security Act (42 U.S.C. § 1395kk-1(a)(3) and 42 C.F.R. Subpart E).

MAC Jurisdiction means the defined geographic territory for the Medicare Part A and Part B Jurisdictions L, 15, H, and F selected for the WISeR Model and as depicted on the "A/B MAC

Jurisdictions" map at https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/who-are-macs (last accessed August 2025) (*see also* Section 911(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173).

Medical Review means the collection and clinical review of medical records and related information to ensure that Medicare payment is made only for services that meet all Medicare Coverage Criteria.

Medically Necessary means reasonable and necessary as determined in accordance with Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)).

Medicare Coverage Criteria means the existing Medicare coverage criteria as set forth in statute, regulation, NCD, or LCD.

Model Participant means a technology company that has signed an agreement with CMS to participate in WISeR and is not the WISeR Participant.

Model Performance Period means the period of time, regardless of the Agreement Performance Period, that begins on January 1, 2026 and ends on December 31, 2031, unless sooner terminated in accordance with Section 12.3.

Navigation Services means services and information including Medicare Coverage Criteria, Prior Authorization performance data, and such other services as detailed in the WISeR Participant Guide that are provided by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers, as applicable, to all WISeR Providers and WISeR Suppliers to increase clinically appropriate care.

NCDs stands for **National Coverage Determinations** and has the meaning set forth in Section 1869(f)(1)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(1)(B).

NPI stands for **National Provider Identifier**.

Payable Non-Affirmation means an Initial Prior Authorization Determination of Prior Authorization Non-Affirmation that qualifies for a WISeR Payment because there was no Resubmission within 120 Days that received a determination of Prior Authorization Affirmation and, at the time of Reconciliation, there was no associated claim paid by Medicare due to the successful appeal of a claim denial.

Performance Period means the three-month period in which the WISeR Participant issues Initial Prior Authorization Determinations for Prior Authorization requests and issues

determinations for Pre-Payment Reviews, including without limitation all associated Resubmissions submitted within 120 days of the Initial Prior Authorization Determination.

Performance Year or **PY** means the 12-month period beginning on January 1 of each year during the Model Performance Period.

Pre-Payment Review means the review by the WISeR Participant to verify consistency with Medicare Coverage Criteria for a claim for one or more Select Items and Services furnished in the MAC Jurisdiction that is submitted to Medicare without requesting Prior Authorization, consistent with 42 C.F.R. § 405.903.

Prior Authorization is a request by the WISeR Provider or WISeR Supplier for provisional affirmation of Medicare Coverage Criteria for one of the Select Items and Services prior to furnishing such items and services to the WISeR Beneficiary and before the claim is submitted for processing.

Prior Authorization Process means the process detailed in Article VI of the Agreement.

Prior Authorization Provisional Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Prior Authorization Non-Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is not accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Program Integrity Screening means a review of an individual's or entity's program integrity history and current status, which may include a review of the individual's or entity's eligibility, history of exclusion or other sanctions imposed with respect to participation in Medicare, Medicaid, or CHIP; history of failure to pay Medicare debts in a timely manner; current or prior law enforcement investigations or administrative actions regardless of whether such investigations or actions relate to participation in Medicare, Medicaid, or CHIP; affiliations with individuals or entities that have a history of program integrity issues; and other information pertaining to the trustworthiness of the individual or entity.

Reconciliation means the process by which CMS calculates the WISeR Payment amount owed to the WISeR Participant for a specific Performance Period as set forth in Article VIII.

Reconciliation Report means the report issued by CMS that details the Reconciliation calculations for the WISeR Participant and the amount of any WISeR Payment for one or more specified Performance Periods.

Regional Benchmark means a payment amount calculated by CMS for each of the Select Items and Services for a given Locality and Performance Period that CMS uses to calculate the WISeR Payment amount for a Payable Non-Affirmation as set forth in Section 8.3.

Resubmission means a Prior Authorization submitted to the WISeR Participant within 120 Days of an Initial Prior Authorization Determination for a Prior Authorization previously submitted by the same WISeR Provider or WISeR Supplier for the same WISeR Beneficiary and same Select Item or Service.

Resubmission Determination means the communication to the WISeR Provider and/or WISeR Supplier detailing the Prior Authorization Provisional Affirmation or Prior Authorization Non-Affirmation for a Resubmission.

Select Items and Services means the Covered Services detailed in Appendix A that are subject to the Prior Authorization Process. When used in its singular form this term is referred to as "**Select Item or Service**".

Start Date means January 1, 2026.

TIN stands for taxpayer identification number.

VDC stands for CMS Virtual Data Center and means the comprehensive information technology infrastructure designed to centralize and modernize CMS' digital operations.

WISeR Beneficiary means a Beneficiary that meets the requirements set forth in Section 4.1.

WISeR Clinician means an individual that satisfies the requirements of Section 3.6.

WISeR Clinical Reviewer means an individual that satisfies the requirements of Section 3.6.

WISeR Data Reporting Guide means the guidance paper that CMS publishes and provides to the WISeR Participant that sets forth the WISeR Participant's reporting obligations during the Model. CMS may modify the WISeR Data Reporting Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Data Reporting Guide at least 30 Days prior to the effective date of such revisions.

WISeR Discount means the discount specified in Section 8.3.C that CMS applies when calculating the WISeR Payment.

WISeR Jurisdiction means the defined geographic states of New Jersey (Jurisdiction L/Novitas Solutions, Inc.), Ohio (Jurisdiction 15/CGS Administrators, LLC), Oklahoma and Texas (JH/Novitas), and Arizona and Washington (JF/Noridian) selected for the WISeR Model

for which the WISeR Participant conducts Prior Authorization Process on claims for Select Items and Services from institutional providers, physicians, clinicians and suppliers.

WISeR Participant means the technology company that meets the requirements set forth in Article III and has signed this Agreement with CMS to participate in the Model.

WISeR Participant Guide means a guidance paper that CMS publishes and provides to the WISeR Participant that sets forth additional details to support the WISeR Participant's activities and obligations during the Model. CMS may modify the WISeR Participant Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Participant Guide at least 30 Days prior to the effective date of such revisions.

WISeR Payment means the Model specific payment made by CMS for a Payable Non-Affirmation or a Pre-Payment Review that qualifies for payment as set forth in Article VIII.

WISeR Performance Measure Set means the measures detailed in Appendix B, and as may be revised in the WISeR Data Reporting Guide, that CMS uses in calculating the AQS.

WISeR Provider means a provider, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction that furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

WISeR Recoupment means the amount owed to CMS if CMS pays a WISeR Payment to the WISeR Participant and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

WISeR Supplier means a supplier, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction and who furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

Article III. General Requirements

Section 3.1 WISeR Participant Requirements

A. During the Agreement Term, the WISeR Participant shall:
    1. Be a legal entity formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates for the purpose of carrying out the activities required by this Agreement;
    2. Have Enhanced Technology and be identified by a single TIN, to provide specified health insurance benefit administrative services, including

Medicare Prior Authorization and Pre-Payment Review services to interpret and apply Medicare Coverage Criteria and clinical coverage criteria derived from NCDs and LCDs, in support of the Medicare FFS program;

3. Use its Enhanced Technology for implementing and streamlining the Prior Authorization Process and Pre-Payment Review for Select Items and Services in its assigned WISeR Jurisdiction;
4. Have a valid Business Associate Agreement ("**BAA**") with CMS;
5. Support CMS in its efforts to make accurate and timely payments to WISeR Providers or WISeR Suppliers for Select Items and Services furnished to WISeR Beneficiaries;
6. Support CMS in its efforts to ensure care provided to Beneficiaries is Medically Necessary and adheres to Medicare Coverage Criteria, thus protecting Beneficiaries and the Medicare Trust Fund; and
7. Not have a conflict of interest as detailed in Section 3.3 of this Agreement.

The WISeR Participant states that it satisfies the requirements of this Section 3.1.A as of the Effective Date.

B. The WISeR Participant shall satisfy the requirements of this Section 3.1.B no later than 45 Days before the Start Date and throughout the remainder of the Agreement Term:
    1. Have access to Federal Risk and Authorization Management Program ("**FedRAMP**") certified workflows;
    2. Comply with all applicable Federal data protection and security requirements including Federal Information Security Management Act ("**FISMA**") requirements, CMS Information Systems Security & Privacy Policy ("**IS2P2**"), CMS Acceptable Risk Safeguard ("**ARS**");
    3. Follow CMS Authority to Operate ("**ATO**") guidelines for connections established between the Medicare Administrative Contractor ("**MAC**") and WISeR Participant; and
    4. Enter into a valid Joint Operating Agreement ("**JOA**") with the applicable MAC.
C. Changes to the WISeR Participant
    1. Change of WISeR Participant Name. The WISeR Participant shall provide written notice to CMS at least 60 Days before any change in the WISeR Participant's legal name becomes effective. The WISeR Participant shall forward to CMS a copy of the document effectuating the name change, authenticated by the appropriate state official (if applicable), and the parties shall execute an agreement reflecting the change of the WISeR Participant's name. This obligation shall remain in effect until the latter of the effective date

of termination of this Agreement or when the final payment by or to the WISeR Participant has been made under this Agreement.

2. Change in WISeR Participant TIN. The WISeR Participant shall provide at least 90 Days advanced written notice before the effective date of any change in the WISeR Participant's TIN. Such notice must be submitted in the form and manner specified by CMS. In response to a change in the WISeR Participant's TIN, CMS may terminate the Agreement or Agreement Performance Period, or take any other actions consistent with the terms of this Agreement. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
3. Change in Control.
    i. The WISeR Participant shall provide written notice to CMS at least 90 Days before the effective date of any Change in Control. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
    ii. Upon learning of a Change in Control, CMS may conduct a Program Integrity Screening and take other appropriate action to ensure compliance with the terms of the Model by the new controlling entity and may require the new controlling entity to execute a novation agreement with CMS or require the new controlling entity to execute a new Participation Agreement with CMS. CMS may also terminate the Participation Agreement between the former controlling entity and CMS.
    iii. If the WISeR Participant undergoes a Change in Control, CMS may take one or more of the following actions: terminate this Agreement; terminate the Agreement Performance Period; or immediately conduct financial settlement in accordance with Section 8.9.
4. Change in Primary Point of Contact. The WISeR Participant shall provide written notice to CMS of any changes to the contact information for the WISeR Participant's primary point of contact no later than 15 Days after the change.

D. Information for Electronic Funds Transfer

1. The WISeR Participant shall submit to CMS a completed Electronic Funds Transfer Authorization Agreement in the form and manner and by the date(s) specified by CMS.

2. The WISeR Participant shall promptly update its Electronic Funds Transfer Authorization Agreement if there are account or bank changes, or any change to the WISeR Participant set forth in Section 3.1.C.
3. If the WISeR Participant fails to submit or accurately complete the Electronic Funds Transfer Authorization Agreement, CMS may withhold any WISeR Payment owed to the WISeR Participant until the WISeR Participant has submitted and CMS has processed an Electronic Funds Transfer Authorization Agreement with the correct information. In addition, the failure to submit or accurately complete an Electronic Funds Transfer Authorization Agreement could delay the WISeR Participant's receipt and timely payment of a demand for payment under this Agreement, and thereby cause the WISeR Participant to be liable for interest on the amount owed to CMS.

E. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, the WISeR Participant fails to meet any requirements set forth in Section 3.1. The WISeR Participant shall provide such written notice to CMS at least 30 Days before failing to satisfy any requirements in Section 3.1.A, or within 5 Days of becoming aware that the WISeR Participant has failed to satisfy any requirements in Section 3.1(B)-(D).

Section 3.2 WISeR Participant Governance

A. General.
   1. The WISeR Participant shall maintain an identifiable governing body with sole and exclusive authority to execute the functions of the WISeR Participant and make final decisions on behalf of the WISeR Participant. The WISeR Participant shall have a governing body that satisfies the following criteria:
      i. The governing body has responsibility for oversight and strategic direction of the WISeR Participant and is responsible for holding the WISeR Participant management accountable for the WISeR Participant's activities;
      ii. The governing body has a transparent governing process;
      iii. When acting as a member of the governing body of the WISeR Participant, each governing body member has a fiduciary duty to the WISeR Participant and to CMS for actions relating to the terms of this Agreement, the Model and the terms set forth in the Business Associate Agreement, including the duty of loyalty, and shall act consistent with that fiduciary duty; and

iv. The governing body shall receive regular reports from the designated compliance official of the WISeR Participant who satisfies the requirements of Section 11.1.

2. The WISeR Participant shall provide each member of the governing body with a copy of the Agreement and any amendments hereto.
3. If CMS determines that the composition of the WISeR Participant's governing body, executive leadership, or parent organization(s) (as applicable) compromises the WISeR Participant's ability to participate in the Model or to comply with the terms of the Agreement, CMS may take one or more of the remedial actions specified in Section 13.2.
4. The WISeR Participant shall ensure that its governing body implements a process for documenting governing body composition, meetings and decisions, and shall retain such documentation in accordance with Section 12.2.

B. Composition and Control of the Governing Body.

1. The WISeR Participant's governing body shall not include any individual with pending or open investigations, or a history of convictions or sanctions, including without limitation:
    i. Investigations or actions related to participation in Medicare, Medicaid, or Children's Health Insurance Program;
    ii. A history of failure to pay Medicare debts in a timely manner;
    iii. Affiliations with individuals or entities that have a history of program integrity issues;
    iv. Conduct that a reasonable person would deem to be unfit conduct; or
    v. A history of legal or monetary sanctions.
2. The WISeR Participant shall routinely monitor each individual on its governing body to ensure compliance with the provisions of this Section 3.2.
3. The WISeR Participant shall immediately remove from its governing body any individual that becomes subject to a conviction or sanction.
4. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, it removes an individual from its governing body. The WISeR Participant shall provide such written notice to CMS within 5 Days of such removal.
5. The governing body members may serve in similar or complementary roles or positions, subject to Section 3.3.

Section 3.3 Conflict of Interest

A. The WISeR Participant shall have a conflict of interest policy that applies to members of the governing body and satisfies the following criteria:
    1. Requires each member of the governing body to disclose relevant financial interests and other interests that could prevent impartiality;
    2. Requires each member of the governing body to update its disclosure statement whenever the member's personal or financial circumstances change in such a way that a new conflict of interest might occur;
    3. Provides a procedure to determine whether a conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses remedial actions for members of the governing body that fail to comply with the policy.

B. Notwithstanding the obligations set forth in Section 3.3.A, the WISeR Participant shall have a conflict of interest policy that applies to its business operations and satisfies the following criteria:
    1. Requires that the WISeR Participant refrain from engaging in activities that would lead to the preferential or non-preferential treatment of any WISeR Provider, WISeR Supplier, WISeR Clinician, WISeR Clinical Reviewer, individual clinician, medical group, medical practice, Beneficiary, or any other individual or entity with an interest in the Prior Authorization Process or Pre-Payment Review;
    2. Requires that the WISeR Participant prohibit WISeR Clinicians and WISeR Clinical Reviewers from participating in the Prior Authorization Process and Pre-Payment Review associated with a provider or supplier under the same TIN as the reviewing WISeR Clinician or WISeR Clinical Reviewer;
    3. Provides a procedure to determine whether such conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses plans of action to correct instances that fail to comply with the policy.

C. The WISeR Participant shall ensure that its conflict of interest policy sets forth a process to address situations where an individual employed by or contracted by the WISeR Participant and has a financial interest, personal activity, or relationship that could impair that individual's ability to act impartially and in the best interest of CMS when performing under the terms of this Agreement, the Business Associate Agreement, or the Model.

D. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Prior Authorization request not participate in the review of that request or any associated Resubmissions related to that Prior Authorization request.
E. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Pre-Payment Review not participate in the review of that claim or any associated Resubmissions related to that Pre-Payment Review.
F. The WISeR Participant shall de-identify Prior Authorization requests, Resubmissions, and Pre-Payment Review claims prior to permitting its WISeR Clinicians and WISeR Clinical Reviewers to conduct a Medical Review or peer-to-peer review.
G. The WISeR Participant shall designate a committee or group responsible for evaluating disclosed potential conflicts of interest and determine whether they pose a risk to the fairness of the Prior Authorization review or the Pre-Payment Review.
    1. The WISeR Participant shall provide immediate written notice of disclosed potential conflicts of interest to CMS. Such written notice shall be made within 5 Days of becoming aware of the potential conflicts of interest.
    2. The WISeR Participant shall include CMS in the determination process associated with the disclosed potential conflicts of interest.

Section 3.4 Required Prior Authorization Activities

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.
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.
C. The WISeR Participant shall review Prior Authorizations in its WISeR Jurisdiction submitted by all WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).
D. Consistent with Section 3.4.C, the WISeR Participant shall perform its Prior Authorization Process on Prior Authorizations received.
E. Consistent with the terms of this Agreement and the requirements set forth in the WISeR Participant Guide, the WISeR Participant shall issue Prior Authorization determinations to the requesting WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction with a copy to the applicable WISeR Beneficiary.

Section 3.5 WISeR Providers and WISeR Suppliers

A. WISeR Providers and WISeR Suppliers may submit Prior Authorization requests directly to the WISeR Participant and receive a determination for Select Items and Services.

B. If the WISeR Provider or WISeR Supplier submits a Prior Authorization request to its MAC for a Select Item or Service, then:

   1. CMS, through the applicable MAC, will re-route the Prior Authorization request to the WISeR Participant;
   2. The WISeR Participant must perform its Prior Authorization Process on the re-routed Prior Authorization from the MAC for the Select Item or Service and issue a determination directly to the WISeR Provider or WISeR Supplier with copy to the MAC and the WISeR Beneficiary identified on the Prior Authorization request; and
   3. Perform any additional requirements as described in the WISeR Participant Guide.

C. CMS, through the applicable MAC, will notify the WISeR Participant if a WISeR Provider or WISeR Supplier submits a claim to Medicare for one or more Select Items and Services furnished to a WISeR Beneficiary in the WISeR Jurisdiction without requesting Prior Authorization.

D. The WISeR Participant must conduct Pre-Payment Review in accordance with Section 6.5 of this Agreement for each Select Item or Service that does not have a Prior Authorization request from the WISeR Provider or WISeR Supplier.

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.

F. CMS will provide written notice, which may be in the form of the WISeR Participant Guide, to the WISeR Participant regarding additional determination letter requirements.

G. The WISeR Participant shall provide to its WISeR Providers and WISeR Suppliers prior authorization criteria and relevant evidence-based clinical practice guidelines for Select Items and Services in a form and manner and by the date(s) determined by CMS. Such compliance assistance information shall include examples of documentation that would support approval of a Prior Authorization request for each Select Item or Service, as well as examples of common mistakes, omissions, and evidence that would result in a denial of Prior Authorization.

Section 3.6 WISeR Clinicians and WISeR Clinical Reviewers

A. General.

1. The WISeR Participant may choose to:
    i. Directly employ clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinicians**"); or
    ii. Subcontract with a separate entity that provides appropriate clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinical Reviewers**"); or
    iii. Do both (i) and (ii).
2. The WISeR Participant must provide to its subcontractor, if applicable, necessary and appropriate WISeR Participant Guide provisions to ensure that each WISeR Clinical Reviewer meets the Medical Review requirements to ensure proper coverage determinations that adheres to Medicare Coverage Criteria and CMS coverage policy.
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.

B. <u>WISeR Clinicians</u>.
1. The WISeR Participant shall ensure that each WISeR Clinician:
    i. Be a board-certified clinician, including a:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;

iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;

vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and

vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinician performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant shall ensure that each WISeR Clinician performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers in a form and manner determined by CMS, as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that the WISeR Clinician has an active, valid and unrestricted license.

C. Record of WISeR Clinicians. The WISeR Participant shall maintain, in accordance with Article XII, a record of all its WISeR Clinicians.
   1. The WISeR Participant shall retain current and historical records of all its WISeR Clinicians in accordance with Section 12.2 of this Agreement.
   2. CMS may request and the WISeR Participant must provide to CMS a certified copy of all WISeR Clinicians at any given time during the Agreement Term.

D. Monitoring and Compliance of WISeR Clinicians.
   1. CMS will monitor the program integrity history of the WISeR Participant's WISeR Clinicians. CMS may require the WISeR Participant to exclude an individual WISeR Clinician or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
   2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinician be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure that each WISeR Clinician conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks, and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that each WISeR Clinician uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items and Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Items and Services;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

E. WISeR Clinical Reviewers.

1. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer:
    i. Be a board-certified clinician, including:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;
    iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;
vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and
vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinical Reviewer performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall require its subcontractor to ensure that the WISeR Clinical Reviewer has an active, valid and unrestricted license.

F. Record of WISeR Clinical Reviewers. The WISeR Participant must require its subcontractor to maintain, in accordance with Article XII of this Agreement, a record of all WISeR Clinical Reviewers performing activities related to this Model.
1. The WISeR Participant shall require the subcontractor to retain current and historical records of all WISeR Clinical Reviewers consistent with Section 12.2 of this Agreement.
2. The WISeR Participant shall require its subcontractor to provide the WISeR Participant with a certified copy of all WISeR Clinical Reviewers at any given time during the Agreement Term. The WISeR Participant shall provide such information to CMS in a form and manner and by the date(s) specified by CMS.

G. Monitoring and Compliance of WISeR Clinical Reviewers.
1. CMS will monitor the program integrity history of the WISeR Participant's use of WISeR Clinical Reviewers. CMS may require the WISeR Participant to exclude an individual WISeR Clinical Reviewer or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinical Reviewer be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items or Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Item or Service;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

Section 3.7 Customer Service

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.
B. The WISeR Participant shall provide an overall environment where WISeR Providers and WISeR Suppliers understand the Prior Authorization Process and Pre-Payment Review process for Select Items and Services.
C. The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.
D. The WISeR Participant shall maintain effective WISeR Provider and WISeR Supplier education that helps ensure complete Prior Authorization submissions for Select Items and Services and reduces the need for re-submissions, requests for appeal, and overturn of coverage determinations on appeal.
E. The WISeR Participant shall educate WISeR Providers and WISeR Suppliers on how to submit Prior Authorization requests and provide its WISeR Providers and WISeR Suppliers with information related to the Medicare Coverage Criteria associated with

the Select Items and Services. Such educational activities shall be conducted in a form and manner determined or approved by CMS, and as may be detailed in the WISeR Participant Guide.

F. The WISeR Participant must educate WISeR Providers and WISeR Suppliers within its assigned WISeR Jurisdiction about the Prior Authorization Process consistent with the provisions of this Agreement and the WISeR Participant Guide.

Section 3.8 Operational Requirements

A. The WISeR Participant shall promote corporate integrity and establish internal controls and an effective compliance program to achieve Agreement goals and objectives.

B. The WISeR Participant shall work collaboratively with CMS, WISeR Providers, WISeR Suppliers, Medicare Administrative Contractors, and other CMS contractors to foster integration of Medicare operations.

C. The WISeR Participant shall develop and continually refine business processes to foster excellence and quality in the administration of the Medicare program.

D. The WISeR Participant shall foster efficiencies in the administration of the Medicare FFS program to promote best value for the government.

E. The WISeR Participant shall use innovative and creative solutions to improve program operations.

Section 3.9 Overlap with Other CMS Programs and Initiatives

A. The parties agree that the WISeR Model is not a shared savings model and there is no Beneficiary alignment in this Model.

B. The WISeR Participant may simultaneously participate in the WISeR Model and any other Innovation Center model.

C. CMS reserves the right to unilaterally update this overlaps policy upon written notice to the WISeR Participant.

Article IV. Beneficiary Eligibility, Engagement, Verification, and Protections

Section 4.1 Beneficiary Eligibility

A. To be considered a WISeR Beneficiary, a Beneficiary must meet the following criteria:

1. Be identified on a Prior Authorization request or a claim subject to Pre-Payment Review for a Select Item or Service from a WISeR Provider or WISeR Supplier in the WISeR Participant's WISeR Jurisdiction;

2. Is eligible for Medicare Part A and enrolled in Medicare Part B at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review;
3. Is a legal adult aged 18 years or older;
4. Is not enrolled in Medicare Advantage at the time of the Prior Authorization request or the date of service on the claim subject to Pre-Payment Review;
5. Has Medicare as the primary payer at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review; and
6. Is not covered under the United Mine Worker Health and Retirement Funds.

Section 4.2 Beneficiary Engagement and Beneficiary Verification

A. The WISeR Participant does not have Beneficiaries aligned or assigned to it for this Model.
B. CMS may require the WISeR Participant to educate Beneficiaries, including WISeR Beneficiaries, within its WISeR Jurisdiction on the Prior Authorization Process for Select Items and Services.
C. The WISeR Participant must ensure that each Prior Authorization request submitted by a WISeR Provider, WISeR Supplier, or a MAC is for a Select Item or Service that will be furnished to a WISeR Beneficiary within the WISeR Jurisdiction.

Section 4.3 Beneficiary Protections and Non-Affirmed Decisions

A. The WISeR Participant shall provide written Prior Authorization Process decisions to the WISeR Provider and/or WISeR Supplier with a copy to the applicable WISeR Beneficiary and appropriate MAC.
B. The WISeR Participant's Prior Authorization Non-Affirmation decision for the Select Item or Service that is determined to not be Medically Necessary must require the WISeR Provider or WISeR Supplier to notify the WISeR Beneficiary and issue an Advance Beneficiary Notice of Non-coverage (ABN) prior to performing such item(s) or service(s) if it is expected that payment would be denied.
C. For purposes of the WISeR Provider and WISeR Supplier notifications required under Sections 4.3.A and 4.3.B, the WISeR Participant shall use a template letter provided by CMS, in which CMS will designate letter content that the WISeR Participant shall not change, as well as places in which the WISeR Participant may insert its own original content.
D. Beneficiaries continue to have all applicable administrative appeal rights under Original Medicare.

Section 4.4 Prohibition on Beneficiary Inducements

Except as otherwise permitted by applicable law, the WISeR Participant shall not provide gifts or other remuneration to Beneficiaries to induce them to receive or to continue to receive items or services from one or more of the following: WISeR Providers, WISeR Suppliers, WISeR Clinicians, or WISeR Clinical Reviewers.

Section 4.5 HIPAA Requirements

A. The WISeR Participant acknowledges that it is either a covered entity or business associate, as those terms are defined in 45 C.F.R. § 160.103, of CMS that is a covered entity.
B. The WISeR Participant shall have all appropriate administrative, technical, and physical safeguards in place before the Start Date to protect the privacy and security of protected health information ("**PHI**") in accordance with 45 C.F.R. § 164.530(c).
C. The WISeR Participant shall maintain the privacy and security of all Model-related information that identifies individual Beneficiaries in accordance with the Health Insurance Portability and Accountability Act ("**HIPAA**") Privacy and Security Rules and all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of PHI by covered entities and their business associates, as well as all other applicable federal and state laws and regulations.

Article V. Functional Requirements

Section 5.1 Functional and Infrastructure Requirements

A. The WISeR Participant shall develop, execute, and maintain a risk management plan that includes:
    1. WISeR Jurisdiction-wide risks, including without limitation risks related to cybersecurity issues;
    2. Periodic assessment, conducted monthly at a minimum, of new risks; and
    3. Mitigation and contingency planning.
B. The WISeR Participant shall provide and use infrastructure to fulfill the requirements of this Agreement.
C. The WISeR Participant shall provide the infrastructure required to integrate and interact with the assigned CMS Virtual Data Center ("**VDC**") and to accomplish services not provided by the VDC to fulfill the requirements of this Agreement.
    1. The WISeR Participant shall work with all Base Function entities, including the VDC, to interface and/or facilitate the receipt or transmission of files, programs or other such products.

2. **Base Functions** are functions provided either by the shared system or the VDC and include interfaces that are part of the base system processing such as the Common Working File (CWF), Comprehensive Error Rate Testing (CERT), Correct Coding Initiative (CCI), BDRD, PECOS, PIMR, Pricer, PULSE, etc.
3. **Non-base/Non-core applications or interfaces** refers to any applications or interfaces that are not part of the base system processing or are not provided or maintained as part of the Medicare Shared Systems (FISS or MCS).
    i. Non-base/non-core applications or interfaces may involve an outside vendor, a Medicare Data Center, or any entity with which the WISeR Participant communicates or shares information through a software application (not including commercial word processing or spreadsheet programs) in processing Medicare claims.
    ii. Examples of non-base/non-core processes include but are not limited to the following:
        a. Print mail;
        b. American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N Transaction Translation Services (via Commercial Off the Shelf (COTS) products);
        c. Workload Management reports;
        d. Scanning Administration;
        e. ICR/OCR Imaging;
        f. Fraud, Waste, or Abuse reporting;
        g. Data Analysis (Easytrieve, SAS extracts, etc.); and
        h. Data files the WISeR Participant routinely receives.

D. The WISeR Participant shall provide translation software that is HIPAA-compliant and strictly adheres to the ASC X12N Technical Report Type 3 (TR3s) for inbound transactions (e.g., ASC X12N claim, ASC X12N 276 claim status request) and outbound transactions (e.g., ASC X12N 835 remittance advice, ASC X123N 277 claim status response, ASC X12N TA1 interchange acknowledgement, ASC X12N 999 implementation acknowledgment, ASC X12N 277 claim acknowledgment).

E. In the event of termination by CMS or the WISeR Participant pursuant to Article XIII, the WISeR Participant shall be required to perform certain closeout activities detailed by CMS in a form and manner and by the date(s) specified by CMS.

Section 5.2 Telecommunications

A. Unless directed to use another connection by CMS, the WISeR Participant shall use only the CMS-supplied telecommunications network to transmit Medicare data to ensure the privacy and security of this protected information for:
    1. Medicare communications between the WISeR Participant and Medicare Administrative Contractor(s), if any;
    2. Communications between the WISeR Participant and subcontractors, if any; and
    3. Communications between the WISeR Participant and CMS.
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.
C. As applicable, the WISeR Participant shall interact with CMS' current enterprise identity access management systems, or any future enterprise identity access management system as directed by CMS, to ensure that the electronic data interchange (EDI) submitter/receiver is an authorized EDI submitter for each transaction.
D. As applicable, the WISeR Participant shall be responsible for the verification/validation of the WISeR Providers and WISeR Suppliers that will be exchanging EDI with the WISeR Participant.

Section 5.3 CMS Audits and Reviews of Software

A. The WISeR Participant shall allow CMS the use of provided software and software documentation, tools, and equipment to conduct audit reviews, tests, and assessments of the WISeR Participant at its facility, its data center and/or in its data cloud.
B. Consistent with Section 5.3.A, the WISeR Participant shall allow CMS use and access to, without limitation, the WISeR Participant's Enhanced Technology, artificial intelligence, machine learning technology, and other similar technologies.

Article VI. Prior Authorization Process

Section 6.1 General

A. The WISeR Participant shall use its Enhanced Technology to review and assess Prior Authorization requests within its assigned WISeR Jurisdiction ("**Prior Authorization Process**").

B. The WISeR Participant must review and assess each Prior Authorization request to ensure that the request meets the following criteria:
    1. Include all documentation necessary to show that the Select Items and Services meet applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The Prior Authorization request is submitted before the Select Items and Services are provided to the WISeR Beneficiary and before the claim is submitted.
C. The WISeR Participant reviews and assesses each expedited Prior Authorization request to ensure that the expedited request meets the following criteria:
    1. Includes all documentation necessary to show that the Select Item or Service meets applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The expedited Prior Authorization request is submitted before the Select Item or Service is provided to the WISeR Beneficiary and before the claim is submitted.
    3. Includes documentation showing that the processing of the Prior Authorization must be expedited due to the WISeR Beneficiary's life, health, or ability to regain maximum function being in serious jeopardy.
D. The WISeR Participant shall evaluate and refine its Prior Authorization Process to ensure accuracy in its Prior Authorization determinations and to prevent harm to Beneficiaries, including WISeR Beneficiaries.
E. The WISeR Participant shall engage in activities such as Navigation Services to reduce clinically inappropriate care and promote clinically appropriate care with its WISeR Providers and WISeR Suppliers in a form and manner and by the date(s) specified by CMS.
F. The WISeR Participant shall report Prior Authorization Process related activities and metrics to CMS through monthly, yearly, and ad hoc reports in a form and manner and by the date(s) specified by CMS.

Section 6.2 Prior Authorization Process and Exemption Status

A. General. 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).
B. Upon receipt of a Prior Authorization, the WISeR Participant shall review the request for compliance with applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act.

1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to the Select Items and Services detailed in Table 1 of Appendix A of this Agreement.
2. The WISeR Participant shall verify that the Prior Authorization is for a Select Item or Service as detailed in Table 1 of Appendix A.
3. The WISeR Participant must further verify that the Prior Authorization request is from a WISeR Provider or WISeR Supplier within the WISeR Jurisdiction.
4. The WISeR Participant shall verify that the requested Select Item or Service would be furnished to an individual that is a WISeR Beneficiary.

C. The WISeR Participant, its WISeR Clinician(s) and its WISeR Clinical Reviewers shall conduct Medical Review of the Prior Authorization, any Resubmissions, render determinations, and communicate decisions to the WISeR Providers, WISeR Suppliers, and WISeR Beneficiaries in accordance with the terms of this Agreement and the applicable requirements detailed in the WISeR Participant Guide.

D. Resubmission. The WISeR Participant shall accept Resubmissions from a WISeR Provider or WISeR Supplier for a Select Item or Service.
1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to each Resubmission; or
2. At the request of the WISeR Provider or WISeR Supplier through its Resubmission, the WISeR Participant shall require its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, to perform peer-to-peer review of the Resubmission. Such peer-to-peer review activities and requirements are detailed in the WISeR Participant Guide and the WISeR Participant acknowledges and agrees that its WISeR Clinicians and WISeR Clinical Reviewers will comply with such requirements.

E. Exemption Status. The WISeR Participant shall provide Exemption Status to a WISeR Provider or WISeR Supplier that has:
1. Submitted the minimum number of Prior Authorization requests for Select Items and Services furnished to WISeR Beneficiaries within the WISeR Jurisdiction as detailed in the WISeR Participant Guide;
2. Has met the CMS threshold percentage of Prior Authorization Provisional Affirmations as detailed in the WISeR Participant Guide; and
3. Met any additional criteria set forth by CMS in the WISeR Participant Guide.

F. Exemption Status List. The WISeR Participant shall retain current and historical lists of WISeR Providers and WISeR Suppliers that have earned Exemption Status.
1. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it has earned Exemption Status and has been added to the Exemption Status list.

i. The WISeR Participant shall specify in its notice to the WISeR Provider or WISeR Supplier the effective date of its Exemption Status, the process for retaining Exemption Status, and provide such other details as described in the WISeR Participant Guide.

2. The WISeR Participant shall provide current and historical Exemption Status lists to CMS in a form and manner and by the date(s) specified by CMS in accordance with the terms of this Agreement and applicable requirements set forth in the WISeR Participant Guide.
3. The WISeR Participant may remove a WISeR Provider or WISeR Supplier from the Exemption Status list if it fails to meet the requirements for Exemption Status as described in the WISeR Participant Guide.
4. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it is removed from the Exemption Status list and such notice shall specify the effective date of removal, the process for re-earning Exemption Status, and provide such other details as described in the WISeR Participant Guide.

Section 6.3 Prior Authorization Determinations

A. Determination Letters.

1. CMS may develop and provide to the WISeR Participant and Model Participants template determination letters.
2. Upon request of the WISeR Participant to CMS, and at the discretion of CMS, the WISeR Participant may create its own template determination letter(s), and such template(s) must be submitted to CMS for review and written approval prior to use and include at a minimum the following information and any other information as specified in the WISeR Participant Guide:
    i. A Unique Tracking Number (UTN);
    ii. For Prior Authorization Non-Affirmation decisions:
        a. A detailed explanation for the decision;
        b. The availability of unlimited resubmissions by the WISeR Provider or WISeR Supplier;
        c. Instructions for how the WISeR Provider or WISeR Supplier may request peer-to-peer review; and
        d. The opportunity to forego the resubmission process, provide one or more of the Select Items and Services, submit the claim for payment and:
            1. The claim will be denied; and
            2. All Medicare appeal rights will be available.
    iii. For re-routed Prior Authorization decisions:

a. Contact information for the WISeR Participant;
b. Instructions to the requesting WISeR Provider and/or WISeR Supplier on how it may choose to submit future Prior Authorization requests for Select Items and Services directly to the WISeR Participant; and
c. Any additional information that CMS may require through written notification to the WISeR Participant.

3. If CMS determines that the template(s) submitted by the WISeR Participant contains misinformation or is otherwise inconsistent with the terms of this Agreement or the WISeR Participant Guide, CMS may reject the template(s) or require the WISeR Participant to amend the template(s) and resubmit such amended template(s) to CMS for review and approval prior to use.

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.

C. Resubmission of Prior Authorization.
1. The WISeR Participant shall issue a Resubmission Determination to the WISeR Provider or WISeR Supplier within 3 Days of the WISeR Participant's receipt of the Prior Authorization resubmission.
2. The WISeR Participant shall ensure the Resubmission Determination is delivered to the WISeR Provider or WISeR Supplier in the same manner it was submitted via postmark, fax, or electronic delivery.

D. Expedited Circumstances. The WISeR Participant may only consider an expedited review of a Prior Authorization request upon receipt of request for expedited review by the WISeR Provider or WISeR Supplier.
1. If the WISeR Participant, in consultation with its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, determines that delays in receipt of a Prior Authorization decision could jeopardize the life, health, or ability to regain maximum function of the WISeR Beneficiary, then the WISeR Participant will process the Prior Authorization under an expedited timeframe, upon request.
i. The WISeR Participant will communicate a determination within 2 business days of receipt of the expedited request.

ii. WISeR Providers and WISeR Suppliers, and their MAC(s) when applicable, are encouraged to use fax, Electronic Submission of Medical Documentation (esMD), or any other CMS approved electronic portal to avoid delays with mailing.

E. Prior Authorization Provisional Affirmation. The WISeR Participant will issue a Prior Authorization Provisional Affirmation of coverage to a WISeR Provider or WISeR Supplier, with a copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and any applicable criteria in the WISeR Participant Guide are met to support the rendering of such item or service to a WISeR Beneficiary.

1. The WISeR Participant's Prior Authorization Provisional Affirmation decision is valid for 120 days from the date the determination was made.

F. Prior Authorization Non-Affirmation.

1. Consistent with Section 3.6.B.2 and Section 3.6.E.2, the WISeR Participant must require its WISeR Clinician(s) and WISeR Clinical Reviewer(s), as applicable, to perform a Medical Review of each Prior Authorization request that may not meet Medicare Coverage Criteria.
    i. The Medical Review of a Prior Authorization request by a WISeR Clinician or WISeR Clinical Reviewer, as applicable, must be performed before the WISeR Participant issues a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier.
2. The WISeR Participant will issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier, with copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and applicable criteria in the WISeR Participant Guide are not met and do not support the rendering of such item or service to a WISeR Beneficiary.
3. The WISeR Participant may issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier for a Select Item or Service via the same method it was requested if the Prior Authorization request contains technical errors or is otherwise insufficient to meet the requirements for Prior Authorization Provisional Affirmation.

G. Appeals. The WISeR Participant acknowledges and agrees that nothing in this Agreement nor in the WISeR Participant Guide shall be construed to limit or otherwise prevent a WISeR Provider, WISeR Supplier, WISeR Beneficiary or Beneficiary from

engaging in the Medicare appeals process permitted by applicable law, regulations, or Medicare program requirements.

Section 6.4 Prior Authorization Non-Affirmation and Resubmissions

A. The WISeR Participant shall provide written notice consistent with Section 6.3.A of this Agreement to the WISeR Provider or WISeR Supplier that the WISeR Provider or WISeR Supplier may resubmit a Prior Authorization upon receipt of a Prior Authorization Non-Affirmation.
B. The WISeR Participant shall provide written notice, consistent with Section 6.3.A, to the WISeR Provider or WISeR Supplier that it may resubmit a Prior Authorization for expedited review consistent with the requirements in Section 6.3.D of this Agreement.
C. The WISeR Participant shall consider all Resubmissions for Prior Authorization received within 120 Days of the Initial Prior Authorization Determination.
D. The WISeR Participant shall review a Resubmission for Prior Authorization received after 120 Days of the Initial Prior Authorization Determination as an Initial Prior Authorization request.

Section 6.5 Pre-Payment Review

A. The WISeR Participant acknowledges that Prior Authorization is not a condition of payment to the WISeR Provider or WISeR Supplier.
B. The WISeR Participant agrees that the WISeR Provider or WISeR Supplier may elect not to submit a Prior Authorization before furnishing one or more of the Select Items and Services to a WISeR Beneficiary.
C. If the WISeR Provider or WISeR Supplier elects not to submit a Prior Authorization for one or more Select Items and Services it furnishes to a WISeR Beneficiary, then the WISeR Participant shall coordinate with the appropriate MAC to subject the claim to Pre-Payment Review consistent with the terms of this Agreement, Sections 6.5.C.1 and 6.5.C.2, and the requirements detailed in the WISeR Participant Guide.
    1. CMS, through its appropriate MAC, will flag claims submitted by the WISeR Provider or WISeR Supplier for Select Items and Services without a Prior Authorization request.
    2. CMS, through its appropriate MAC, will re-route flagged claims to the WISeR Participant for Pre-Payment Review.
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.

Article VII. Quality Performance

Section 7.1 Quality Score

CMS shall use the quality score in determining the WISeR Participant's Aggregate Quality Score ("**AQS**") according to the methodology described in this Article VII and the WISeR Data Reporting Guide.

Section 7.2 Quality Measures

A. General
   1. The WISeR Participant shall complete reporting for all quality measures and for all Prior Authorizations received, Prior Authorization Provisional Affirmations, Prior Authorization Non-Affirmations, and Resubmissions in accordance with the WISeR Data Reporting Guide.
   2. CMS will publish, at least annually, a WISeR Data Reporting Guide, detailing the WISeR quality reporting requirements.
   3. CMS may modify the WISeR Performance Measure Set, or the number of measures that the WISeR Participant must report, or both. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Performance Measure Set at least 30 Days prior to the effective date of the change.
      i. If CMS removes a quality measure from the WISeR Performance Measure Set in advance of a Performance Period, CMS will not use the removed quality measure to evaluate the WISeR Participant, and the WISeR Participant will not be accountable for performance on such quality measures during the relevant Performance Period.

B. WISeR Performance Measure Set
   1. The WISeR Participant shall report all measures to CMS that are listed in the WISeR Performance Measure Set as described in Appendix B to this Agreement and the WISeR Data Reporting Guide. CMS shall use these measures for the purposes of calculating the WISeR Participant's AQS, the monitoring and evaluation of the overall efficiency and accuracy in WISeR, and to evaluate the WISeR Participant's performance during the Model.
   2. CMS will determine what version of specifications will be used for each measure included in the WISeR Performance Measure Set for the applicable Performance Period. CMS will notify the WISeR Participant of the version of specifications that will be used for each measure included in the WISeR Performance Measure Set as early as possible after such information becomes available.

3. The WISeR Participant must report all required measures from the WISeR Performance Measure Set in order to be eligible to earn the WISeR Payment for a Performance Period in accordance with Section 8.3.

C. Quality Measure Reporting
   1. The WISeR Participant must submit all quality measures that are listed in the WISeR Performance Measure Set to CMS during the defined reporting period for quality measures as communicated in the WISeR Data Reporting Guide.
   2. CMS reserves the right to require submission via any other format, including the Fast Healthcare Interoperability Resources ("**FHIR®**") standard, at any time during the Agreement Term without the consent of the WISeR Participant. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the reporting format of measures at least 90 Days prior to the measurement period.
   3. The WISeR Participant shall comply with the requirements described in this Article VII and Appendix B of this Agreement, and the requirements detailed in the WISeR Data Reporting Guide.

Section 7.3 Collection of Data and Purpose

A. Pursuant to 42 C.F.R. § 403.1110(b), the WISeR Participant must collect and report data described in Section 7.2 to CMS for CMS' Model monitoring and evaluation purposes.
B. The WISeR Participant, at CMS' request, will administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
C. CMS reserves the right to administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
D. CMS may require the WISeR Participant to implement surveys of WISeR Providers, WISeR Suppliers, and/or WISeR Beneficiaries in the WISeR Participant's designated WISeR Jurisdiction and report any survey measures included in the WISeR Data Reporting Guide to CMS.

Section 7.4 Quality Performance Scoring

A. CMS will calculate the WISeR Participant's AQS for each Performance Period at the time of Reconciliation.
B. CMS will calculate the AQS based on quality measures specified in the WISeR Data Reporting Guide.

C. CMS will calculate the AQS by totaling the quality points for all quality measures included in the AQS calculation for a given Performance Period and dividing by the maximum quality points available for these included quality measures.
D. CMS may modify the methodology for Quality Performance Scoring and shall notify the WISeR Participant in writing at least 30 Days before the start of the Performance Period in which such change would take effect. Modifications to the Quality Performance Scoring methodology may include, but are not limited to:
    1. Modifications to the set of quality measures included in the AQS;
    2. Modifications to the point values and point distributions for one or more quality measures included in the AQS;
    3. Modifications to the benchmark for one or more quality measures included in the AQS; and
    4. Modifications to the metrics for one or more quality measures included in the AQS.
E. CMS will convert the AQS to a quality multiplier that will be applied to each WISeR payment for the applicable Performance Period, as detailed in the WISeR Data Reporting Guide.

Article VIII. Financial Management and Payment

Section 8.1 General

A. CMS shall make, adjust, settle, and seek repayment of WISeR Payments in accordance with this Article VIII and Article XIII.
B. CMS may unilaterally amend Article VIII and to the extent practicable will issue advance written notice to the WISeR Participant 30 Days before the start of the Performance Period in which the amendment would take effect.

Section 8.2 Financial Management Requirements

A. The WISeR Participant shall promote the fiscal integrity of the Medicare FFS program and be an accountable steward of public funds.
B. The WISeR Participant shall adhere to the CMS Medicare integrity program.

Section 8.3 WISeR Payments

A. General.
    1. CMS pays the WISeR Payment to the WISeR Participant, as set forth in this Article VIII, subject to initial Reconciliation, financial settlement, and recoupment.

2. The WISeR Participant may receive a WISeR Payment for each Pre-Payment Review that results in a denied claim for a Select Item or Service and for each Payable Non-Affirmation.
3. CMS shall not pay the WISeR Participant a WISeR Payment if the WISeR Participant conducts a Prior Authorization or a Pre-Payment Review and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
4. The WISeR Participant owes a WISeR Recoupment and shall remit all WISeR Recoupments to CMS if Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to a WISeR Beneficiary due to the successful appeal of a claim denial.
5. CMS calculates the WISeR Payment as set forth in Section 8.3.D.

B. Calculation of Regional Benchmark.

1. For each Performance Period and each Locality within the WISeR Participant's designated WISeR Jurisdiction, CMS determines a Locality-specific Regional Benchmark for each of the Select Items and Services identified in Table 1 of Appendix A of this Agreement.
2. Except as specified in Section 8.3.B.3, CMS calculates the Regional Benchmark by:
    i. Identifying all claims that were submitted within the state that include the applicable Locality, were submitted by a WISeR Provider or a WISeR Supplier, include the applicable Select Item or Service, and have a date of service in the 12 months preceding the start of the applicable Performance Period;
    ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the Locality and applicable to the calendar year that includes the Performance Period being reconciled; and
    iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.
3. In the event change in law or Medicare policy changes effective during the Agreement Performance Period and applicable to a Select Item(s) or Service(s), CMS may, at its sole discretion, calculate the Regional Benchmark for the applicable Select Item or Service for one or more Performance Periods by:

i. Identifying all claims for the Select Item or Service that were submitted by Medicare-enrolled providers or suppliers within the WISeR Participant's designated MAC Jurisdiction with a date of service that is:
    a. No earlier than the effective date of the applicable legislation or Medicare policy change;
    b. No earlier than 9 months before the start of the applicable Performance Period; and
    c. No later than the final Day of the applicable Performance Period; and
ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the calendar year that includes the Performance Period being reconciled; and
iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.

4. When calculating the average claim-level payment as set forth in Section 8.3.B.2.iii and Section 8.3.B.3.iii, CMS may exclude payments for certain items or services billed on the same claim as the applicable Select Item or Service. CMS will maintain a list of such exclusions in the WISeR Participant Guide.

C. WISeR Discount. CMS calculates the WISeR Discount separately by state for each of the Select Items and Services as the percentage of claims with a medical necessity denial among all claims submitted by WISeR Providers and WISeR Suppliers within the state for that Select Item or Service with a date of service in 12 months preceding the start of the Model Performance Period. CMS may modify the WISeR Discount, including the dates of service for claims included in the calculation of the WISeR Discount, and to the extent practicable will provide 30 Days' advance written notice before the effective date of such modifications.

D. WISeR Payment. The WISeR Participant may earn a WISeR Payment for each Payable Non-Affirmation and for each Pre-Payment Review resulting in a denied claim for a Select Item or Service.

1. CMS calculates the WISeR Payment for each Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state;
    ii. Multiplying by the WISeR payment rate of 25 percent; and
    iii. Applying the quality adjustment determined by the WISeR Participant's AQS.

2. CMS calculates the WISeR Payment for each Pre-Payment Review resulting in a denied claim for a Select Item or Service by:
    i. Calculating the amount billed on the claim, less any approved payments for services other than the Select Item or Service that were billed on the same claim and less any denied payments billed on the same claim for one or more excluded service(s) noted in the WISeR Participant Guide;
    ii. Reducing the amount set forth in Section 8.3.D.2.i by the WISeR Discount applicable to the Select Item or Service and state;
    iii. Multiplying by the WISeR payment rate of 25 percent; and
    iv. Applying the quality adjustment determined by the WISeR Participant's AQS.

E. WISeR Recoupment. CMS will recoup a WISeR Recoupment from the WISeR Participant if CMS pays the WISeR Participant a WISeR Payment and Medicare subsequently pays the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
    1. The amount of the WISeR Recoupment will equal the amount of the previous WISeR Payment that CMS paid to the WISeR Participant for the applicable Payable Non-Affirmation or Pre-Payment Review.
    2. CMS will identify any WISeR Recoupments on a quarterly basis.
    3. To the extent possible, CMS will net any WISeR Recoupments against the total of WISeR Payments for a future Performance Period as set forth in Section 8.5.
    4. If CMS cannot collect WISeR Recoupments for claims appeals adjudicated after the Reconciliation of the final Performance Period under the Agreement or any other CMS program or initiative, CMS shall issue a demand letter to the WISeR Participant and the WISeR Participant shall pay CMS the amount owed within 30 Days of the date of demand letter.
    5. If CMS does not timely receive payment in full, the remaining amount owed will be considered a delinquent debt subject to the provisions of Section 8.8.D.

Section 8.4 Advance WISeR Payment

A. At the sole discretion of CMS, CMS may pay the WISeR Participant an Advance WISeR Payment prior to completing Reconciliation for a given Performance Period.

B. Eligibility Criteria.
    1. At the sole discretion of CMS, CMS may provide an Advance WISeR Payment to the WISeR Participant for an applicable Performance Period.

2. The WISeR Participant may be eligible to receive an Advance WISeR Payment during an applicable Performance Year if:
    i. CMS has notified the WISeR Participant of the availability of an Advance WISeR Payment for a specified Performance Period;
    ii. CMS has detailed specific data elements that the WISeR Participant must report to CMS in a form and manner and by the date(s) specified by CMS ("**Preliminary Data**");
    iii. The WISeR Participant timely reports the required data elements to CMS; and
    iv. CMS has approved the WISeR Participant's reported data elements and eligibility for an Advance WISeR Payment for the specified Performance Period.
3. If CMS determines that the WISeR Participant has not timely or accurately reported all required data elements, then CMS may deem the WISeR Participant ineligible for an Advance WISeR Payment for the applicable Performance Period.
4. If CMS has approved the WISeR Participant's eligibility for an Advance WISeR Payment for the applicable Performance Period, then CMS calculates the Advance WISeR Payment as set forth in Section 8.4.D.
5. In applicable Performance Periods, CMS will calculate the Advance WISeR Payment no earlier than the first Day after the end of the Performance Period.

C. Adjustments to Future WISeR Payment(s). If CMS determines that the WISeR Participant is eligible to receive an Advance WISeR Payment, CMS will net the amount of the Advance WISeR Payment against future WISeR Payments, including as applicable:
    1. Any WISeR Payments that CMS calculates for the applicable Performance Period during Reconciliation; and
    2. Any WISeR Payments that CMS calculates for subsequent Performance Periods.

D. Calculation of an Advance WISeR Payment. CMS calculates an Advance WISeR Payment using Preliminary Data for the Performance Period submitted by the WISeR Participant as set forth in Section 8.4.B. CMS calculates the Advance WISeR Payment for the applicable Performance Period as follows:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will provisionally determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will provisionally identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will estimate the WISeR Payment for each provisionally identified Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state; and
    ii. Multiplying by the WISeR payment rate of 25 percent.
5. CMS will estimate the WISeR Payment for each provisionally identified Pre-Payment Review qualifying for a WISeR Payment by:
    i. Calculating the amount billed on the claim, less any payments for services other than the Select Item or Service that were billed on the same claim;
    ii. Reducing this amount by the WISeR Discount applicable to the Select Item or Service and state; and
    iii. Multiplying by the WISeR payment rate of 25 percent.
6. CMS will total the estimated WISeR Payments as set forth in Section 8.4.E.4 and Section 8.4.E.5 and multiply this total by 50 percent to obtain the Advance WISeR Payment.

Section 8.5 Reconciliation Process

A. CMS will perform Reconciliation for a Performance Period by completing the following calculations:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will calculate the AQS for the WISeR Participant as set forth in Section 7.4 and in the WISeR Data Reporting Guide.
5. CMS will calculate the WISeR Payment as set forth in Section 8.3.D.
6. CMS will identify any pending WISeR Recoupments as set forth in Section 8.3.E. and will net these WISeR Recoupments against the total of WISeR Payments for the Performance Period.

B. CMS will perform Reconciliation for a Performance Period no earlier than the Day after the last Day on which a Resubmission for a Prior Authorization may be submitted, except as otherwise provided in Section 8.5.C.
    1. After calculating the WISeR Payment amount for the Reconciliation for a Performance Period, CMS will compare this amount against any WISeR Payment that was calculated in the initial Reconciliation for the same Performance Period and already paid or recouped by CMS, to determine the net amount of any WISeR Payment still owed for that Performance Period.
    2. If CMS issues a Reconciliation Report detailing the results of the Reconciliation, as described in Section 8.6, simultaneously with the Reconciliation Report detailing the results of the initial Reconciliation for a subsequent Performance Period, CMS may net any WISeR Payment amount specified in the Reconciliation Report for the initial Reconciliation against the net WISeR Payment amount that CMS calculates for the Reconciliation in accordance with Section 8.5.B.1.
C. If the Agreement or Agreement Performance Period is terminated pursuant to Article XIII, CMS shall conduct an initial Reconciliation and a final financial settlement, in accordance with Section 8.9, for the WISeR Participant's final Performance Period, which shall include all Prior Authorizations and Pre-Payment Reviews conducted by the WISeR Participant through the effective date of termination or expiration of this Agreement.

Section 8.6 Reconciliation Report

A. After performing Reconciliation for a given Performance Period as set forth in Section 8.5, CMS shall issue a Reconciliation Report to the WISeR Participant.
B. The Reconciliation Report will set forth the calculation of the WISeR Participant's Regional Benchmarks, AQS, Payable Non-Affirmations, and any applicable WISeR Payment for that Performance Period. In accordance with Section 8.5, the Reconciliation Report for any subsequent Reconciliation for a given Performance Period will also set forth any necessary adjustments to the WISeR Payment amount, if applicable, calculated in the initial Reconciliation for that Performance Period.
C. CMS shall make reasonable efforts to issue the initial Reconciliation Report for each Performance Period within 6 months after the last Day of that Performance Period.
D. Unless CMS receives a timely calculation error notice in accordance with Section 8.7, the Reconciliation Report shall be deemed final 30 Days from the date of issuance by CMS.

Section 8.7 Reconciliation Report Calculation Error

A. The WISeR Participant may contest a Reconciliation Report in accordance with this Section 8.7.
B. The WISeR Participant shall have 30 Days from the date the Reconciliation Report is issued to provide written notice to CMS of an error in the calculation of the WISeR Payment specified in that Reconciliation Report. The calculation error notice must contain a detailed, written explanation of the basis for the calculation error, including any supporting documentation.
C. If CMS receives a timely calculation error notice, CMS shall issue a written determination within 30 Days to either confirm or revise the calculation error, although CMS may extend the deadline for its determination upon written notice to the WISeR Participant.
    1. If CMS issues a written determination that the amount was calculated in error, CMS shall issue a revised Reconciliation Report, which is final on the date of issuance. The WISeR Participant may dispute the revised Reconciliation Report in accordance with Article XIV if the dispute is not precluded from review.
    2. If CMS issues a written determination that the amount is correct, the Reconciliation Report is final on the date the determination is issued.
    3. The WISeR Participant may dispute the determination issued by CMS in accordance with Article XIV if the dispute is not precluded from review.

D. If the WISeR Participant does not submit a timely calculation error notice to CMS in accordance with this Section 8.7, the WISeR Participant is precluded from later contesting the WISeR Payment amounts specified in that Reconciliation Report.
E. If as a result of any later inspection, evaluation, investigation, or audit, it is determined that any WISeR Payment amounts have been calculated in error, CMS may adjust such amounts, issue a revised Reconciliation Report, and make or demand payment of any additional amounts owed in accordance with this Section 8.7.

Section 8.8 Payment of Amounts Owed

A. CMS will pay the WISeR Participant any WISeR Payment amount owed to the WISeR Participant that is specified in Reconciliation Report within 30 Days after the date the Reconciliation Report is deemed final, as set forth in this Section 8.8.
B. CMS shall issue to the WISeR Participant a demand letter for any WISeR Payment owed pursuant to a Reconciliation Report that has been deemed final. The demand letter will be sent to the WISeR Participant at the address specified on the most recent Electronic Funds Transfer Authorization Agreement submitted by the WISeR Participant in accordance with Section 3.1.E.
C. The WISeR Participant shall pay any WISeR Payment amount owed to CMS within 30 Days of the date of a demand letter.
D. Delinquent Debt
    i. If the WISeR Participant fails to pay amounts due to CMS in full by the date specified in any demand letter, CMS shall assess simple interest on the unpaid balance at the rate applicable to other Medicare debts under 42 C.F.R. § 405.378. Interest shall be calculated in 30-Day periods and shall be assessed for each 30-Day period that payment is not made in full. Any payments received by CMS first shall be applied toward accrued interest and then to any outstanding principal balance due.
    ii. If CMS does not receive payment in full by the date the payment is due, CMS shall invoke all legal means to collect the debt and will use any applicable debt collection tools, including referral of the debt to the United States Department of Treasury, pursuant to 31 U.S.C. § 3711(g).

Section 8.9 Financial Settlement Report

A. Upon the expiration or termination of the Agreement Performance Period, CMS will issue to the WISeR Participant a financial settlement report that sets forth the amount of any WISeR Recoupments that the WISeR Participant must repay to CMS

or the amount of any WISeR Payment that CMS must make to the WISeR Participant, in accordance with this Agreement ("**Financial Settlement Report**").

B. If the Financial Settlement Report indicates that CMS owes the WISeR Participant additional payment, CMS shall make such payment within 30 Days after the Financial Settlement Report is deemed final.

C. If the Financial Settlement Report indicates that the WISeR Participant owes CMS a WISeR Recoupment, CMS will issue the WISeR Participant a demand letter for such monies owed to CMS. The WISeR Participant shall pay CMS any WISeR Recoupment within 30 Days of the date of a demand letter. If CMS does not timely receive payment in full, the remaining monies owed shall be considered a delinquent debt in accordance with Section 8.8.D.

Section 8.10 Extreme and Uncontrollable Circumstances

A. CMS may, in its sole discretion, provide Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers if the WISeR Providers and WISeR Suppliers:

   1. Are located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act; and
   2. Are located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

B. CMS has the sole discretion to determine the time period during which Prior Authorization flexibilities are provided to the WISeR Participant's WISeR Providers and WISeR Suppliers.

C. In the event that CMS provides Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers, CMS will provide written notice to the WISeR Participant of any impact such flexibilities have on the terms of this Agreement.

D. The WISeR Participant shall identify, develop, and coordinate prevention, response, and recovery procedures to ensure the availability of critical resources, and facilitate the continuity of essential business functions in an emergency situation, including natural disasters, manmade incidents, catastrophic emergencies, and public health emergencies ("**Continuity of Operations (COOP) Plan**").

E. The WISeR Participant shall maintain a COOP Plan that addresses protection of the physical infrastructure and business continuity (with or without system availability) of mission essential functions, to include without limitation the Prior Authorization Process, and communicating to WISeR Providers and WISeR Suppliers.

F. The WISeR Participant's COOP Plan shall include an information technology (IT) contingency and disaster recovery plan that addresses identified IT risks and vulnerabilities including, without limitation, cybersecurity issues.

Article IX. Business Associate Agreement, Data Sharing and Reports

Section 9.1 Business Associate Agreement

A. The WISeR Participant agrees to execute a valid Business Associate Agreement ("**BAA**") with CMS no later than 5 Days after the Effective Date of this Agreement.
B. If the WISeR Participant fails to execute a valid BAA pursuant to Section 9.1.A by the date specified by CMS, CMS will terminate the Agreement or the Agreement Performance Period or both in accordance with Section 13.3.
C. The WISeR Participant's BAA with CMS shall be active and valid for the duration of the Agreement Term.
D. The WISeR Participant shall comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") Privacy, Security, and Breach Notification Rules (45 C.F.R. Part 160 & Part 164, subparts A through E) ("**HIPAA Rules**").
E. The parties agree that the terms and conditions of the executed BAA between the WISeR Participant and CMS are hereby incorporated by reference into this Agreement as if fully set forth herein.

Section 9.2 Data Sharing and Reports – General

A. The WISeR Participant shall implement information technology (IT) systems security controls in order to maintain the confidentiality, integrity, and availability of the Medicare systems operations in the event of computer incidents or physical disasters.
B. Subject to the limitations discussed in this Agreement, and in accordance with applicable law, including HIPAA and the regulations in 42 C.F.R. Part 2, in advance of the Start Date of this Agreement, during the Agreement Performance Period, and any other time deemed necessary by CMS, CMS will offer the WISeR Participant an opportunity to request certain Beneficiary-identifiable data and reports in accordance with the terms and conditions set forth in this Agreement and in the BAA.
C. The Beneficiary-identifiable data available for request are described in Section 9.3 of this Agreement and in the BAA between CMS and the WISeR Participant.
D. Consistent with 42 C.F.R. § 403.1110(b), the WISeR Participant shall report data metrics for monitoring and evaluation purposes related to the WISeR Participant's Prior Authorization Process that include without limitation:

1. The total number of Prior Authorizations received during the data reporting period with a detailed description of:
    i. The number of Prior Authorization Provisional Affirmations during the data reporting period; and
    ii. The number of Prior Authorization Non-Affirmations during the data reportion period; and
2. The time (e.g., Days, weeks, hours, etc.) taken for the WISeR Participant's Prior Authorization Process to reach a determination;
    i. The total number of Resubmissions for each Prior Authorization received during the data reporting window or for a previous data reporting window;
    ii. The number of reversals of the Initial Prior Authorization Determination.

Section 9.3 Provision of Certain Beneficiary-Identifiable Claims Data

A. At CMS' sole discretion based on CMS' available resources, the limitations in this Agreement, the limitations in the BAA, and applicable law, CMS and the WISeR Participant may share certain Beneficiary-identifiable data for Beneficiaries in the WISeR Jurisdiction subject to the Prior Authorization Process.
B. The Beneficiary-identifiable data includes the data and reports described in this Section 9.3.B.
    1. Detailed Beneficiary Claims Data. These data will include individual Beneficiary-identifiable Medicare FFS claims data for Select Items and Services provided to Beneficiaries within the WISeR Jurisdiction. This includes without limitation data on Medicare FFS expenditures and utilization, and Prior Authorization Process metrics (e.g., timing, Prior Authorization request determinations, Resubmissions of Prior Authorizations, etc.).
    2. Quality Performance Scoring Data. These data will include Beneficiary-identifiable data and quality performance data specific to the Prior Authorization Process.
C. The parties mutually agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by CMS.
D. The parties further agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by the WISeR Participant as it relates to the Prior Authorization Process.

E. The WISeR Participant represents, and in furnishing the data files specified in Section 9.3.B of this Agreement and the BAA CMS relies upon such representation, that such data files will be used solely for the purpose of carrying out the provisions of this Agreement to improve the efficiency and accuracy of Prior Authorizations, quality improvement activities, reducing health care costs for the Medicare FFS program without causing harm to Beneficiaries, identifying or reducing fraud, waste, and abuse in Medicare FFS, and such other purposes described int his Agreement. The WISeR Participant agrees not to disclosure, use, or reuse the data excepts as specified in this Agreement, the BAA, or except as CMS shall authorize in writing or as otherwise required by law. The WISeR Participant further agrees not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement and the BAA.

F. Information derived from the CMS data specified in Section 9.3.B of this Agreement and in the BAA may be shared and used within the legal confines of the WISeR Participant and its WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers and WISeR Suppliers in a manner consistent with the provisions of this Agreement and the BAA to improve the Prior Authorization Process and Beneficiary care.

G. The WISeR Participant may reuse original or derivative data without prior written authorization from CMS for quality improvement activities relating to improving health or reducing health care costs through the Prior Authorization Process, but shall not disseminate (unless required by law) any individually identifiable original or derived information from the data specified in Section 9.3.B of this Agreement to anyone who is not a HIPAA Covered Entity, a HIPAA Business Associate, a WISeR Clinician or WISeR Clinical Reviewer performing activities related to this Model, or a WISeR Provider or WISeR Supplier in treatment relationship with the subject WISeR Beneficiary. When using or disclosing PHI or personally identifiable information ("**PII**"), obtained from data specified in Section 9.3.B, the WISeR Participant must make "reasonable efforts to limit" the information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure, or request.

H. The WISeR Participant shall establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget ("**OMB**") in OMB Circular No. A-130, Appendix I – Responsibilities for Protecting and Managing Federal Information Resources (https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A130/a130revised.pdf) as well as Federal Information Processing Standard 200 entitled

"Minimum Security Requirement for Federal Information and Information Systems" (http:// (http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf); and, NIST Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" (http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf). The WISeR Participant acknowledges that the use of unsecured telecommunications, including the Internet, to transmit directly or indirectly identifiable information from the files specified in Section 9.2.B or any such derivative data files is strictly prohibited.

I. The WISeR Participant shall grant access to the data and/or the facility(ies) in which the data is maintained to the authorized representatives of CMS or Office of Inspector General of the Department of Health and Human Services ("**OIG**") for the purpose of inspecting to confirm compliance with the terms of this Agreement and the BAA.

J. The WISeR Participant agrees that any use of CMS data in the creation of any document concerning the purpose specified in this section must adhere to CMS' current cell size suppression policy. The policy stipulates that no cell (e.g., patients, services) representing 10 or fewer Beneficiaries may be displayed. Also, no percentages or other mathematical formulas may be used if they result in the display of a cell representing 10 or fewer Beneficiaries. A cell that represents or uses percentages or other mathematical formulas to represent zero Beneficiaries must be displayed.

Article X. Participation in Evaluation, Shared Learning Activities, and Site Visits

Section 10.1 Evaluation Requirement

A. General. The WISeR Participant shall participate and cooperate in any independent evaluation activities conducted by or on behalf of CMS aimed at assessing the impact of the Model on the goals of improving quality of care and reducing fraud, waste, and abuse expenditures for the Medicare program. The WISeR Participant shall require its WISeR Clinicians and WISeR Clinical Reviewers to participate and cooperate in any such independent evaluation activities conducted by or on behalf of CMS. Termination or expiration of this Agreement shall not affect the right of CMS to evaluate WISeR.

B. Primary Data. In its evaluation activities, CMS or its designee(s) may collect qualitative and quantitative data. These data may include, but are not limited to the following sources:

1. Site visits with the WISeR Participant;
2. Surveys or interviews with WISeR Providers and WISeR Suppliers;
3. Surveys or interviews with Beneficiaries and their caregivers;
4. Focus groups of WISeR Providers and WISeR Suppliers;
5. Focus groups of Beneficiaries and their caregivers;
6. Interviews with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
7. Focus groups with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
8. Direct observation of WISeR Provider and/or WISeR Supplier interactions with the WISeR Participant and its staff, and other activities related to the WISeR Participant's participation in the Model;
9. Review of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates; and
10. Surveys.

C. Secondary Data. In its evaluation activities, CMS may use data or information submitted by the WISeR Participant as well as claims submitted to CMS for Select Items and Services furnished to Beneficiaries. These data may include, but are not limited to:
    1. Claims data;
    2. Survey data from Patient Experience surveys;
    3. Medical records;
    4. Clinical data;
    5. Monitoring data (e.g., audit results, etc.); and
    6. Quality and clinical data submitted to CMS.
D. Reporting Requirements. CMS may add or modify evaluation-related reporting requirements during the Agreement Term. CMS will notify the WISeR Participant of any additions or modifications as soon as practicable or at least 30 Days prior to the Day on which such change would take effect.

Section 10.2 Shared Learning Activities

A. The WISeR Participant shall participate in CMS-sponsored learning activities designed to drive improvement and foster innovations in using technology-assisted decision-making through sharing best practices or new knowledge that emerges from participation in the Model.
B. The WISeR Participant shall actively engage in a variety of learning events, learning communities, and sharing promising tools and ideas, as well as their lessons learned.

Section 10.3 Site Visits

A. The WISeR Participant shall cooperate and require its staff to cooperate in any site visits conducted by or on behalf of CMS.
B. CMS or its designee(s) shall, to the extent practicable, schedule any site visits to the WISeR Participant no fewer than 15 Days in advance. To the extent practicable, CMS will attempt to accommodate the WISeR Participant's request for particular dates in scheduling site visits. However, the WISeR Participant may not request a date that is more than 60 Days after the date of the initial site visit notice from CMS.
C. The WISeR Participant shall ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during the site visit.
D. Notwithstanding the foregoing, CMS or its designee(s) may perform unannounced site visits at any of the WISeR Participant's office locations at any time to investigate concerns or other program integrity issues.
E. Nothing in this Agreement shall be construed to limit or otherwise prevent CMS from performing site visits permitted by applicable law or regulations.

Section 10.4 Rights in Data and Intellectual Property

A. CMS may use any data obtained pursuant to the Model to evaluate the Model and to disseminate quantitative results and successful care management techniques to other providers and suppliers and to the public. Data to be disseminated may include results of WISeR Provider and WISeR Supplier surveys, results of patient experience of care and quality of life surveys as well as measures based upon claims, medical records, and other data sources. The WISeR Participant will be permitted to comment on evaluation reports when the WISeR Participant has been specifically cited to ensure factual accuracy but may not edit conclusions or control the dissemination of reports.
B. The parties agree that by participating in the Model, the WISeR Participant grants to CMS and its designees a limited, royalty-free, worldwide, non-sublicensable, non-exclusive license on a warranty-free basis during the term of this Agreement (and for any agreed to extension thereof) in, to and under all intellectual property and information technology owned or licensable (without the consent of, or payment to, any third party) by the WISeR Participant or any of its affiliates, solely for CMS or any of its designees or affiliates to receive and use such information technology.
C. Notwithstanding any other provision in the Agreement, the parties agree that any intellectual property or information technology developed as a result of the collaborative activity under the terms of this Agreement and the requirements associated with this Model will be dealt with by appropriate written agreements

D. Notwithstanding any other provision in the Agreement, all proprietary trade secret information and technology of the WISeR Participant that existed prior to the Effective Date of this Agreement is and shall remain the sole property of the WISeR Participant, and, except as required by federal law, shall not be released by CMS without express written consent. The regulation at 48 C.F.R. § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into the Agreement. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property right or other rights to the WISeR Participant's proprietary information or technology.

E. If the WISeR Participant maintains any information that should not be publicly disclosed because the WISeR Participant considers such information to be proprietary and confidential, the WISeR Participant acknowledges that it may submit to CMS a form, using either the template attached as Appendix C, or a form substantially the same as Appendix C, identifying specific examples of information the WISeR Participant considers to be proprietary and confidential. The WISeR Participant must notify CMS, in a form and manner to be specified by CMS, of any updates to this form. If the WISeR Participant does not submit such a form, the WISeR Participant will be deemed to have confirmed that it has no information it considers proprietary and confidential.

Section 10.5 WISeR Participant Public Release of Information

A. The WISeR Participant shall obtain prior approval from CMS during the Agreement Term and for 6 months thereafter for the publication or release of any press release, external report or statistical/analytical material that materially and substantially references the WISeR Participant's participation in the Model. External reports and statistical/analytical material may include but are not limited to papers, articles, professional publications, speeches, and testimony.

B. All external reports and statistical/analytical material that are subject to this Section 10.5 must include the following statement on the first page: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

Article XI. Compliance and Oversight

Section 11.1 WISeR Participant Compliance Plan

A. The WISeR Participant shall have a compliance plan that includes at least the following elements:

1. A designated compliance official or individual who is not legal counsel to the WISeR Participant and reports directly to the WISeR Participant's governing body;
2. Mechanisms for identifying and addressing compliance problems related to the WISeR Participant's operations and performance;
3. A method for employees or contractors of the WISeR Participant performing functions or services related to this Model to anonymously report suspected problems related to the WISeR Participant's compliance official;
4. Compliance training for the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers; and
5. A requirement for the WISeR Participant to report probable violations of law to an appropriate law enforcement agency.

B. The WISeR Participant shall ensure that its compliance plan is in compliance with all applicable laws and regulations. The WISeR Participant shall periodically update its compliance plan to reflect changes in those laws and regulations.

Section 11.2 CMS Monitoring and Oversight Activities

A. CMS shall conduct monitoring activities to assess compliance by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers with the terms of this Agreement. Such monitoring activities may include, but are not limited to:
   1. Claims analyses to identify fraudulent behavior or program integrity risks such as efforts to manipulate Prior Authorization Process accuracy and efficiency;
   2. Claims and appeals data to identify fraudulent behavior or program integrity risks, including data between the WISeR Participant and any MAC;
   3. Review of documents from the WISeR Participant, WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers, and WISeR Suppliers, including surveys and questionnaires;
   4. Review and audits of the WISeR Participant's Enhanced Technology, including without limitation, reliance on artificial intelligence, machine learning capabilities, and its impact on the timing and accuracy of Prior Authorization determinations, denial rates, affirmation rates, resubmission rates, and other data related to such Enhanced Technology;
   5. Review and audits of the WISeR Participant's Pre-Payment Review processes performed by its WISeR Clinicians and WISeR Clinical Reviewers, and the impact on the timing and accuracy of Pre-Payment Review determinations, denial rates, affirmation rates, resubmission rates, and other data related to such reviews;
   6. Interviews with Beneficiaries and their caregivers;

7. Audits of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant;
8. Audits of data related to Pre-Payment Review, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant; and
9. Site visits to the WISeR Participant.

B. In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including, without limitation, all Medicare claims submitted for items and/or services furnished to Beneficiaries.

C. In conducting monitoring and oversight activities, CMS or its designee(s) may use any relevant data or information including, without limitation, all Prior Authorization requests, Pre-Payment Review activities, determinations, and resubmissions submitted for items and/or services furnished to Beneficiaries.

D. Nothing in this Agreement limits or otherwise prevents CMS from monitoring the WISeR Participant for compliance as permitted by applicable law or regulations.

E. CMS may conduct monitoring activities pursuant to this Article XI for up to two calendar years after the effective date of termination or expiration of this Agreement.

Section 11.3 Compliance with Monitoring and Oversight Activities

A. The WISeR Participant shall cooperate with, and require its WISeR Clinicians and WISeR Clinical Reviewers to cooperate with, all CMS monitoring and oversight requests and activities.

B. The WISeR Participant shall ensure it has sufficient access to all records, data, and information necessary to comply with the monitoring activities described in this Agreement. As necessary, the WISeR Participant shall request this information from any WISeR Clinician, or any WISeR Clinical Reviewer, or individual performing functions or providing services related to WISeR.

Section 11.4 Compliance with Laws

A. Agreement to Comply

1. The WISeR Participant shall comply with, and shall require all WISeR Clinicians and WISeR Clinical Reviewers to comply with, the applicable terms of the Agreement and all applicable statutes, regulations, and guidance, including without limitation: (a) federal criminal laws; (b) the Social Security Act (Public Law 74-271); (c) Title XVIII of the Act; (d) the False Claims Act (31 U.S.C. § 3729 et seq.); (e) the antikickback statute (42 U.S.C. § 1320a-7b(b)); (f) the civil monetary penalties law (42 U.S.C. § 1320a-7a); (g) the federal

physician self-referral law (42 U.S.C. § 1395nn); and (h) any applicable State laws.

2. This Agreement does not waive any obligation of the WISeR Participant to comply with the terms of any other CMS contract, agreement, model, or demonstration.

B. Reservation of Rights

1. Nothing contained in this Agreement or in the application process for WISeR constitutes a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS Office of the Inspector General, or CMS of any right to institute any proceeding or action for violations of any statutes, rules, or regulations administered by the government, or to prevent or limit the rights of the government to obtain relief under any other federal statutes or regulations, or on account of any violation of the Agreement or any other provision of law. This Agreement does not bind any government agency except CMS and the Agreement binds CMS only to the extent provided in this Agreement.
2. The failure by CMS to require performance of any provision of this Agreement does not affect CMS' right to require performance at any time thereafter, nor does a waiver of any breach or default of the Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

C. Office of Inspector General of the Department of Health and Human Services (OIG) Authority. None of the provisions of this Agreement limit or restrict the OIG's authority to audit, evaluate, investigate, or inspect the WISeR Participant or its WISeR Clinicians or its WISeR Clinical Reviewers.

D. Other Government Authority. None of the provisions of this Agreement limit or restrict any other government authority that is permitted by law to audit, evaluate, investigate, or inspect the WISeR Participant.

Section 11.5 Applicable Statutes, Regulations, Manuals, and Documents

In addition to all referenced statutes, regulations, manuals, and documents, the following statutes, regulations, manuals, and documents apply to this Agreement and are hereby incorporated by reference.

A. Financial management and internal controls (e.g., the Federal Managers' Financial Integrity Act of 1982 (FMFIA), the Chief Financial Officers' Act of 1990, etc.);
B. Federal Information Security Management Act of 2014 (FISMA);
C. Privacy and information technology requirements (Privacy Act of 1974, Information Technology Management Reform Act of 1996);

D. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191);
E. Rehabilitation Act of 1973 (including section 508, Accessibility Standards);
F. Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248);
G. Administrative Simplification Compliance Act of 2002 (Public Law 107-105);
H. Benefit Improvement and Protection Act of 2000 (Public Law 106-554);
I. Executive Order 13410, to the extent practicable, Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs;

Medicare manuals (e.g., internet only manuals – IOMs) to administer CMS programs. In the event of any conflict, this Agreement shall have precedence over the IOMs located at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index;

Article XII. Audits and Record Retention

Section 12.1 Right to Audit and Inspect

The WISeR Participant agrees that the government (including CMS, HHS, and the Comptroller General or their designees) has the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the WISeR Participant that pertain to the following:

A. The WISeR Participant's compliance with the terms of this Agreement, including provisions that require the WISeR Participant to impose duties or requirements on its WISeR Clinicians and its WISeR Clinical Reviewers;
B. Whether the WISeR Clinicians and WISeR Clinical Reviewers complied with the duties and requirements imposed on them by the WISeR Participant pursuant to the terms of this Agreement;
C. The quality of services performed under this Agreement;
D. Any activity by the WISeR Participant that may pose a potential risk of harm to Beneficiaries or a vulnerability to the integrity of the Model test;
E. The WISeR Participant's right to WISeR Payments;
F. The ability of the WISeR Participant to repay amounts owed to CMS under this Agreement;
G. The WISeR Participant's financial arrangements.

Section 12.2 Maintenance of Records

The WISeR Participant shall maintain and shall give the government (including CMS, HHS, and the Comptroller General or their designees) access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs,

quality performance measures, and financial arrangements) sufficient to enable the audit, evaluation, inspection, or investigation of the Model, including the subjects identified in Section 11.2. The WISeR Participant shall maintain such books, contracts, records, documents, and other evidence for a period of six years from the expiration or termination of this Agreement or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:

A. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the WISeR Participant at least 30 Days before expiration of the six-year period described above; or
B. There has been a termination, dispute, or allegation of fraud or similar fault against the WISeR Participant in which case the records shall be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

Article XIII. Remedial Action and Termination

Section 13.1 Grounds for Remedial Action

A. CMS may take remedial action against the WISeR Participant if CMS determines that the WISeR Participant:
    1. Has failed to comply with any applicable term of the Agreement or any Medicare program requirement, rule, or regulation;
    2. Has failed to comply with the American with Disabilities Act of 1990, 42 U.S.C. § 12101 *et seq*. (1990);
    3. Has failed to comply with the WISeR Participant's Corrective Action Plan (CAP), the monitoring or auditing plan, or both, developed by CMS for the WISeR Participant, or other remedial action imposed by CMS, if applicable;
    4. Has taken any action that threatens the health or safety of a Beneficiary, including a WISeR Beneficiary;
    5. Has failed to rectify deficiencies following any remedial action;
    6. Has undergone a Change in Control that renders it ineligible for participation in the Model or presents a program integrity risk;
    7. Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model or any requirement of the Medicare program;
    8. Has failed to pay amounts owed to CMS by the date specified in a demand letter;
    9. Has failed to pay a WISeR Recoupment;

10. Has a conflict of interest; or
11. Poses significant program integrity risks, including but not limited to:
    i. Is subject to sanctions or other actions of a federal, state, or local government agency;
    ii. Is subject to investigation or action by HHS (including, but not limited to OIG and CMS) or the Department of Justice due to an allegation of fraud or similar misconduct, including but not limited to being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

Section 13.2 Types of Remedial Action

A. If grounds for remedial action exist, CMS may take one or more of the following actions:
    1. Notify the WISeR Participant of the violation;
    2. Require the WISeR Participant to provide additional information to CMS or its designees;
    3. Conduct site visits, interview WISeR Providers and/or WISeR Suppliers, interview Beneficiaries, or take other actions to gather information;
    4. Place the WISeR Participant on a monitoring and/or auditing plan developed by CMS;
    5. Require the WISeR Participant to not use a WISeR Clinician or WISeR Clinical Reviewer for Medical Review, immediately or within a timeframe specified by CMS;
    6. Withhold, deny, or recoup WISeR Payments;
    7. Withhold, deny, or recoup any Advance WISeR Payments;
    8. Suspend or terminate the WISeR Participant's ability to perform its Prior Authorization Process on new requests;
    9. Require a CAP from the WISeR Participant that is acceptable to CMS. If CMS requires a CAP from the WISeR Participant, the following requirements apply:
        i. The WISeR Participant shall submit a CAP to CMS for approval by a deadline established by CMS:
        ii. CMS must approve the WISeR Participant's CAP;
        iii. The CAP must address what actions the WISeR Participant will take within a specified time period to ensure that all deficiencies will be corrected and that the WISeR Participant will be in compliance with the terms of this Agreement; and

iv. If the WISeR Participant does not comply with the terms of the CAP within the specified period of time, CMS may take additional remedial actions or terminate the Agreement or Agreement Performance Period in accordance with Section 13.3.

B. CMS may impose additional remedial actions, including but not limited to terminating the Agreement or Agreement Performance Period pursuant to Section 13.3, if CMS determines that the WISeR Participant's efforts to address noncompliance or other grounds for remedial action were insufficient.

Section 13.3 Termination by CMS

CMS may immediately or with advance notice terminate the Agreement or Agreement Performance Period if:

A. CMS determines that it no longer has the funds to support the Model;
B. CMS modifies or terminates the Model pursuant to section 1115A(b)(3)(B) of the Act;
C. CMS offers the WISeR Participant an amendment to this Agreement pursuant to Section 1.4, and the WISeR Participant does not sign such amendment by the date specified by CMS;
D. CMS determines that any grounds for remedial action exist;
E. CMS determines that the WISeR Participant has failed to submit, obtain approval for, implement, or fully comply with the terms of a CAP;
F. CMS determines that the WISeR Participant has failed to demonstrate improved performance following any remedial action imposed by CMS;
G. The WISeR Participant has a conflict of interest that cannot be resolved;
H. The WISeR Participant has not executed a valid BAA; or
I. The WISeR Participant assigns or purports to assign any of the rights or obligations under the Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

Section 13.4 Termination of the Agreement Performance Period by WISeR Participant

The WISeR Participant may terminate the Agreement Performance Period upon advance written notice to CMS. Such notice must specify the effective date of the termination, which must be at least 90 Days after the date of the notice.

Section 13.5 Financial Settlement Upon Termination

If CMS terminates the Agreement or the Agreement Performance Period is terminated by either party, CMS shall conduct settlement for the entire Performance Year in which the Agreement is terminated in accordance with Article VIII of the Agreement.

Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination

If the Agreement or Agreement Performance Period is terminated under Section 13.3 or Section 13.4, the WISeR Participant shall provide written notice of the termination to all WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction. The WISeR Participant shall deliver such written notice no later than 45 Days before the effective date of termination unless a different date is specified by CMS. The WISeR Participant shall include in such notices any content specified by CMS.

Article XIV. Limitation on Review and Dispute Resolution

Section 14.1 Limitations on Review

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

A. The selection of organizations, sites, or participants to test models selected for testing or expansion under section 1115A of the Act, including the decision by CMS to terminate the Agreement or Agreement Performance Period;
B. The elements, parameters, scope, and duration of such models for testing or dissemination;
C. Determinations regarding budget neutrality under section 1115A(b)(3);
D. The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B);
E. Determinations about expansion of the duration and scope of a model under section 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection (c);
F. The selection of quality performance standards by CMS;
G. The methodology applied to calculate Regional Benchmarks, WISeR Discount, AQS, and WISeR Payments;
H. The methodology used to calculate the WISeR Participant's WISeR Payment; and
I. The methodology used to calculate the WISeR Recoupment.

Section 14.2 Dispute Resolution

A. Right to Reconsideration. The WISeR Participant may request reconsideration of a determination made by CMS pursuant to the Agreement only if such reconsideration is not precluded by section 1115A(d)(2) of the Act or the Agreement.
    1. Such a request for reconsideration by the WISeR Participant must satisfy the following criteria:

i. The request must be submitted to a designee of CMS ("**Reconsideration Official**") who –
    a. Is authorized to receive such requests;
    b. Did not participate in the determination that is the subject of the reconsideration request; and
    c. May be, but does not have to be, an Inferior Officer.
ii. The request must include a copy of the initial determination issued by CMS and contain a detailed, written explanation of the basis for the dispute, including supporting documentation;
iii. The request must be made within 30 Days of the date of the initial determination for which reconsideration is being requested and
iv. The request must be delivered via email to CMS at InnovationModelsReconsideration@cms.hhs.gov or at such other address specified by CMS.

2. Requests that do not meet the requirements of Section 14.2.A.1 will be denied.
3. Within 15 Days of receiving a request for reconsideration, the parties will be sent a written acknowledgement of receipt of the reconsideration request. Such an acknowledgement will set forth:
    i. The review procedures; and
    ii. A briefing schedule that permits each party to submit written briefs, including any evidence or documentation in support of the party's position for consideration by the Reconsideration Official.

B. Standards for Reconsideration
1. The parties shall proceed diligently with the performance of this Agreement during the course of any dispute arising under the Agreement.
2. The reconsideration will consist of a review of documentation that is submitted timely and in accordance with the standards specified by the Reconsideration Official.
3. The burden of proof is on the WISeR Participant to demonstrate to the Reconsideration Official with clear and convincing evidence that the determination is inconsistent with the terms of the Agreement.

C. Reconsideration Determination
1. The reconsideration determination will be based only upon:
    i. Position papers and supporting documentation that are timely submitted to the Reconsideration Official and meet the standards for submission under Section 14.2.B.2; and

ii. Documents and data that were timely submitted to CMS in the required format before the agency made the determination that is the subject of the reconsideration request.

2. The Reconsideration Official will issue to CMS and the WISeR Participant a written notification of the reconsideration determination ("**Reconsideration Determination**"). Absent unusual circumstances, the Reconsideration Determination will be issued within 60 Days of receipt of timely filed position papers and supporting documentation.
3. The Reconsideration Determination is final and binding 30 Days after its issuance, unless the WISeR Participant or CMS timely requests review of the Reconsideration Determination in accordance with Sections 14.2.D.1 and 2.

D. CMS Administrator Review. The WISeR Participant or CMS may request CMS Administrator review of the Reconsideration Determination.

1. The request must be made via email to InnovationModelsReconsideration@cms.hhs.gov or such other address as specified by CMS within 30 Days after the date of the Reconsideration Determination.
2. The request must include a copy of the Reconsideration Determination and a detailed, written explanation of why the WISeR Participant or CMS disagrees with the Reconsideration Determination.
3. Within 30 business days after receiving a request for review, the CMS Administrator (or a delegate acting on behalf of the CMS Administrator) will determine whether the request for review is granted or denied. The CMS Administrator will promptly send the parties written acknowledgement of receipt of the request for review. Such an acknowledgement will set forth:
    i. Whether the request for review is granted or denied; and
    ii. If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.
4. If the request for review is denied, the Reconsideration Determination is final and binding as of the date the request for review is denied.
5. If the request for review is granted:
    i. The record for review will consist of timely submitted briefs and the evidence contained in the record of the proceedings before the Reconsideration Official. The CMS Administrator will not consider documentation submitted for review other than documents and date described in Section 14.2.B.2;

ii. The CMS Administrator will review the record and issue to CMS and to the WISeR Participant a written determination; and
iii. The written determination of the CMS Administrator is final and binding.

E. Effect of Dispute Resolution. The dispute resolution process under this Agreement shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

Article XV. Miscellaneous

Section 15.1 Agency Notifications and Submission of Reports

A. For a notice or other communication required under this Agreement to be valid, it must be in writing.
B. Unless otherwise specified in this Agreement or stated in writing after the Effective Date, all notifications and reports required under this Agreement must be submitted to the parties at the addresses set forth below:

CMS:
WISeR Model
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop: WB-06-05
Baltimore, MD 21244
Email: WISeR@cms.hhs.gov

WISeR Participant:
Cohere Health, Inc.
226 Causeway Street, Suite 403
Boston
MA
02114

Section 15.2 Notice of Bankruptcy

A. If the WISeR Participant has filed a bankruptcy petition, whether voluntary or involuntary, the WISeR Participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the WISeR Participant under the terms of each model tested under section 1115A of the Act in which the WISeR Participant is participating or has participated and all administrative or judicial review proceedings related to any payments under such models have been fully and finally resolved.

B. The notice of bankruptcy must be sent by certified mail no later than 5 Days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the WISeR Participant is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the WISeR Participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the WISeR Participant and CMS have been fully and finally resolved with respect to that model.

C. The notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3-01-24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices.

Section 15.3 Severability

In the event that any one or more of the provisions of this Agreement is, for any reason, held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had never been included in the Agreement, unless the deletion of such provision or provisions would result in such a material change to the Agreement so as to cause continued participation under the terms of this Agreement to be unreasonable.

Section 15.4 Entire Agreement; Amendment

This Agreement, including all appendices, constitutes the entire agreement between the parties. The parties may amend this Agreement or any appendix hereto at any time by mutual written consent; provided, however, that CMS may amend this Agreement or any appendix hereto in writing without the consent of the WISeR Participant as specified in this Agreement or any appendix hereto, or for good cause or as necessary to comply with applicable federal

or state law, regulatory requirements, accreditation standards, or licensing guidelines or rules. To the extent practicable, CMS shall provide the WISeR Participant with 30 Days' advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

Section 15.5 Survival

Expiration or termination of this Agreement by CMS shall not affect the rights and obligations of the parties accrued prior to the effective date of the expiration or termination of this Agreement, except as provided in this Agreement. The rights and duties under the following sections of this Agreement shall survive the expiration or termination of this Agreement and apply thereafter:

Article VIII. Payment;
Article IX. Data Sharing and Reports;
Section 10.1 Evaluation Requirements;
Section 10.4 Rights in Data and Intellectual Property;
Section 10.5 WISeR Participant Public Release of Information;
Section 11.3 Compliance with Monitoring and Oversight Activities;
Article XII. Audits and Record Retention;
Section 13.5 Financial Settlement Upon Termination;
Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination;
Section 14.1 Limitations on Review;
Section 15.2 Notice of Bankruptcy;
Section 15.5 Survival; and
Section 15.7 Prohibition on Assignment.

Section 15.6 Precedence

If any provision of this Agreement conflicts with a provision of any document incorporated herein by reference, the provision of this Agreement shall prevail.

Section 15.7 Prohibition on Assignment

Except with the prior written consent of CMS, the WISeR Participant shall not transfer, including by merger (whether the WISeR Participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under this Agreement; (2) any right that it has to satisfy a condition under this Agreement; (3) any remedy that it has under this Agreement; or (4) any obligation imposed on it under this Agreement. The WISeR Participant shall provide CMS 90 Days' advance written notice of any such proposed transfer. This obligation remains in effect until final payment by or to the WISeR Participant has been made under this Agreement. CMS may condition its consent to transfer on full payment of any amounts owed by the WISeR Participant under this Agreement or owed to CMS by the

proposed assignee. Any purported transfer in violation of this Section is voidable at the discretion of CMS.

Section 15.8 Certification

The WISeR Participant executive signing this Agreement certifies to the best of his or her knowledge, information, and belief that the WISeR Participant satisfies the requirements of Section 3.1.A, that all WISeR Clinicians and WISeR Clinical Reviewers satisfy the requirements of Section 3.4, and that he or she is authorized by the WISeR Participant to execute this Agreement and to legally bind the WISeR Participant to its terms and conditions.

Section 15.9 Execution in Counterpart

This Agreement and any amendments hereto may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof. This Agreement and any amendments hereto may be signed by autopen or electronic signature (e.g., DocuSign or similar electronic signature technology) and may be transmitted by electronic means. Copies of this Agreement and any amendments hereto that are so executed and delivered have the same force and effect as if executed with handwritten signatures and physically delivered.

[SIGNATURE PAGE FOLLOWS]

Each party is signing this Agreement on the date stated opposite that party's signature. If a party signs but fails to date a signature, the date that the other party receives the signing party's signature will be deemed to be the date that the signing party signed the Agreement.

WISeR Participant: Cohere Health, Inc.

WISeR ID: WISeR-00018

(b)(6)

Date: 2025-09-25 17:16:40

By: _____

(b)(6)

Name of Authorized Signatory

(b)(6)

Title

CMS:

Date: 2025-10-01 14:14:13

By: _____

Arrah Tabe-Bedward

Name of Authorized Signatory

CMS Executive

Appendices

Appendix A: Select Items and Services

Appendix B: Quality Measures

Appendix C: WISeR Participant Proprietary and Confidential Information

Appendix A: Select Items and Services

CMS uses Covered Services that correspond to the LCDs and NCDs identified in the Table 1 below ("**Select Items and Services**") to determine whether the WISeR Provider's and/or WISeR Supplier's Medicare claim is subject to the Prior Authorization Process for Performance Year 1. The WISeR Participant performs its Prior Authorization Process for each Select Item or Service identified in a Prior Authorization request within its WISeR Jurisdiction.

CMS may unilaterally revise the Select Items and Services identified in Table 1 prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any revisions to the Select Items and Services for a Performance Period prior to the start of the Performance Period in which such change will take effect.

Table 1

Select Items and Services	Associated NCD/LCDs
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)	NCD 160.7 NCD 230.18 NCD 160.19 NCD 160.24 NCD 160.18
Induced Lesions of Nerve Tracts	NCD 160.1
Epidural Steroid Injections for Pain Management	L39015, L39242, L36920
Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L34106, L38201, L35130
Cervical Fusion Excluding codes already included in OPD	L39741, L39762, L39793
Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee	NCD 150.9

Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea	L38307, L38312, L38385
Incontinence Control Devices	NCD 230.10
Diagnosis and Treatment of Impotence	NCD 230.4
Percutaneous Image-Guided Lumbar Decompression for Spinal Stenosis	NCD 150.13
Skin and Tissue Substitutes • Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds • Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities	L35041 L36690

Appendix B: Quality Measures

Consistent with Article VII and the WISeR Data Reporting Guide, CMS shall use the following WISeR Performance Measure Set for purposes of calculating the AQS of the WISeR Participant for Performance Year 1. CMS will also use the following WISeR Performance Measure Set for purposes of monitoring and evaluating the overall performance of the WISeR Participant during the Model.

CMS may update the quality measures identified in the WISeR Performance Measure Set prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any updates for a Performance Period prior to the start of the Performance Period in which such change will take effect.

WISeR Performance Measure Set

Domain	First Applicable Performance Period	Data Source	Measurement Frequency
Timeliness of Determinations	PP1	WISeR Participant-Reported	Quarterly
Accuracy of Determinations	PP1	CMS Audit of WISeR Participant-Reported Data	Quarterly

Appendix C: WISeR Participant Proprietary and Confidential Information

The following are specific examples, without limitation, of what the WISeR Participant considers proprietary and confidential information currently maintained by the WISeR Participant that should not be publicly disclosed:

1) (a) Patent, patent applications, inventions, know-how, and proprietary methodologies, including processes, techniques, workflows, best practices, product roadmaps, testing protocols, optimization strategies we have developed or which have been developed for us, and materials, documents and written communications containing the foregoingnn(b) Confidential information enabling our current, future and planned

2) Logical, physical and functional architectural designs, and specificationsnSoftware programs, software source documents, and proprietary application metadatanAI, machine learning and statistical models, algorithms, and formulaenData models and knowledge representation frameworksnProprietary data generated by our technologies or employees to enable product design & development, including but not

3) Materials, documents and written communications containing the foregoingnn(c) Business and contractual relationships, business and actuarial forecasts, procurement requirements, sales and marketing plans, pricing strategies, and materials, documents and written communications containing the foregoingn

4) (d) Data related to prospects, customers, investors, employees, or others, including but not limited to contracts, agreements, financial and contact information, passwords and credentials, operational and performance metrics related to our approach to reviews, and materials, documents and written communications containing the foregoing

In accordance with Section 10.4 of the Agreement, this information shall not be released by CMS without the express written consent of the WISeR Participant except as required by federal law.

Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Patient Care Models Group
7500 Security Blvd
Baltimore, MD 21244

Wasteful and Inappropriate Service Reduction (WISeR) Model

Participation Agreement

Segment 1: January 1, 2026-December 31, 2028

August 29, 2025

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PARTICIPATION AGREEMENT

This Participation Agreement (the "**Agreement**") is between the CENTERS FOR MEDICARE & MEDICAID SERVICES ("**CMS**") and

Genzeon Corporation , ("**WISeR Participant**").

CMS is the agency within the U.S. Department of Health and Human Services ("**HHS**") that is charged with administering the Medicare and Medicaid programs.

The WISeR Participant is a legal entity identified by a single TIN and has Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process and Pre-Payment Review for Select Items and Services on Medicare fee-for-service ("**FFS**") Claims.

CMS is implementing the Wasteful and Inappropriate Service Reduction Model ("**WISeR**" or "**Model**") under section 1115A of the Social Security Act ("**Act**"), which authorizes CMS through its Center for Medicare and Medicaid Innovation ("**Innovation Center**") to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program expenditures while preserving or enhancing the quality of care furnished to Beneficiaries.

The Model seeks to reduce or maintain Medicare FFS expenditures while improving the quality of care and health outcomes for Medicare FFS beneficiaries through the WISeR Participant's Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process for Select Items and Services that do not satisfy existing Medicare Coverage Criteria and may be fraudulent, wasteful, or of low-value to Medicare FFS beneficiaries.

The WISeR Participant applied to participate in WISeR, and CMS has approved the WISeR Participant for participation in the Model for the MAC Jurisdiction of JL Novitas and the state of New Jersey. The designated state is the WISeR Participant's WISeR Jurisdiction.

The parties therefore agree as follows:

Article I. Agreement Term

Section 1.1 Effective Date

This Agreement will become effective when it is signed by the last party to sign it (as indicated by the date associated with that party's signature) ("**Effective Date**").

Section 1.2 Agreement Term

The term of this Agreement ("**Agreement Term**") begins on the Effective Date and expires two years after the last Day of the Agreement Performance Period, as defined in Section 1.3, unless the Agreement is sooner terminated by CMS in accordance with Section 13.3, in which case the Agreement Term ends on the effective date of such termination.

Section 1.3 Agreement Performance Period

A. The performance period of this Agreement ("**Agreement Performance Period**") begins on the Effective Date and ends at 11:59 PM ET on December 31, 2028, unless the Agreement Period or the Agreement is sooner terminated in accordance with Section 1.4.B or Article XIII, in which case the Agreement Performance Period ends on the date specified in the termination notice.

B. CMS may offer the WISeR Participant the option to participate in a second segment of this Model which would begin on January 1, 2029, and end at 11:59 PM ET on December 31, 2031. The WISeR Participant must execute a new agreement with CMS to participate in the Model during the second segment. Any such agreement will authorize CMS to take remedial action against the WISeR Participant for non-compliance with the terms of this Agreement, regardless of when the non-compliance is discovered by CMS.

Section 1.4 Amended and Restated Agreements

A. No later than 30 Days prior to the start of a calendar year during the Agreement Performance Period, CMS may offer the WISeR Participant the opportunity to sign an amendment to this Agreement, which may be in the form of an amended and restated version of this Agreement.

B. If the WISeR Participant fails to sign an amendment offered by CMS pursuant to Section 1.4.A by a date specified by CMS, CMS may terminate the Agreement Performance Period on December 31 of the year in which the amendment was offered.

Article II. Definitions

Advance WISeR Payment means the payment that meets the requirements in Section 8.4.

Aggregate Quality Score (AQS) means the score that is calculated from the WISeR Participant's quality data and used to determine the quality multiplier applied during the calculation of the WISeR Payment.

ARS stands for **CMS Acceptable Risk Safeguard** and means the standard to CMS and its contractors, including the WISeR Participant, as to the minimum level of required security and privacy controls. *See* https://security.cms.gov/policy-guidance/cms-acceptable-risk-safeguards-ars (last accessed August 2025).

ATO stands for **CMS Authority to Operate** and means the information systems operated by or on behalf of the U.S. federal government that meet FISMA standards.

BAA stands for **Business Associate Agreement** and means the legally binding contract required under HIPAA between CMS and the WISeR Participant that handles Protected Health Information.

Beneficiary means an individual who is entitled to Medicare FFS benefits under Part A or enrolled under Part B.

Change in Control means: (1) the acquisition by any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the WISeR Participant representing more than 50 percent of the WISeR Participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the WISeR Participant by any other individual or entity; (3) the sale, lease exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the WISeR Participant; or (4) the approval and completion of a plan of liquidation of the WISeR Participant, or an agreement for the sale or liquidation of the WISeR Participant.

Covered Services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Day(s) means calendar day(s) unless otherwise specified.

Electronic Submission of Medical Documentation (esMD) means a system used by CMS to enable providers, suppliers, and other entities to reduce or eliminate the need to mail or fax paper documents and instead electronically submit or request supporting medical documentation related to CMS claims and Prior Authorization.

Enhanced Technology means the WISeR Participant's technology that is intended to improve the accuracy and efficiency of the Prior Authorization Process and Pre-Payment Review.

Exemption Status means the status that a WISeR Provider or WISeR Supplier may earn to be exempt from requesting Prior Authorization for the Select Items and Services in accordance with Section 6.2 of this Agreement and the WISeR Participant Guide.

FedRAMP stands for **Federal Risk and Authorization Management Program** and means the government-wide program that standardizes security assessments for cloud services (44 U.S.C. § 3607).

Financial Settlement Report means the report that is defined in Section 8.9.

FISMA stands for **Federal Information Security Management Act of 2002, as amended by the Federal Information Security Modernization Act of 2014** and means the framework of guidelines and security standards to protect government information and operations as set forth in 44 U.S.C. § 3541, *et seq.* and 44 U.S.C. § 3551, *et seq*..

Initial Prior Authorization Determination means the communication to the WISeR Provider or WISeR Supplier detailing the Prior Authorization Affirmation or Prior Authorization Non-Affirmation for an initial Prior Authorization submission.

IS2P2 stands for **CMS Information Systems Security & Privacy Policy** and means the policy that defines how CMS protects and controls access to its information and systems as required under FISMA of 2014 (44 U.S.C. Chapter 35).

Locality means a CMS-defined geographic area within a MAC Jurisdiction (e.g., a state, or other geographic boundary) that CMS uses to determine Medicare payment rates for Covered Services.

LCDs stands for **Local Coverage Determinations** and has the meaning set forth in Section 1869(f)(2)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(2)(B)).

MAC stands for Medicare Administrative Contractor and means a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B medical claims or Durable Medical Equipment (DME) claims for Medicare fee-for-service beneficiaries, as further defined in Section 1874A(a)(3) of the Social Security Act (42 U.S.C. § 1395kk-1(a)(3) and 42 C.F.R. Subpart E).

MAC Jurisdiction means the defined geographic territory for the Medicare Part A and Part B Jurisdictions L, 15, H, and F selected for the WISeR Model and as depicted on the "A/B MAC

Jurisdictions" map at https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/who-are-macs (last accessed August 2025) (*see also* Section 911(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173).

Medical Review means the collection and clinical review of medical records and related information to ensure that Medicare payment is made only for services that meet all Medicare Coverage Criteria.

Medically Necessary means reasonable and necessary as determined in accordance with Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)).

Medicare Coverage Criteria means the existing Medicare coverage criteria as set forth in statute, regulation, NCD, or LCD.

Model Participant means a technology company that has signed an agreement with CMS to participate in WISeR and is not the WISeR Participant.

Model Performance Period means the period of time, regardless of the Agreement Performance Period, that begins on January 1, 2026 and ends on December 31, 2031, unless sooner terminated in accordance with Section 12.3.

Navigation Services means services and information including Medicare Coverage Criteria, Prior Authorization performance data, and such other services as detailed in the WISeR Participant Guide that are provided by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers, as applicable, to all WISeR Providers and WISeR Suppliers to increase clinically appropriate care.

NCDs stands for **National Coverage Determinations** and has the meaning set forth in Section 1869(f)(1)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(1)(B).

NPI stands for **National Provider Identifier**.

Payable Non-Affirmation means an Initial Prior Authorization Determination of Prior Authorization Non-Affirmation that qualifies for a WISeR Payment because there was no Resubmission within 120 Days that received a determination of Prior Authorization Affirmation and, at the time of Reconciliation, there was no associated claim paid by Medicare due to the successful appeal of a claim denial.

Performance Period means the three-month period in which the WISeR Participant issues Initial Prior Authorization Determinations for Prior Authorization requests and issues

determinations for Pre-Payment Reviews, including without limitation all associated Resubmissions submitted within 120 days of the Initial Prior Authorization Determination.

Performance Year or **PY** means the 12-month period beginning on January 1 of each year during the Model Performance Period.

Pre-Payment Review means the review by the WISeR Participant to verify consistency with Medicare Coverage Criteria for a claim for one or more Select Items and Services furnished in the MAC Jurisdiction that is submitted to Medicare without requesting Prior Authorization, consistent with 42 C.F.R. § 405.903.

Prior Authorization is a request by the WISeR Provider or WISeR Supplier for provisional affirmation of Medicare Coverage Criteria for one of the Select Items and Services prior to furnishing such items and services to the WISeR Beneficiary and before the claim is submitted for processing.

Prior Authorization Process means the process detailed in Article VI of the Agreement.

Prior Authorization Provisional Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Prior Authorization Non-Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is not accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Program Integrity Screening means a review of an individual's or entity's program integrity history and current status, which may include a review of the individual's or entity's eligibility, history of exclusion or other sanctions imposed with respect to participation in Medicare, Medicaid, or CHIP; history of failure to pay Medicare debts in a timely manner; current or prior law enforcement investigations or administrative actions regardless of whether such investigations or actions relate to participation in Medicare, Medicaid, or CHIP; affiliations with individuals or entities that have a history of program integrity issues; and other information pertaining to the trustworthiness of the individual or entity.

Reconciliation means the process by which CMS calculates the WISeR Payment amount owed to the WISeR Participant for a specific Performance Period as set forth in Article VIII.

Reconciliation Report means the report issued by CMS that details the Reconciliation calculations for the WISeR Participant and the amount of any WISeR Payment for one or more specified Performance Periods.

Regional Benchmark means a payment amount calculated by CMS for each of the Select Items and Services for a given Locality and Performance Period that CMS uses to calculate the WISeR Payment amount for a Payable Non-Affirmation as set forth in Section 8.3.

Resubmission means a Prior Authorization submitted to the WISeR Participant within 120 Days of an Initial Prior Authorization Determination for a Prior Authorization previously submitted by the same WISeR Provider or WISeR Supplier for the same WISeR Beneficiary and same Select Item or Service.

Resubmission Determination means the communication to the WISeR Provider and/or WISeR Supplier detailing the Prior Authorization Provisional Affirmation or Prior Authorization Non-Affirmation for a Resubmission.

Select Items and Services means the Covered Services detailed in Appendix A that are subject to the Prior Authorization Process. When used in its singular form this term is referred to as "**Select Item or Service**".

Start Date means January 1, 2026.

TIN stands for taxpayer identification number.

VDC stands for CMS Virtual Data Center and means the comprehensive information technology infrastructure designed to centralize and modernize CMS' digital operations.

WISeR Beneficiary means a Beneficiary that meets the requirements set forth in Section 4.1.

WISeR Clinician means an individual that satisfies the requirements of Section 3.6.

WISeR Clinical Reviewer means an individual that satisfies the requirements of Section 3.6.

WISeR Data Reporting Guide means the guidance paper that CMS publishes and provides to the WISeR Participant that sets forth the WISeR Participant's reporting obligations during the Model. CMS may modify the WISeR Data Reporting Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Data Reporting Guide at least 30 Days prior to the effective date of such revisions.

WISeR Discount means the discount specified in Section 8.3.C that CMS applies when calculating the WISeR Payment.

WISeR Jurisdiction means the defined geographic states of New Jersey (Jurisdiction L/Novitas Solutions, Inc.), Ohio (Jurisdiction 15/CGS Administrators, LLC), Oklahoma and Texas (JH/Novitas), and Arizona and Washington (JF/Noridian) selected for the WISeR Model

for which the WISeR Participant conducts Prior Authorization Process on claims for Select Items and Services from institutional providers, physicians, clinicians and suppliers.

WISeR Participant means the technology company that meets the requirements set forth in Article III and has signed this Agreement with CMS to participate in the Model.

WISeR Participant Guide means a guidance paper that CMS publishes and provides to the WISeR Participant that sets forth additional details to support the WISeR Participant's activities and obligations during the Model. CMS may modify the WISeR Participant Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Participant Guide at least 30 Days prior to the effective date of such revisions.

WISeR Payment means the Model specific payment made by CMS for a Payable Non-Affirmation or a Pre-Payment Review that qualifies for payment as set forth in Article VIII.

WISeR Performance Measure Set means the measures detailed in Appendix B, and as may be revised in the WISeR Data Reporting Guide, that CMS uses in calculating the AQS.

WISeR Provider means a provider, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction that furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

WISeR Recoupment means the amount owed to CMS if CMS pays a WISeR Payment to the WISeR Participant and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

WISeR Supplier means a supplier, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction and who furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

Article III. General Requirements

Section 3.1 WISeR Participant Requirements

A. During the Agreement Term, the WISeR Participant shall:
    1. Be a legal entity formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates for the purpose of carrying out the activities required by this Agreement;
    2. Have Enhanced Technology and be identified by a single TIN, to provide specified health insurance benefit administrative services, including

Medicare Prior Authorization and Pre-Payment Review services to interpret and apply Medicare Coverage Criteria and clinical coverage criteria derived from NCDs and LCDs, in support of the Medicare FFS program;

3. Use its Enhanced Technology for implementing and streamlining the Prior Authorization Process and Pre-Payment Review for Select Items and Services in its assigned WISeR Jurisdiction;
4. Have a valid Business Associate Agreement ("**BAA**") with CMS;
5. Support CMS in its efforts to make accurate and timely payments to WISeR Providers or WISeR Suppliers for Select Items and Services furnished to WISeR Beneficiaries;
6. Support CMS in its efforts to ensure care provided to Beneficiaries is Medically Necessary and adheres to Medicare Coverage Criteria, thus protecting Beneficiaries and the Medicare Trust Fund; and
7. Not have a conflict of interest as detailed in Section 3.3 of this Agreement.

The WISeR Participant states that it satisfies the requirements of this Section 3.1.A as of the Effective Date.

B. The WISeR Participant shall satisfy the requirements of this Section 3.1.B no later than 45 Days before the Start Date and throughout the remainder of the Agreement Term:
    1. Have access to Federal Risk and Authorization Management Program ("**FedRAMP**") certified workflows;
    2. Comply with all applicable Federal data protection and security requirements including Federal Information Security Management Act ("**FISMA**") requirements, CMS Information Systems Security & Privacy Policy ("**IS2P2**"), CMS Acceptable Risk Safeguard ("**ARS**");
    3. Follow CMS Authority to Operate ("**ATO**") guidelines for connections established between the Medicare Administrative Contractor ("**MAC**") and WISeR Participant; and
    4. Enter into a valid Joint Operating Agreement ("**JOA**") with the applicable MAC.
C. Changes to the WISeR Participant
    1. Change of WISeR Participant Name. The WISeR Participant shall provide written notice to CMS at least 60 Days before any change in the WISeR Participant's legal name becomes effective. The WISeR Participant shall forward to CMS a copy of the document effectuating the name change, authenticated by the appropriate state official (if applicable), and the parties shall execute an agreement reflecting the change of the WISeR Participant's name. This obligation shall remain in effect until the latter of the effective date

of termination of this Agreement or when the final payment by or to the WISeR Participant has been made under this Agreement.

2. Change in WISeR Participant TIN. The WISeR Participant shall provide at least 90 Days advanced written notice before the effective date of any change in the WISeR Participant's TIN. Such notice must be submitted in the form and manner specified by CMS. In response to a change in the WISeR Participant's TIN, CMS may terminate the Agreement or Agreement Performance Period, or take any other actions consistent with the terms of this Agreement. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
3. Change in Control.
    i. The WISeR Participant shall provide written notice to CMS at least 90 Days before the effective date of any Change in Control. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
    ii. Upon learning of a Change in Control, CMS may conduct a Program Integrity Screening and take other appropriate action to ensure compliance with the terms of the Model by the new controlling entity and may require the new controlling entity to execute a novation agreement with CMS or require the new controlling entity to execute a new Participation Agreement with CMS. CMS may also terminate the Participation Agreement between the former controlling entity and CMS.
    iii. If the WISeR Participant undergoes a Change in Control, CMS may take one or more of the following actions: terminate this Agreement; terminate the Agreement Performance Period; or immediately conduct financial settlement in accordance with Section 8.9.
4. Change in Primary Point of Contact. The WISeR Participant shall provide written notice to CMS of any changes to the contact information for the WISeR Participant's primary point of contact no later than 15 Days after the change.

D. Information for Electronic Funds Transfer

1. The WISeR Participant shall submit to CMS a completed Electronic Funds Transfer Authorization Agreement in the form and manner and by the date(s) specified by CMS.

2. The WISeR Participant shall promptly update its Electronic Funds Transfer Authorization Agreement if there are account or bank changes, or any change to the WISeR Participant set forth in Section 3.1.C.
3. If the WISeR Participant fails to submit or accurately complete the Electronic Funds Transfer Authorization Agreement, CMS may withhold any WISeR Payment owed to the WISeR Participant until the WISeR Participant has submitted and CMS has processed an Electronic Funds Transfer Authorization Agreement with the correct information. In addition, the failure to submit or accurately complete an Electronic Funds Transfer Authorization Agreement could delay the WISeR Participant's receipt and timely payment of a demand for payment under this Agreement, and thereby cause the WISeR Participant to be liable for interest on the amount owed to CMS.

E. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, the WISeR Participant fails to meet any requirements set forth in Section 3.1. The WISeR Participant shall provide such written notice to CMS at least 30 Days before failing to satisfy any requirements in Section 3.1.A, or within 5 Days of becoming aware that the WISeR Participant has failed to satisfy any requirements in Section 3.1(B)-(D).

Section 3.2 WISeR Participant Governance

A. General.
   1. The WISeR Participant shall maintain an identifiable governing body with sole and exclusive authority to execute the functions of the WISeR Participant and make final decisions on behalf of the WISeR Participant. The WISeR Participant shall have a governing body that satisfies the following criteria:
      i. The governing body has responsibility for oversight and strategic direction of the WISeR Participant and is responsible for holding the WISeR Participant management accountable for the WISeR Participant's activities;
      ii. The governing body has a transparent governing process;
      iii. When acting as a member of the governing body of the WISeR Participant, each governing body member has a fiduciary duty to the WISeR Participant and to CMS for actions relating to the terms of this Agreement, the Model and the terms set forth in the Business Associate Agreement, including the duty of loyalty, and shall act consistent with that fiduciary duty; and

iv. The governing body shall receive regular reports from the designated compliance official of the WISeR Participant who satisfies the requirements of Section 11.1.

2. The WISeR Participant shall provide each member of the governing body with a copy of the Agreement and any amendments hereto.
3. If CMS determines that the composition of the WISeR Participant's governing body, executive leadership, or parent organization(s) (as applicable) compromises the WISeR Participant's ability to participate in the Model or to comply with the terms of the Agreement, CMS may take one or more of the remedial actions specified in Section 13.2.
4. The WISeR Participant shall ensure that its governing body implements a process for documenting governing body composition, meetings and decisions, and shall retain such documentation in accordance with Section 12.2.

B. Composition and Control of the Governing Body.

1. The WISeR Participant's governing body shall not include any individual with pending or open investigations, or a history of convictions or sanctions, including without limitation:
    i. Investigations or actions related to participation in Medicare, Medicaid, or Children's Health Insurance Program;
    ii. A history of failure to pay Medicare debts in a timely manner;
    iii. Affiliations with individuals or entities that have a history of program integrity issues;
    iv. Conduct that a reasonable person would deem to be unfit conduct; or
    v. A history of legal or monetary sanctions.
2. The WISeR Participant shall routinely monitor each individual on its governing body to ensure compliance with the provisions of this Section 3.2.
3. The WISeR Participant shall immediately remove from its governing body any individual that becomes subject to a conviction or sanction.
4. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, it removes an individual from its governing body. The WISeR Participant shall provide such written notice to CMS within 5 Days of such removal.
5. The governing body members may serve in similar or complementary roles or positions, subject to Section 3.3.

Section 3.3 Conflict of Interest

A. The WISeR Participant shall have a conflict of interest policy that applies to members of the governing body and satisfies the following criteria:
    1. Requires each member of the governing body to disclose relevant financial interests and other interests that could prevent impartiality;
    2. Requires each member of the governing body to update its disclosure statement whenever the member's personal or financial circumstances change in such a way that a new conflict of interest might occur;
    3. Provides a procedure to determine whether a conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses remedial actions for members of the governing body that fail to comply with the policy.

B. Notwithstanding the obligations set forth in Section 3.3.A, the WISeR Participant shall have a conflict of interest policy that applies to its business operations and satisfies the following criteria:
    1. Requires that the WISeR Participant refrain from engaging in activities that would lead to the preferential or non-preferential treatment of any WISeR Provider, WISeR Supplier, WISeR Clinician, WISeR Clinical Reviewer, individual clinician, medical group, medical practice, Beneficiary, or any other individual or entity with an interest in the Prior Authorization Process or Pre-Payment Review;
    2. Requires that the WISeR Participant prohibit WISeR Clinicians and WISeR Clinical Reviewers from participating in the Prior Authorization Process and Pre-Payment Review associated with a provider or supplier under the same TIN as the reviewing WISeR Clinician or WISeR Clinical Reviewer;
    3. Provides a procedure to determine whether such conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses plans of action to correct instances that fail to comply with the policy.

C. The WISeR Participant shall ensure that its conflict of interest policy sets forth a process to address situations where an individual employed by or contracted by the WISeR Participant and has a financial interest, personal activity, or relationship that could impair that individual's ability to act impartially and in the best interest of CMS when performing under the terms of this Agreement, the Business Associate Agreement, or the Model.

D. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Prior Authorization request not participate in the review of that request or any associated Resubmissions related to that Prior Authorization request.
E. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Pre-Payment Review not participate in the review of that claim or any associated Resubmissions related to that Pre-Payment Review.
F. The WISeR Participant shall de-identify Prior Authorization requests, Resubmissions, and Pre-Payment Review claims prior to permitting its WISeR Clinicians and WISeR Clinical Reviewers to conduct a Medical Review or peer-to-peer review.
G. The WISeR Participant shall designate a committee or group responsible for evaluating disclosed potential conflicts of interest and determine whether they pose a risk to the fairness of the Prior Authorization review or the Pre-Payment Review.
    1. The WISeR Participant shall provide immediate written notice of disclosed potential conflicts of interest to CMS. Such written notice shall be made within 5 Days of becoming aware of the potential conflicts of interest.
    2. The WISeR Participant shall include CMS in the determination process associated with the disclosed potential conflicts of interest.

Section 3.4 Required Prior Authorization Activities

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.
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.
C. The WISeR Participant shall review Prior Authorizations in its WISeR Jurisdiction submitted by all WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).
D. Consistent with Section 3.4.C, the WISeR Participant shall perform its Prior Authorization Process on Prior Authorizations received.
E. Consistent with the terms of this Agreement and the requirements set forth in the WISeR Participant Guide, the WISeR Participant shall issue Prior Authorization determinations to the requesting WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction with a copy to the applicable WISeR Beneficiary.

Section 3.5 WISeR Providers and WISeR Suppliers

A. WISeR Providers and WISeR Suppliers may submit Prior Authorization requests directly to the WISeR Participant and receive a determination for Select Items and Services.

B. If the WISeR Provider or WISeR Supplier submits a Prior Authorization request to its MAC for a Select Item or Service, then:

   1. CMS, through the applicable MAC, will re-route the Prior Authorization request to the WISeR Participant;
   2. The WISeR Participant must perform its Prior Authorization Process on the re-routed Prior Authorization from the MAC for the Select Item or Service and issue a determination directly to the WISeR Provider or WISeR Supplier with copy to the MAC and the WISeR Beneficiary identified on the Prior Authorization request; and
   3. Perform any additional requirements as described in the WISeR Participant Guide.

C. CMS, through the applicable MAC, will notify the WISeR Participant if a WISeR Provider or WISeR Supplier submits a claim to Medicare for one or more Select Items and Services furnished to a WISeR Beneficiary in the WISeR Jurisdiction without requesting Prior Authorization.

D. The WISeR Participant must conduct Pre-Payment Review in accordance with Section 6.5 of this Agreement for each Select Item or Service that does not have a Prior Authorization request from the WISeR Provider or WISeR Supplier.

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.

F. CMS will provide written notice, which may be in the form of the WISeR Participant Guide, to the WISeR Participant regarding additional determination letter requirements.

G. The WISeR Participant shall provide to its WISeR Providers and WISeR Suppliers prior authorization criteria and relevant evidence-based clinical practice guidelines for Select Items and Services in a form and manner and by the date(s) determined by CMS. Such compliance assistance information shall include examples of documentation that would support approval of a Prior Authorization request for each Select Item or Service, as well as examples of common mistakes, omissions, and evidence that would result in a denial of Prior Authorization.

Section 3.6 WISeR Clinicians and WISeR Clinical Reviewers

A. General.

1. The WISeR Participant may choose to:
    i. Directly employ clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinicians**"); or
    ii. Subcontract with a separate entity that provides appropriate clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinical Reviewers**"); or
    iii. Do both (i) and (ii).
2. The WISeR Participant must provide to its subcontractor, if applicable, necessary and appropriate WISeR Participant Guide provisions to ensure that each WISeR Clinical Reviewer meets the Medical Review requirements to ensure proper coverage determinations that adheres to Medicare Coverage Criteria and CMS coverage policy.
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.

B. <u>WISeR Clinicians</u>.
1. The WISeR Participant shall ensure that each WISeR Clinician:
    i. Be a board-certified clinician, including a:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;

iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;

vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and

vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinician performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant shall ensure that each WISeR Clinician performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers in a form and manner determined by CMS, as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that the WISeR Clinician has an active, valid and unrestricted license.

C. Record of WISeR Clinicians. The WISeR Participant shall maintain, in accordance with Article XII, a record of all its WISeR Clinicians.
   1. The WISeR Participant shall retain current and historical records of all its WISeR Clinicians in accordance with Section 12.2 of this Agreement.
   2. CMS may request and the WISeR Participant must provide to CMS a certified copy of all WISeR Clinicians at any given time during the Agreement Term.

D. Monitoring and Compliance of WISeR Clinicians.
   1. CMS will monitor the program integrity history of the WISeR Participant's WISeR Clinicians. CMS may require the WISeR Participant to exclude an individual WISeR Clinician or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
   2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinician be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure that each WISeR Clinician conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks, and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that each WISeR Clinician uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items and Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Items and Services;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

E. WISeR Clinical Reviewers.

1. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer:
    i. Be a board-certified clinician, including:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;
    iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;
vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and
vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinical Reviewer performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall require its subcontractor to ensure that the WISeR Clinical Reviewer has an active, valid and unrestricted license.

F. Record of WISeR Clinical Reviewers. The WISeR Participant must require its subcontractor to maintain, in accordance with Article XII of this Agreement, a record of all WISeR Clinical Reviewers performing activities related to this Model.
1. The WISeR Participant shall require the subcontractor to retain current and historical records of all WISeR Clinical Reviewers consistent with Section 12.2 of this Agreement.
2. The WISeR Participant shall require its subcontractor to provide the WISeR Participant with a certified copy of all WISeR Clinical Reviewers at any given time during the Agreement Term. The WISeR Participant shall provide such information to CMS in a form and manner and by the date(s) specified by CMS.

G. Monitoring and Compliance of WISeR Clinical Reviewers.
1. CMS will monitor the program integrity history of the WISeR Participant's use of WISeR Clinical Reviewers. CMS may require the WISeR Participant to exclude an individual WISeR Clinical Reviewer or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinical Reviewer be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items or Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Item or Service;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

Section 3.7 Customer Service

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.
B. The WISeR Participant shall provide an overall environment where WISeR Providers and WISeR Suppliers understand the Prior Authorization Process and Pre-Payment Review process for Select Items and Services.
C. The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.
D. The WISeR Participant shall maintain effective WISeR Provider and WISeR Supplier education that helps ensure complete Prior Authorization submissions for Select Items and Services and reduces the need for re-submissions, requests for appeal, and overturn of coverage determinations on appeal.
E. The WISeR Participant shall educate WISeR Providers and WISeR Suppliers on how to submit Prior Authorization requests and provide its WISeR Providers and WISeR Suppliers with information related to the Medicare Coverage Criteria associated with

the Select Items and Services. Such educational activities shall be conducted in a form and manner determined or approved by CMS, and as may be detailed in the WISeR Participant Guide.

F. The WISeR Participant must educate WISeR Providers and WISeR Suppliers within its assigned WISeR Jurisdiction about the Prior Authorization Process consistent with the provisions of this Agreement and the WISeR Participant Guide.

Section 3.8 Operational Requirements

A. The WISeR Participant shall promote corporate integrity and establish internal controls and an effective compliance program to achieve Agreement goals and objectives.

B. The WISeR Participant shall work collaboratively with CMS, WISeR Providers, WISeR Suppliers, Medicare Administrative Contractors, and other CMS contractors to foster integration of Medicare operations.

C. The WISeR Participant shall develop and continually refine business processes to foster excellence and quality in the administration of the Medicare program.

D. The WISeR Participant shall foster efficiencies in the administration of the Medicare FFS program to promote best value for the government.

E. The WISeR Participant shall use innovative and creative solutions to improve program operations.

Section 3.9 Overlap with Other CMS Programs and Initiatives

A. The parties agree that the WISeR Model is not a shared savings model and there is no Beneficiary alignment in this Model.

B. The WISeR Participant may simultaneously participate in the WISeR Model and any other Innovation Center model.

C. CMS reserves the right to unilaterally update this overlaps policy upon written notice to the WISeR Participant.

Article IV. Beneficiary Eligibility, Engagement, Verification, and Protections

Section 4.1 Beneficiary Eligibility

A. To be considered a WISeR Beneficiary, a Beneficiary must meet the following criteria:

1. Be identified on a Prior Authorization request or a claim subject to Pre-Payment Review for a Select Item or Service from a WISeR Provider or WISeR Supplier in the WISeR Participant's WISeR Jurisdiction;

2. Is eligible for Medicare Part A and enrolled in Medicare Part B at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review;
3. Is a legal adult aged 18 years or older;
4. Is not enrolled in Medicare Advantage at the time of the Prior Authorization request or the date of service on the claim subject to Pre-Payment Review;
5. Has Medicare as the primary payer at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review; and
6. Is not covered under the United Mine Worker Health and Retirement Funds.

Section 4.2 Beneficiary Engagement and Beneficiary Verification

A. The WISeR Participant does not have Beneficiaries aligned or assigned to it for this Model.
B. CMS may require the WISeR Participant to educate Beneficiaries, including WISeR Beneficiaries, within its WISeR Jurisdiction on the Prior Authorization Process for Select Items and Services.
C. The WISeR Participant must ensure that each Prior Authorization request submitted by a WISeR Provider, WISeR Supplier, or a MAC is for a Select Item or Service that will be furnished to a WISeR Beneficiary within the WISeR Jurisdiction.

Section 4.3 Beneficiary Protections and Non-Affirmed Decisions

A. The WISeR Participant shall provide written Prior Authorization Process decisions to the WISeR Provider and/or WISeR Supplier with a copy to the applicable WISeR Beneficiary and appropriate MAC.
B. The WISeR Participant's Prior Authorization Non-Affirmation decision for the Select Item or Service that is determined to not be Medically Necessary must require the WISeR Provider or WISeR Supplier to notify the WISeR Beneficiary and issue an Advance Beneficiary Notice of Non-coverage (ABN) prior to performing such item(s) or service(s) if it is expected that payment would be denied.
C. For purposes of the WISeR Provider and WISeR Supplier notifications required under Sections 4.3.A and 4.3.B, the WISeR Participant shall use a template letter provided by CMS, in which CMS will designate letter content that the WISeR Participant shall not change, as well as places in which the WISeR Participant may insert its own original content.
D. Beneficiaries continue to have all applicable administrative appeal rights under Original Medicare.

Section 4.4 Prohibition on Beneficiary Inducements

Except as otherwise permitted by applicable law, the WISeR Participant shall not provide gifts or other remuneration to Beneficiaries to induce them to receive or to continue to receive items or services from one or more of the following: WISeR Providers, WISeR Suppliers, WISeR Clinicians, or WISeR Clinical Reviewers.

Section 4.5 HIPAA Requirements

A. The WISeR Participant acknowledges that it is either a covered entity or business associate, as those terms are defined in 45 C.F.R. § 160.103, of CMS that is a covered entity.
B. The WISeR Participant shall have all appropriate administrative, technical, and physical safeguards in place before the Start Date to protect the privacy and security of protected health information ("**PHI**") in accordance with 45 C.F.R. § 164.530(c).
C. The WISeR Participant shall maintain the privacy and security of all Model-related information that identifies individual Beneficiaries in accordance with the Health Insurance Portability and Accountability Act ("**HIPAA**") Privacy and Security Rules and all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of PHI by covered entities and their business associates, as well as all other applicable federal and state laws and regulations.

Article V. Functional Requirements

Section 5.1 Functional and Infrastructure Requirements

A. The WISeR Participant shall develop, execute, and maintain a risk management plan that includes:
    1. WISeR Jurisdiction-wide risks, including without limitation risks related to cybersecurity issues;
    2. Periodic assessment, conducted monthly at a minimum, of new risks; and
    3. Mitigation and contingency planning.
B. The WISeR Participant shall provide and use infrastructure to fulfill the requirements of this Agreement.
C. The WISeR Participant shall provide the infrastructure required to integrate and interact with the assigned CMS Virtual Data Center ("**VDC**") and to accomplish services not provided by the VDC to fulfill the requirements of this Agreement.
    1. The WISeR Participant shall work with all Base Function entities, including the VDC, to interface and/or facilitate the receipt or transmission of files, programs or other such products.

2. **Base Functions** are functions provided either by the shared system or the VDC and include interfaces that are part of the base system processing such as the Common Working File (CWF), Comprehensive Error Rate Testing (CERT), Correct Coding Initiative (CCI), BDRD, PECOS, PIMR, Pricer, PULSE, etc.
3. **Non-base/Non-core applications or interfaces** refers to any applications or interfaces that are not part of the base system processing or are not provided or maintained as part of the Medicare Shared Systems (FISS or MCS).
    i. Non-base/non-core applications or interfaces may involve an outside vendor, a Medicare Data Center, or any entity with which the WISeR Participant communicates or shares information through a software application (not including commercial word processing or spreadsheet programs) in processing Medicare claims.
    ii. Examples of non-base/non-core processes include but are not limited to the following:
        a. Print mail;
        b. American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N Transaction Translation Services (via Commercial Off the Shelf (COTS) products);
        c. Workload Management reports;
        d. Scanning Administration;
        e. ICR/OCR Imaging;
        f. Fraud, Waste, or Abuse reporting;
        g. Data Analysis (Easytrieve, SAS extracts, etc.); and
        h. Data files the WISeR Participant routinely receives.

D. The WISeR Participant shall provide translation software that is HIPAA-compliant and strictly adheres to the ASC X12N Technical Report Type 3 (TR3s) for inbound transactions (e.g., ASC X12N claim, ASC X12N 276 claim status request) and outbound transactions (e.g., ASC X12N 835 remittance advice, ASC X123N 277 claim status response, ASC X12N TA1 interchange acknowledgement, ASC X12N 999 implementation acknowledgment, ASC X12N 277 claim acknowledgment).

E. In the event of termination by CMS or the WISeR Participant pursuant to Article XIII, the WISeR Participant shall be required to perform certain closeout activities detailed by CMS in a form and manner and by the date(s) specified by CMS.

Section 5.2 Telecommunications

A. Unless directed to use another connection by CMS, the WISeR Participant shall use only the CMS-supplied telecommunications network to transmit Medicare data to ensure the privacy and security of this protected information for:
    1. Medicare communications between the WISeR Participant and Medicare Administrative Contractor(s), if any;
    2. Communications between the WISeR Participant and subcontractors, if any; and
    3. Communications between the WISeR Participant and CMS.
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.
C. As applicable, the WISeR Participant shall interact with CMS' current enterprise identity access management systems, or any future enterprise identity access management system as directed by CMS, to ensure that the electronic data interchange (EDI) submitter/receiver is an authorized EDI submitter for each transaction.
D. As applicable, the WISeR Participant shall be responsible for the verification/validation of the WISeR Providers and WISeR Suppliers that will be exchanging EDI with the WISeR Participant.

Section 5.3 CMS Audits and Reviews of Software

A. The WISeR Participant shall allow CMS the use of provided software and software documentation, tools, and equipment to conduct audit reviews, tests, and assessments of the WISeR Participant at its facility, its data center and/or in its data cloud.
B. Consistent with Section 5.3.A, the WISeR Participant shall allow CMS use and access to, without limitation, the WISeR Participant's Enhanced Technology, artificial intelligence, machine learning technology, and other similar technologies.

Article VI. Prior Authorization Process

Section 6.1 General

A. The WISeR Participant shall use its Enhanced Technology to review and assess Prior Authorization requests within its assigned WISeR Jurisdiction ("**Prior Authorization Process**").

B. The WISeR Participant must review and assess each Prior Authorization request to ensure that the request meets the following criteria:
    1. Include all documentation necessary to show that the Select Items and Services meet applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The Prior Authorization request is submitted before the Select Items and Services are provided to the WISeR Beneficiary and before the claim is submitted.
C. The WISeR Participant reviews and assesses each expedited Prior Authorization request to ensure that the expedited request meets the following criteria:
    1. Includes all documentation necessary to show that the Select Item or Service meets applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The expedited Prior Authorization request is submitted before the Select Item or Service is provided to the WISeR Beneficiary and before the claim is submitted.
    3. Includes documentation showing that the processing of the Prior Authorization must be expedited due to the WISeR Beneficiary's life, health, or ability to regain maximum function being in serious jeopardy.
D. The WISeR Participant shall evaluate and refine its Prior Authorization Process to ensure accuracy in its Prior Authorization determinations and to prevent harm to Beneficiaries, including WISeR Beneficiaries.
E. The WISeR Participant shall engage in activities such as Navigation Services to reduce clinically inappropriate care and promote clinically appropriate care with its WISeR Providers and WISeR Suppliers in a form and manner and by the date(s) specified by CMS.
F. The WISeR Participant shall report Prior Authorization Process related activities and metrics to CMS through monthly, yearly, and ad hoc reports in a form and manner and by the date(s) specified by CMS.

Section 6.2 Prior Authorization Process and Exemption Status

A. General. 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).
B. Upon receipt of a Prior Authorization, the WISeR Participant shall review the request for compliance with applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act.

1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to the Select Items and Services detailed in Table 1 of Appendix A of this Agreement.
2. The WISeR Participant shall verify that the Prior Authorization is for a Select Item or Service as detailed in Table 1 of Appendix A.
3. The WISeR Participant must further verify that the Prior Authorization request is from a WISeR Provider or WISeR Supplier within the WISeR Jurisdiction.
4. The WISeR Participant shall verify that the requested Select Item or Service would be furnished to an individual that is a WISeR Beneficiary.

C. The WISeR Participant, its WISeR Clinician(s) and its WISeR Clinical Reviewers shall conduct Medical Review of the Prior Authorization, any Resubmissions, render determinations, and communicate decisions to the WISeR Providers, WISeR Suppliers, and WISeR Beneficiaries in accordance with the terms of this Agreement and the applicable requirements detailed in the WISeR Participant Guide.

D. Resubmission. The WISeR Participant shall accept Resubmissions from a WISeR Provider or WISeR Supplier for a Select Item or Service.
1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to each Resubmission; or
2. At the request of the WISeR Provider or WISeR Supplier through its Resubmission, the WISeR Participant shall require its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, to perform peer-to-peer review of the Resubmission. Such peer-to-peer review activities and requirements are detailed in the WISeR Participant Guide and the WISeR Participant acknowledges and agrees that its WISeR Clinicians and WISeR Clinical Reviewers will comply with such requirements.

E. Exemption Status. The WISeR Participant shall provide Exemption Status to a WISeR Provider or WISeR Supplier that has:
1. Submitted the minimum number of Prior Authorization requests for Select Items and Services furnished to WISeR Beneficiaries within the WISeR Jurisdiction as detailed in the WISeR Participant Guide;
2. Has met the CMS threshold percentage of Prior Authorization Provisional Affirmations as detailed in the WISeR Participant Guide; and
3. Met any additional criteria set forth by CMS in the WISeR Participant Guide.

F. Exemption Status List. The WISeR Participant shall retain current and historical lists of WISeR Providers and WISeR Suppliers that have earned Exemption Status.
1. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it has earned Exemption Status and has been added to the Exemption Status list.

i. The WISeR Participant shall specify in its notice to the WISeR Provider or WISeR Supplier the effective date of its Exemption Status, the process for retaining Exemption Status, and provide such other details as described in the WISeR Participant Guide.

2. The WISeR Participant shall provide current and historical Exemption Status lists to CMS in a form and manner and by the date(s) specified by CMS in accordance with the terms of this Agreement and applicable requirements set forth in the WISeR Participant Guide.
3. The WISeR Participant may remove a WISeR Provider or WISeR Supplier from the Exemption Status list if it fails to meet the requirements for Exemption Status as described in the WISeR Participant Guide.
4. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it is removed from the Exemption Status list and such notice shall specify the effective date of removal, the process for re-earning Exemption Status, and provide such other details as described in the WISeR Participant Guide.

Section 6.3 Prior Authorization Determinations

A. Determination Letters.

1. CMS may develop and provide to the WISeR Participant and Model Participants template determination letters.
2. Upon request of the WISeR Participant to CMS, and at the discretion of CMS, the WISeR Participant may create its own template determination letter(s), and such template(s) must be submitted to CMS for review and written approval prior to use and include at a minimum the following information and any other information as specified in the WISeR Participant Guide:
    i. A Unique Tracking Number (UTN);
    ii. For Prior Authorization Non-Affirmation decisions:
        a. A detailed explanation for the decision;
        b. The availability of unlimited resubmissions by the WISeR Provider or WISeR Supplier;
        c. Instructions for how the WISeR Provider or WISeR Supplier may request peer-to-peer review; and
        d. The opportunity to forego the resubmission process, provide one or more of the Select Items and Services, submit the claim for payment and:
            1. The claim will be denied; and
            2. All Medicare appeal rights will be available.
    iii. For re-routed Prior Authorization decisions:

a. Contact information for the WISeR Participant;
b. Instructions to the requesting WISeR Provider and/or WISeR Supplier on how it may choose to submit future Prior Authorization requests for Select Items and Services directly to the WISeR Participant; and
c. Any additional information that CMS may require through written notification to the WISeR Participant.

3. If CMS determines that the template(s) submitted by the WISeR Participant contains misinformation or is otherwise inconsistent with the terms of this Agreement or the WISeR Participant Guide, CMS may reject the template(s) or require the WISeR Participant to amend the template(s) and resubmit such amended template(s) to CMS for review and approval prior to use.

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.

C. Resubmission of Prior Authorization.
1. The WISeR Participant shall issue a Resubmission Determination to the WISeR Provider or WISeR Supplier within 3 Days of the WISeR Participant's receipt of the Prior Authorization resubmission.
2. The WISeR Participant shall ensure the Resubmission Determination is delivered to the WISeR Provider or WISeR Supplier in the same manner it was submitted via postmark, fax, or electronic delivery.

D. Expedited Circumstances. The WISeR Participant may only consider an expedited review of a Prior Authorization request upon receipt of request for expedited review by the WISeR Provider or WISeR Supplier.
1. If the WISeR Participant, in consultation with its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, determines that delays in receipt of a Prior Authorization decision could jeopardize the life, health, or ability to regain maximum function of the WISeR Beneficiary, then the WISeR Participant will process the Prior Authorization under an expedited timeframe, upon request.
i. The WISeR Participant will communicate a determination within 2 business days of receipt of the expedited request.

ii. WISeR Providers and WISeR Suppliers, and their MAC(s) when applicable, are encouraged to use fax, Electronic Submission of Medical Documentation (esMD), or any other CMS approved electronic portal to avoid delays with mailing.

E. Prior Authorization Provisional Affirmation. The WISeR Participant will issue a Prior Authorization Provisional Affirmation of coverage to a WISeR Provider or WISeR Supplier, with a copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and any applicable criteria in the WISeR Participant Guide are met to support the rendering of such item or service to a WISeR Beneficiary.

1. The WISeR Participant's Prior Authorization Provisional Affirmation decision is valid for 120 days from the date the determination was made.

F. Prior Authorization Non-Affirmation.

1. Consistent with Section 3.6.B.2 and Section 3.6.E.2, the WISeR Participant must require its WISeR Clinician(s) and WISeR Clinical Reviewer(s), as applicable, to perform a Medical Review of each Prior Authorization request that may not meet Medicare Coverage Criteria.
    i. The Medical Review of a Prior Authorization request by a WISeR Clinician or WISeR Clinical Reviewer, as applicable, must be performed before the WISeR Participant issues a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier.
2. The WISeR Participant will issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier, with copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and applicable criteria in the WISeR Participant Guide are not met and do not support the rendering of such item or service to a WISeR Beneficiary.
3. The WISeR Participant may issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier for a Select Item or Service via the same method it was requested if the Prior Authorization request contains technical errors or is otherwise insufficient to meet the requirements for Prior Authorization Provisional Affirmation.

G. Appeals. The WISeR Participant acknowledges and agrees that nothing in this Agreement nor in the WISeR Participant Guide shall be construed to limit or otherwise prevent a WISeR Provider, WISeR Supplier, WISeR Beneficiary or Beneficiary from

engaging in the Medicare appeals process permitted by applicable law, regulations, or Medicare program requirements.

Section 6.4 Prior Authorization Non-Affirmation and Resubmissions

A. The WISeR Participant shall provide written notice consistent with Section 6.3.A of this Agreement to the WISeR Provider or WISeR Supplier that the WISeR Provider or WISeR Supplier may resubmit a Prior Authorization upon receipt of a Prior Authorization Non-Affirmation.
B. The WISeR Participant shall provide written notice, consistent with Section 6.3.A, to the WISeR Provider or WISeR Supplier that it may resubmit a Prior Authorization for expedited review consistent with the requirements in Section 6.3.D of this Agreement.
C. The WISeR Participant shall consider all Resubmissions for Prior Authorization received within 120 Days of the Initial Prior Authorization Determination.
D. The WISeR Participant shall review a Resubmission for Prior Authorization received after 120 Days of the Initial Prior Authorization Determination as an Initial Prior Authorization request.

Section 6.5 Pre-Payment Review

A. The WISeR Participant acknowledges that Prior Authorization is not a condition of payment to the WISeR Provider or WISeR Supplier.
B. The WISeR Participant agrees that the WISeR Provider or WISeR Supplier may elect not to submit a Prior Authorization before furnishing one or more of the Select Items and Services to a WISeR Beneficiary.
C. If the WISeR Provider or WISeR Supplier elects not to submit a Prior Authorization for one or more Select Items and Services it furnishes to a WISeR Beneficiary, then the WISeR Participant shall coordinate with the appropriate MAC to subject the claim to Pre-Payment Review consistent with the terms of this Agreement, Sections 6.5.C.1 and 6.5.C.2, and the requirements detailed in the WISeR Participant Guide.
    1. CMS, through its appropriate MAC, will flag claims submitted by the WISeR Provider or WISeR Supplier for Select Items and Services without a Prior Authorization request.
    2. CMS, through its appropriate MAC, will re-route flagged claims to the WISeR Participant for Pre-Payment Review.
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.

Article VII. Quality Performance

Section 7.1 Quality Score

CMS shall use the quality score in determining the WISeR Participant's Aggregate Quality Score ("**AQS**") according to the methodology described in this Article VII and the WISeR Data Reporting Guide.

Section 7.2 Quality Measures

A. General
   1. The WISeR Participant shall complete reporting for all quality measures and for all Prior Authorizations received, Prior Authorization Provisional Affirmations, Prior Authorization Non-Affirmations, and Resubmissions in accordance with the WISeR Data Reporting Guide.
   2. CMS will publish, at least annually, a WISeR Data Reporting Guide, detailing the WISeR quality reporting requirements.
   3. CMS may modify the WISeR Performance Measure Set, or the number of measures that the WISeR Participant must report, or both. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Performance Measure Set at least 30 Days prior to the effective date of the change.
      i. If CMS removes a quality measure from the WISeR Performance Measure Set in advance of a Performance Period, CMS will not use the removed quality measure to evaluate the WISeR Participant, and the WISeR Participant will not be accountable for performance on such quality measures during the relevant Performance Period.

B. WISeR Performance Measure Set
   1. The WISeR Participant shall report all measures to CMS that are listed in the WISeR Performance Measure Set as described in Appendix B to this Agreement and the WISeR Data Reporting Guide. CMS shall use these measures for the purposes of calculating the WISeR Participant's AQS, the monitoring and evaluation of the overall efficiency and accuracy in WISeR, and to evaluate the WISeR Participant's performance during the Model.
   2. CMS will determine what version of specifications will be used for each measure included in the WISeR Performance Measure Set for the applicable Performance Period. CMS will notify the WISeR Participant of the version of specifications that will be used for each measure included in the WISeR Performance Measure Set as early as possible after such information becomes available.

3. The WISeR Participant must report all required measures from the WISeR Performance Measure Set in order to be eligible to earn the WISeR Payment for a Performance Period in accordance with Section 8.3.

C. Quality Measure Reporting
   1. The WISeR Participant must submit all quality measures that are listed in the WISeR Performance Measure Set to CMS during the defined reporting period for quality measures as communicated in the WISeR Data Reporting Guide.
   2. CMS reserves the right to require submission via any other format, including the Fast Healthcare Interoperability Resources ("**FHIR®**") standard, at any time during the Agreement Term without the consent of the WISeR Participant. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the reporting format of measures at least 90 Days prior to the measurement period.
   3. The WISeR Participant shall comply with the requirements described in this Article VII and Appendix B of this Agreement, and the requirements detailed in the WISeR Data Reporting Guide.

Section 7.3 Collection of Data and Purpose

A. Pursuant to 42 C.F.R. § 403.1110(b), the WISeR Participant must collect and report data described in Section 7.2 to CMS for CMS' Model monitoring and evaluation purposes.
B. The WISeR Participant, at CMS' request, will administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
C. CMS reserves the right to administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
D. CMS may require the WISeR Participant to implement surveys of WISeR Providers, WISeR Suppliers, and/or WISeR Beneficiaries in the WISeR Participant's designated WISeR Jurisdiction and report any survey measures included in the WISeR Data Reporting Guide to CMS.

Section 7.4 Quality Performance Scoring

A. CMS will calculate the WISeR Participant's AQS for each Performance Period at the time of Reconciliation.
B. CMS will calculate the AQS based on quality measures specified in the WISeR Data Reporting Guide.

C. CMS will calculate the AQS by totaling the quality points for all quality measures included in the AQS calculation for a given Performance Period and dividing by the maximum quality points available for these included quality measures.
D. CMS may modify the methodology for Quality Performance Scoring and shall notify the WISeR Participant in writing at least 30 Days before the start of the Performance Period in which such change would take effect. Modifications to the Quality Performance Scoring methodology may include, but are not limited to:
    1. Modifications to the set of quality measures included in the AQS;
    2. Modifications to the point values and point distributions for one or more quality measures included in the AQS;
    3. Modifications to the benchmark for one or more quality measures included in the AQS; and
    4. Modifications to the metrics for one or more quality measures included in the AQS.
E. CMS will convert the AQS to a quality multiplier that will be applied to each WISeR payment for the applicable Performance Period, as detailed in the WISeR Data Reporting Guide.

Article VIII. Financial Management and Payment

Section 8.1 General

A. CMS shall make, adjust, settle, and seek repayment of WISeR Payments in accordance with this Article VIII and Article XIII.
B. CMS may unilaterally amend Article VIII and to the extent practicable will issue advance written notice to the WISeR Participant 30 Days before the start of the Performance Period in which the amendment would take effect.

Section 8.2 Financial Management Requirements

A. The WISeR Participant shall promote the fiscal integrity of the Medicare FFS program and be an accountable steward of public funds.
B. The WISeR Participant shall adhere to the CMS Medicare integrity program.

Section 8.3 WISeR Payments

A. General.
    1. CMS pays the WISeR Payment to the WISeR Participant, as set forth in this Article VIII, subject to initial Reconciliation, financial settlement, and recoupment.

2. The WISeR Participant may receive a WISeR Payment for each Pre-Payment Review that results in a denied claim for a Select Item or Service and for each Payable Non-Affirmation.
3. CMS shall not pay the WISeR Participant a WISeR Payment if the WISeR Participant conducts a Prior Authorization or a Pre-Payment Review and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
4. The WISeR Participant owes a WISeR Recoupment and shall remit all WISeR Recoupments to CMS if Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to a WISeR Beneficiary due to the successful appeal of a claim denial.
5. CMS calculates the WISeR Payment as set forth in Section 8.3.D.

B. Calculation of Regional Benchmark.

1. For each Performance Period and each Locality within the WISeR Participant's designated WISeR Jurisdiction, CMS determines a Locality-specific Regional Benchmark for each of the Select Items and Services identified in Table 1 of Appendix A of this Agreement.
2. Except as specified in Section 8.3.B.3, CMS calculates the Regional Benchmark by:
    i. Identifying all claims that were submitted within the state that include the applicable Locality, were submitted by a WISeR Provider or a WISeR Supplier, include the applicable Select Item or Service, and have a date of service in the 12 months preceding the start of the applicable Performance Period;
    ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the Locality and applicable to the calendar year that includes the Performance Period being reconciled; and
    iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.
3. In the event change in law or Medicare policy changes effective during the Agreement Performance Period and applicable to a Select Item(s) or Service(s), CMS may, at its sole discretion, calculate the Regional Benchmark for the applicable Select Item or Service for one or more Performance Periods by:

i. Identifying all claims for the Select Item or Service that were submitted by Medicare-enrolled providers or suppliers within the WISeR Participant's designated MAC Jurisdiction with a date of service that is:
    a. No earlier than the effective date of the applicable legislation or Medicare policy change;
    b. No earlier than 9 months before the start of the applicable Performance Period; and
    c. No later than the final Day of the applicable Performance Period; and
ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the calendar year that includes the Performance Period being reconciled; and
iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.

4. When calculating the average claim-level payment as set forth in Section 8.3.B.2.iii and Section 8.3.B.3.iii, CMS may exclude payments for certain items or services billed on the same claim as the applicable Select Item or Service. CMS will maintain a list of such exclusions in the WISeR Participant Guide.

C. WISeR Discount. CMS calculates the WISeR Discount separately by state for each of the Select Items and Services as the percentage of claims with a medical necessity denial among all claims submitted by WISeR Providers and WISeR Suppliers within the state for that Select Item or Service with a date of service in 12 months preceding the start of the Model Performance Period. CMS may modify the WISeR Discount, including the dates of service for claims included in the calculation of the WISeR Discount, and to the extent practicable will provide 30 Days' advance written notice before the effective date of such modifications.

D. WISeR Payment. The WISeR Participant may earn a WISeR Payment for each Payable Non-Affirmation and for each Pre-Payment Review resulting in a denied claim for a Select Item or Service.

1. CMS calculates the WISeR Payment for each Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state;
    ii. Multiplying by the WISeR payment rate of 25 percent; and
    iii. Applying the quality adjustment determined by the WISeR Participant's AQS.

2. CMS calculates the WISeR Payment for each Pre-Payment Review resulting in a denied claim for a Select Item or Service by:
    i. Calculating the amount billed on the claim, less any approved payments for services other than the Select Item or Service that were billed on the same claim and less any denied payments billed on the same claim for one or more excluded service(s) noted in the WISeR Participant Guide;
    ii. Reducing the amount set forth in Section 8.3.D.2.i by the WISeR Discount applicable to the Select Item or Service and state;
    iii. Multiplying by the WISeR payment rate of 25 percent; and
    iv. Applying the quality adjustment determined by the WISeR Participant's AQS.

E. WISeR Recoupment. CMS will recoup a WISeR Recoupment from the WISeR Participant if CMS pays the WISeR Participant a WISeR Payment and Medicare subsequently pays the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
    1. The amount of the WISeR Recoupment will equal the amount of the previous WISeR Payment that CMS paid to the WISeR Participant for the applicable Payable Non-Affirmation or Pre-Payment Review.
    2. CMS will identify any WISeR Recoupments on a quarterly basis.
    3. To the extent possible, CMS will net any WISeR Recoupments against the total of WISeR Payments for a future Performance Period as set forth in Section 8.5.
    4. If CMS cannot collect WISeR Recoupments for claims appeals adjudicated after the Reconciliation of the final Performance Period under the Agreement or any other CMS program or initiative, CMS shall issue a demand letter to the WISeR Participant and the WISeR Participant shall pay CMS the amount owed within 30 Days of the date of demand letter.
    5. If CMS does not timely receive payment in full, the remaining amount owed will be considered a delinquent debt subject to the provisions of Section 8.8.D.

Section 8.4 Advance WISeR Payment

A. At the sole discretion of CMS, CMS may pay the WISeR Participant an Advance WISeR Payment prior to completing Reconciliation for a given Performance Period.

B. Eligibility Criteria.
    1. At the sole discretion of CMS, CMS may provide an Advance WISeR Payment to the WISeR Participant for an applicable Performance Period.

2. The WISeR Participant may be eligible to receive an Advance WISeR Payment during an applicable Performance Year if:
    i. CMS has notified the WISeR Participant of the availability of an Advance WISeR Payment for a specified Performance Period;
    ii. CMS has detailed specific data elements that the WISeR Participant must report to CMS in a form and manner and by the date(s) specified by CMS ("**Preliminary Data**");
    iii. The WISeR Participant timely reports the required data elements to CMS; and
    iv. CMS has approved the WISeR Participant's reported data elements and eligibility for an Advance WISeR Payment for the specified Performance Period.
3. If CMS determines that the WISeR Participant has not timely or accurately reported all required data elements, then CMS may deem the WISeR Participant ineligible for an Advance WISeR Payment for the applicable Performance Period.
4. If CMS has approved the WISeR Participant's eligibility for an Advance WISeR Payment for the applicable Performance Period, then CMS calculates the Advance WISeR Payment as set forth in Section 8.4.D.
5. In applicable Performance Periods, CMS will calculate the Advance WISeR Payment no earlier than the first Day after the end of the Performance Period.

C. Adjustments to Future WISeR Payment(s). If CMS determines that the WISeR Participant is eligible to receive an Advance WISeR Payment, CMS will net the amount of the Advance WISeR Payment against future WISeR Payments, including as applicable:
    1. Any WISeR Payments that CMS calculates for the applicable Performance Period during Reconciliation; and
    2. Any WISeR Payments that CMS calculates for subsequent Performance Periods.

D. Calculation of an Advance WISeR Payment. CMS calculates an Advance WISeR Payment using Preliminary Data for the Performance Period submitted by the WISeR Participant as set forth in Section 8.4.B. CMS calculates the Advance WISeR Payment for the applicable Performance Period as follows:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will provisionally determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will provisionally identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will estimate the WISeR Payment for each provisionally identified Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state; and
    ii. Multiplying by the WISeR payment rate of 25 percent.
5. CMS will estimate the WISeR Payment for each provisionally identified Pre-Payment Review qualifying for a WISeR Payment by:
    i. Calculating the amount billed on the claim, less any payments for services other than the Select Item or Service that were billed on the same claim;
    ii. Reducing this amount by the WISeR Discount applicable to the Select Item or Service and state; and
    iii. Multiplying by the WISeR payment rate of 25 percent.
6. CMS will total the estimated WISeR Payments as set forth in Section 8.4.E.4 and Section 8.4.E.5 and multiply this total by 50 percent to obtain the Advance WISeR Payment.

Section 8.5 Reconciliation Process

A. CMS will perform Reconciliation for a Performance Period by completing the following calculations:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will calculate the AQS for the WISeR Participant as set forth in Section 7.4 and in the WISeR Data Reporting Guide.
5. CMS will calculate the WISeR Payment as set forth in Section 8.3.D.
6. CMS will identify any pending WISeR Recoupments as set forth in Section 8.3.E. and will net these WISeR Recoupments against the total of WISeR Payments for the Performance Period.

B. CMS will perform Reconciliation for a Performance Period no earlier than the Day after the last Day on which a Resubmission for a Prior Authorization may be submitted, except as otherwise provided in Section 8.5.C.
    1. After calculating the WISeR Payment amount for the Reconciliation for a Performance Period, CMS will compare this amount against any WISeR Payment that was calculated in the initial Reconciliation for the same Performance Period and already paid or recouped by CMS, to determine the net amount of any WISeR Payment still owed for that Performance Period.
    2. If CMS issues a Reconciliation Report detailing the results of the Reconciliation, as described in Section 8.6, simultaneously with the Reconciliation Report detailing the results of the initial Reconciliation for a subsequent Performance Period, CMS may net any WISeR Payment amount specified in the Reconciliation Report for the initial Reconciliation against the net WISeR Payment amount that CMS calculates for the Reconciliation in accordance with Section 8.5.B.1.
C. If the Agreement or Agreement Performance Period is terminated pursuant to Article XIII, CMS shall conduct an initial Reconciliation and a final financial settlement, in accordance with Section 8.9, for the WISeR Participant's final Performance Period, which shall include all Prior Authorizations and Pre-Payment Reviews conducted by the WISeR Participant through the effective date of termination or expiration of this Agreement.

Section 8.6 Reconciliation Report

A. After performing Reconciliation for a given Performance Period as set forth in Section 8.5, CMS shall issue a Reconciliation Report to the WISeR Participant.
B. The Reconciliation Report will set forth the calculation of the WISeR Participant's Regional Benchmarks, AQS, Payable Non-Affirmations, and any applicable WISeR Payment for that Performance Period. In accordance with Section 8.5, the Reconciliation Report for any subsequent Reconciliation for a given Performance Period will also set forth any necessary adjustments to the WISeR Payment amount, if applicable, calculated in the initial Reconciliation for that Performance Period.
C. CMS shall make reasonable efforts to issue the initial Reconciliation Report for each Performance Period within 6 months after the last Day of that Performance Period.
D. Unless CMS receives a timely calculation error notice in accordance with Section 8.7, the Reconciliation Report shall be deemed final 30 Days from the date of issuance by CMS.

Section 8.7 Reconciliation Report Calculation Error

A. The WISeR Participant may contest a Reconciliation Report in accordance with this Section 8.7.
B. The WISeR Participant shall have 30 Days from the date the Reconciliation Report is issued to provide written notice to CMS of an error in the calculation of the WISeR Payment specified in that Reconciliation Report. The calculation error notice must contain a detailed, written explanation of the basis for the calculation error, including any supporting documentation.
C. If CMS receives a timely calculation error notice, CMS shall issue a written determination within 30 Days to either confirm or revise the calculation error, although CMS may extend the deadline for its determination upon written notice to the WISeR Participant.
    1. If CMS issues a written determination that the amount was calculated in error, CMS shall issue a revised Reconciliation Report, which is final on the date of issuance. The WISeR Participant may dispute the revised Reconciliation Report in accordance with Article XIV if the dispute is not precluded from review.
    2. If CMS issues a written determination that the amount is correct, the Reconciliation Report is final on the date the determination is issued.
    3. The WISeR Participant may dispute the determination issued by CMS in accordance with Article XIV if the dispute is not precluded from review.

D. If the WISeR Participant does not submit a timely calculation error notice to CMS in accordance with this Section 8.7, the WISeR Participant is precluded from later contesting the WISeR Payment amounts specified in that Reconciliation Report.
E. If as a result of any later inspection, evaluation, investigation, or audit, it is determined that any WISeR Payment amounts have been calculated in error, CMS may adjust such amounts, issue a revised Reconciliation Report, and make or demand payment of any additional amounts owed in accordance with this Section 8.7.

Section 8.8 Payment of Amounts Owed

A. CMS will pay the WISeR Participant any WISeR Payment amount owed to the WISeR Participant that is specified in Reconciliation Report within 30 Days after the date the Reconciliation Report is deemed final, as set forth in this Section 8.8.
B. CMS shall issue to the WISeR Participant a demand letter for any WISeR Payment owed pursuant to a Reconciliation Report that has been deemed final. The demand letter will be sent to the WISeR Participant at the address specified on the most recent Electronic Funds Transfer Authorization Agreement submitted by the WISeR Participant in accordance with Section 3.1.E.
C. The WISeR Participant shall pay any WISeR Payment amount owed to CMS within 30 Days of the date of a demand letter.
D. Delinquent Debt
    i. If the WISeR Participant fails to pay amounts due to CMS in full by the date specified in any demand letter, CMS shall assess simple interest on the unpaid balance at the rate applicable to other Medicare debts under 42 C.F.R. § 405.378. Interest shall be calculated in 30-Day periods and shall be assessed for each 30-Day period that payment is not made in full. Any payments received by CMS first shall be applied toward accrued interest and then to any outstanding principal balance due.
    ii. If CMS does not receive payment in full by the date the payment is due, CMS shall invoke all legal means to collect the debt and will use any applicable debt collection tools, including referral of the debt to the United States Department of Treasury, pursuant to 31 U.S.C. § 3711(g).

Section 8.9 Financial Settlement Report

A. Upon the expiration or termination of the Agreement Performance Period, CMS will issue to the WISeR Participant a financial settlement report that sets forth the amount of any WISeR Recoupments that the WISeR Participant must repay to CMS

or the amount of any WISeR Payment that CMS must make to the WISeR Participant, in accordance with this Agreement ("**Financial Settlement Report**").

B. If the Financial Settlement Report indicates that CMS owes the WISeR Participant additional payment, CMS shall make such payment within 30 Days after the Financial Settlement Report is deemed final.

C. If the Financial Settlement Report indicates that the WISeR Participant owes CMS a WISeR Recoupment, CMS will issue the WISeR Participant a demand letter for such monies owed to CMS. The WISeR Participant shall pay CMS any WISeR Recoupment within 30 Days of the date of a demand letter. If CMS does not timely receive payment in full, the remaining monies owed shall be considered a delinquent debt in accordance with Section 8.8.D.

Section 8.10 Extreme and Uncontrollable Circumstances

A. CMS may, in its sole discretion, provide Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers if the WISeR Providers and WISeR Suppliers:

   1. Are located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act; and
   2. Are located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

B. CMS has the sole discretion to determine the time period during which Prior Authorization flexibilities are provided to the WISeR Participant's WISeR Providers and WISeR Suppliers.

C. In the event that CMS provides Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers, CMS will provide written notice to the WISeR Participant of any impact such flexibilities have on the terms of this Agreement.

D. The WISeR Participant shall identify, develop, and coordinate prevention, response, and recovery procedures to ensure the availability of critical resources, and facilitate the continuity of essential business functions in an emergency situation, including natural disasters, manmade incidents, catastrophic emergencies, and public health emergencies ("**Continuity of Operations (COOP) Plan**").

E. The WISeR Participant shall maintain a COOP Plan that addresses protection of the physical infrastructure and business continuity (with or without system availability) of mission essential functions, to include without limitation the Prior Authorization Process, and communicating to WISeR Providers and WISeR Suppliers.

F. The WISeR Participant's COOP Plan shall include an information technology (IT) contingency and disaster recovery plan that addresses identified IT risks and vulnerabilities including, without limitation, cybersecurity issues.

Article IX. Business Associate Agreement, Data Sharing and Reports

Section 9.1 Business Associate Agreement

A. The WISeR Participant agrees to execute a valid Business Associate Agreement ("**BAA**") with CMS no later than 5 Days after the Effective Date of this Agreement.
B. If the WISeR Participant fails to execute a valid BAA pursuant to Section 9.1.A by the date specified by CMS, CMS will terminate the Agreement or the Agreement Performance Period or both in accordance with Section 13.3.
C. The WISeR Participant's BAA with CMS shall be active and valid for the duration of the Agreement Term.
D. The WISeR Participant shall comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") Privacy, Security, and Breach Notification Rules (45 C.F.R. Part 160 & Part 164, subparts A through E) ("**HIPAA Rules**").
E. The parties agree that the terms and conditions of the executed BAA between the WISeR Participant and CMS are hereby incorporated by reference into this Agreement as if fully set forth herein.

Section 9.2 Data Sharing and Reports – General

A. The WISeR Participant shall implement information technology (IT) systems security controls in order to maintain the confidentiality, integrity, and availability of the Medicare systems operations in the event of computer incidents or physical disasters.
B. Subject to the limitations discussed in this Agreement, and in accordance with applicable law, including HIPAA and the regulations in 42 C.F.R. Part 2, in advance of the Start Date of this Agreement, during the Agreement Performance Period, and any other time deemed necessary by CMS, CMS will offer the WISeR Participant an opportunity to request certain Beneficiary-identifiable data and reports in accordance with the terms and conditions set forth in this Agreement and in the BAA.
C. The Beneficiary-identifiable data available for request are described in Section 9.3 of this Agreement and in the BAA between CMS and the WISeR Participant.
D. Consistent with 42 C.F.R. § 403.1110(b), the WISeR Participant shall report data metrics for monitoring and evaluation purposes related to the WISeR Participant's Prior Authorization Process that include without limitation:

1. The total number of Prior Authorizations received during the data reporting period with a detailed description of:
    i. The number of Prior Authorization Provisional Affirmations during the data reporting period; and
    ii. The number of Prior Authorization Non-Affirmations during the data reportion period; and
2. The time (e.g., Days, weeks, hours, etc.) taken for the WISeR Participant's Prior Authorization Process to reach a determination;
    i. The total number of Resubmissions for each Prior Authorization received during the data reporting window or for a previous data reporting window;
    ii. The number of reversals of the Initial Prior Authorization Determination.

Section 9.3 Provision of Certain Beneficiary-Identifiable Claims Data

A. At CMS' sole discretion based on CMS' available resources, the limitations in this Agreement, the limitations in the BAA, and applicable law, CMS and the WISeR Participant may share certain Beneficiary-identifiable data for Beneficiaries in the WISeR Jurisdiction subject to the Prior Authorization Process.
B. The Beneficiary-identifiable data includes the data and reports described in this Section 9.3.B.
    1. Detailed Beneficiary Claims Data. These data will include individual Beneficiary-identifiable Medicare FFS claims data for Select Items and Services provided to Beneficiaries within the WISeR Jurisdiction. This includes without limitation data on Medicare FFS expenditures and utilization, and Prior Authorization Process metrics (e.g., timing, Prior Authorization request determinations, Resubmissions of Prior Authorizations, etc.).
    2. Quality Performance Scoring Data. These data will include Beneficiary-identifiable data and quality performance data specific to the Prior Authorization Process.
C. The parties mutually agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by CMS.
D. The parties further agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by the WISeR Participant as it relates to the Prior Authorization Process.

E. The WISeR Participant represents, and in furnishing the data files specified in Section 9.3.B of this Agreement and the BAA CMS relies upon such representation, that such data files will be used solely for the purpose of carrying out the provisions of this Agreement to improve the efficiency and accuracy of Prior Authorizations, quality improvement activities, reducing health care costs for the Medicare FFS program without causing harm to Beneficiaries, identifying or reducing fraud, waste, and abuse in Medicare FFS, and such other purposes described int his Agreement. The WISeR Participant agrees not to disclosure, use, or reuse the data excepts as specified in this Agreement, the BAA, or except as CMS shall authorize in writing or as otherwise required by law. The WISeR Participant further agrees not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement and the BAA.

F. Information derived from the CMS data specified in Section 9.3.B of this Agreement and in the BAA may be shared and used within the legal confines of the WISeR Participant and its WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers and WISeR Suppliers in a manner consistent with the provisions of this Agreement and the BAA to improve the Prior Authorization Process and Beneficiary care.

G. The WISeR Participant may reuse original or derivative data without prior written authorization from CMS for quality improvement activities relating to improving health or reducing health care costs through the Prior Authorization Process, but shall not disseminate (unless required by law) any individually identifiable original or derived information from the data specified in Section 9.3.B of this Agreement to anyone who is not a HIPAA Covered Entity, a HIPAA Business Associate, a WISeR Clinician or WISeR Clinical Reviewer performing activities related to this Model, or a WISeR Provider or WISeR Supplier in treatment relationship with the subject WISeR Beneficiary. When using or disclosing PHI or personally identifiable information ("**PII**"), obtained from data specified in Section 9.3.B, the WISeR Participant must make "reasonable efforts to limit" the information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure, or request.

H. The WISeR Participant shall establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget ("**OMB**") in OMB Circular No. A-130, Appendix I – Responsibilities for Protecting and Managing Federal Information Resources (https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A130/a130revised.pdf) as well as Federal Information Processing Standard 200 entitled

"Minimum Security Requirement for Federal Information and Information Systems" (http:// (http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf); and, NIST Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" (http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf). The WISeR Participant acknowledges that the use of unsecured telecommunications, including the Internet, to transmit directly or indirectly identifiable information from the files specified in Section 9.2.B or any such derivative data files is strictly prohibited.

I. The WISeR Participant shall grant access to the data and/or the facility(ies) in which the data is maintained to the authorized representatives of CMS or Office of Inspector General of the Department of Health and Human Services ("**OIG**") for the purpose of inspecting to confirm compliance with the terms of this Agreement and the BAA.

J. The WISeR Participant agrees that any use of CMS data in the creation of any document concerning the purpose specified in this section must adhere to CMS' current cell size suppression policy. The policy stipulates that no cell (e.g., patients, services) representing 10 or fewer Beneficiaries may be displayed. Also, no percentages or other mathematical formulas may be used if they result in the display of a cell representing 10 or fewer Beneficiaries. A cell that represents or uses percentages or other mathematical formulas to represent zero Beneficiaries must be displayed.

Article X. Participation in Evaluation, Shared Learning Activities, and Site Visits

Section 10.1 Evaluation Requirement

A. General. The WISeR Participant shall participate and cooperate in any independent evaluation activities conducted by or on behalf of CMS aimed at assessing the impact of the Model on the goals of improving quality of care and reducing fraud, waste, and abuse expenditures for the Medicare program. The WISeR Participant shall require its WISeR Clinicians and WISeR Clinical Reviewers to participate and cooperate in any such independent evaluation activities conducted by or on behalf of CMS. Termination or expiration of this Agreement shall not affect the right of CMS to evaluate WISeR.

B. Primary Data. In its evaluation activities, CMS or its designee(s) may collect qualitative and quantitative data. These data may include, but are not limited to the following sources:

1. Site visits with the WISeR Participant;
2. Surveys or interviews with WISeR Providers and WISeR Suppliers;
3. Surveys or interviews with Beneficiaries and their caregivers;
4. Focus groups of WISeR Providers and WISeR Suppliers;
5. Focus groups of Beneficiaries and their caregivers;
6. Interviews with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
7. Focus groups with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
8. Direct observation of WISeR Provider and/or WISeR Supplier interactions with the WISeR Participant and its staff, and other activities related to the WISeR Participant's participation in the Model;
9. Review of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates; and
10. Surveys.

C. Secondary Data. In its evaluation activities, CMS may use data or information submitted by the WISeR Participant as well as claims submitted to CMS for Select Items and Services furnished to Beneficiaries. These data may include, but are not limited to:
    1. Claims data;
    2. Survey data from Patient Experience surveys;
    3. Medical records;
    4. Clinical data;
    5. Monitoring data (e.g., audit results, etc.); and
    6. Quality and clinical data submitted to CMS.
D. Reporting Requirements. CMS may add or modify evaluation-related reporting requirements during the Agreement Term. CMS will notify the WISeR Participant of any additions or modifications as soon as practicable or at least 30 Days prior to the Day on which such change would take effect.

Section 10.2 Shared Learning Activities

A. The WISeR Participant shall participate in CMS-sponsored learning activities designed to drive improvement and foster innovations in using technology-assisted decision-making through sharing best practices or new knowledge that emerges from participation in the Model.
B. The WISeR Participant shall actively engage in a variety of learning events, learning communities, and sharing promising tools and ideas, as well as their lessons learned.

Section 10.3 Site Visits

A. The WISeR Participant shall cooperate and require its staff to cooperate in any site visits conducted by or on behalf of CMS.
B. CMS or its designee(s) shall, to the extent practicable, schedule any site visits to the WISeR Participant no fewer than 15 Days in advance. To the extent practicable, CMS will attempt to accommodate the WISeR Participant's request for particular dates in scheduling site visits. However, the WISeR Participant may not request a date that is more than 60 Days after the date of the initial site visit notice from CMS.
C. The WISeR Participant shall ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during the site visit.
D. Notwithstanding the foregoing, CMS or its designee(s) may perform unannounced site visits at any of the WISeR Participant's office locations at any time to investigate concerns or other program integrity issues.
E. Nothing in this Agreement shall be construed to limit or otherwise prevent CMS from performing site visits permitted by applicable law or regulations.

Section 10.4 Rights in Data and Intellectual Property

A. CMS may use any data obtained pursuant to the Model to evaluate the Model and to disseminate quantitative results and successful care management techniques to other providers and suppliers and to the public. Data to be disseminated may include results of WISeR Provider and WISeR Supplier surveys, results of patient experience of care and quality of life surveys as well as measures based upon claims, medical records, and other data sources. The WISeR Participant will be permitted to comment on evaluation reports when the WISeR Participant has been specifically cited to ensure factual accuracy but may not edit conclusions or control the dissemination of reports.
B. The parties agree that by participating in the Model, the WISeR Participant grants to CMS and its designees a limited, royalty-free, worldwide, non-sublicensable, non-exclusive license on a warranty-free basis during the term of this Agreement (and for any agreed to extension thereof) in, to and under all intellectual property and information technology owned or licensable (without the consent of, or payment to, any third party) by the WISeR Participant or any of its affiliates, solely for CMS or any of its designees or affiliates to receive and use such information technology.
C. Notwithstanding any other provision in the Agreement, the parties agree that any intellectual property or information technology developed as a result of the collaborative activity under the terms of this Agreement and the requirements associated with this Model will be dealt with by appropriate written agreements

D. Notwithstanding any other provision in the Agreement, all proprietary trade secret information and technology of the WISeR Participant that existed prior to the Effective Date of this Agreement is and shall remain the sole property of the WISeR Participant, and, except as required by federal law, shall not be released by CMS without express written consent. The regulation at 48 C.F.R. § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into the Agreement. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property right or other rights to the WISeR Participant's proprietary information or technology.

E. If the WISeR Participant maintains any information that should not be publicly disclosed because the WISeR Participant considers such information to be proprietary and confidential, the WISeR Participant acknowledges that it may submit to CMS a form, using either the template attached as Appendix C, or a form substantially the same as Appendix C, identifying specific examples of information the WISeR Participant considers to be proprietary and confidential. The WISeR Participant must notify CMS, in a form and manner to be specified by CMS, of any updates to this form. If the WISeR Participant does not submit such a form, the WISeR Participant will be deemed to have confirmed that it has no information it considers proprietary and confidential.

Section 10.5 WISeR Participant Public Release of Information

A. The WISeR Participant shall obtain prior approval from CMS during the Agreement Term and for 6 months thereafter for the publication or release of any press release, external report or statistical/analytical material that materially and substantially references the WISeR Participant's participation in the Model. External reports and statistical/analytical material may include but are not limited to papers, articles, professional publications, speeches, and testimony.

B. All external reports and statistical/analytical material that are subject to this Section 10.5 must include the following statement on the first page: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

Article XI. Compliance and Oversight

Section 11.1 WISeR Participant Compliance Plan

A. The WISeR Participant shall have a compliance plan that includes at least the following elements:

1. A designated compliance official or individual who is not legal counsel to the WISeR Participant and reports directly to the WISeR Participant's governing body;
2. Mechanisms for identifying and addressing compliance problems related to the WISeR Participant's operations and performance;
3. A method for employees or contractors of the WISeR Participant performing functions or services related to this Model to anonymously report suspected problems related to the WISeR Participant's compliance official;
4. Compliance training for the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers; and
5. A requirement for the WISeR Participant to report probable violations of law to an appropriate law enforcement agency.

B. The WISeR Participant shall ensure that its compliance plan is in compliance with all applicable laws and regulations. The WISeR Participant shall periodically update its compliance plan to reflect changes in those laws and regulations.

Section 11.2 CMS Monitoring and Oversight Activities

A. CMS shall conduct monitoring activities to assess compliance by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers with the terms of this Agreement. Such monitoring activities may include, but are not limited to:
   1. Claims analyses to identify fraudulent behavior or program integrity risks such as efforts to manipulate Prior Authorization Process accuracy and efficiency;
   2. Claims and appeals data to identify fraudulent behavior or program integrity risks, including data between the WISeR Participant and any MAC;
   3. Review of documents from the WISeR Participant, WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers, and WISeR Suppliers, including surveys and questionnaires;
   4. Review and audits of the WISeR Participant's Enhanced Technology, including without limitation, reliance on artificial intelligence, machine learning capabilities, and its impact on the timing and accuracy of Prior Authorization determinations, denial rates, affirmation rates, resubmission rates, and other data related to such Enhanced Technology;
   5. Review and audits of the WISeR Participant's Pre-Payment Review processes performed by its WISeR Clinicians and WISeR Clinical Reviewers, and the impact on the timing and accuracy of Pre-Payment Review determinations, denial rates, affirmation rates, resubmission rates, and other data related to such reviews;
   6. Interviews with Beneficiaries and their caregivers;

7. Audits of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant;
8. Audits of data related to Pre-Payment Review, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant; and
9. Site visits to the WISeR Participant.

B. In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including, without limitation, all Medicare claims submitted for items and/or services furnished to Beneficiaries.

C. In conducting monitoring and oversight activities, CMS or its designee(s) may use any relevant data or information including, without limitation, all Prior Authorization requests, Pre-Payment Review activities, determinations, and resubmissions submitted for items and/or services furnished to Beneficiaries.

D. Nothing in this Agreement limits or otherwise prevents CMS from monitoring the WISeR Participant for compliance as permitted by applicable law or regulations.

E. CMS may conduct monitoring activities pursuant to this Article XI for up to two calendar years after the effective date of termination or expiration of this Agreement.

Section 11.3 Compliance with Monitoring and Oversight Activities

A. The WISeR Participant shall cooperate with, and require its WISeR Clinicians and WISeR Clinical Reviewers to cooperate with, all CMS monitoring and oversight requests and activities.

B. The WISeR Participant shall ensure it has sufficient access to all records, data, and information necessary to comply with the monitoring activities described in this Agreement. As necessary, the WISeR Participant shall request this information from any WISeR Clinician, or any WISeR Clinical Reviewer, or individual performing functions or providing services related to WISeR.

Section 11.4 Compliance with Laws

A. Agreement to Comply

1. The WISeR Participant shall comply with, and shall require all WISeR Clinicians and WISeR Clinical Reviewers to comply with, the applicable terms of the Agreement and all applicable statutes, regulations, and guidance, including without limitation: (a) federal criminal laws; (b) the Social Security Act (Public Law 74-271); (c) Title XVIII of the Act; (d) the False Claims Act (31 U.S.C. § 3729 et seq.); (e) the antikickback statute (42 U.S.C. § 1320a-7b(b)); (f) the civil monetary penalties law (42 U.S.C. § 1320a-7a); (g) the federal

physician self-referral law (42 U.S.C. § 1395nn); and (h) any applicable State laws.

2. This Agreement does not waive any obligation of the WISeR Participant to comply with the terms of any other CMS contract, agreement, model, or demonstration.

B. Reservation of Rights

1. Nothing contained in this Agreement or in the application process for WISeR constitutes a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS Office of the Inspector General, or CMS of any right to institute any proceeding or action for violations of any statutes, rules, or regulations administered by the government, or to prevent or limit the rights of the government to obtain relief under any other federal statutes or regulations, or on account of any violation of the Agreement or any other provision of law. This Agreement does not bind any government agency except CMS and the Agreement binds CMS only to the extent provided in this Agreement.
2. The failure by CMS to require performance of any provision of this Agreement does not affect CMS' right to require performance at any time thereafter, nor does a waiver of any breach or default of the Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

C. Office of Inspector General of the Department of Health and Human Services (OIG) Authority. None of the provisions of this Agreement limit or restrict the OIG's authority to audit, evaluate, investigate, or inspect the WISeR Participant or its WISeR Clinicians or its WISeR Clinical Reviewers.

D. Other Government Authority. None of the provisions of this Agreement limit or restrict any other government authority that is permitted by law to audit, evaluate, investigate, or inspect the WISeR Participant.

Section 11.5 Applicable Statutes, Regulations, Manuals, and Documents

In addition to all referenced statutes, regulations, manuals, and documents, the following statutes, regulations, manuals, and documents apply to this Agreement and are hereby incorporated by reference.

A. Financial management and internal controls (e.g., the Federal Managers' Financial Integrity Act of 1982 (FMFIA), the Chief Financial Officers' Act of 1990, etc.);
B. Federal Information Security Management Act of 2014 (FISMA);
C. Privacy and information technology requirements (Privacy Act of 1974, Information Technology Management Reform Act of 1996);

D. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191);
E. Rehabilitation Act of 1973 (including section 508, Accessibility Standards);
F. Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248);
G. Administrative Simplification Compliance Act of 2002 (Public Law 107-105);
H. Benefit Improvement and Protection Act of 2000 (Public Law 106-554);
I. Executive Order 13410, to the extent practicable, Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs;

Medicare manuals (e.g., internet only manuals – IOMs) to administer CMS programs. In the event of any conflict, this Agreement shall have precedence over the IOMs located at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index;

Article XII. Audits and Record Retention

Section 12.1 Right to Audit and Inspect

The WISeR Participant agrees that the government (including CMS, HHS, and the Comptroller General or their designees) has the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the WISeR Participant that pertain to the following:

A. The WISeR Participant's compliance with the terms of this Agreement, including provisions that require the WISeR Participant to impose duties or requirements on its WISeR Clinicians and its WISeR Clinical Reviewers;
B. Whether the WISeR Clinicians and WISeR Clinical Reviewers complied with the duties and requirements imposed on them by the WISeR Participant pursuant to the terms of this Agreement;
C. The quality of services performed under this Agreement;
D. Any activity by the WISeR Participant that may pose a potential risk of harm to Beneficiaries or a vulnerability to the integrity of the Model test;
E. The WISeR Participant's right to WISeR Payments;
F. The ability of the WISeR Participant to repay amounts owed to CMS under this Agreement;
G. The WISeR Participant's financial arrangements.

Section 12.2 Maintenance of Records

The WISeR Participant shall maintain and shall give the government (including CMS, HHS, and the Comptroller General or their designees) access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs,

quality performance measures, and financial arrangements) sufficient to enable the audit, evaluation, inspection, or investigation of the Model, including the subjects identified in Section 11.2. The WISeR Participant shall maintain such books, contracts, records, documents, and other evidence for a period of six years from the expiration or termination of this Agreement or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:

A. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the WISeR Participant at least 30 Days before expiration of the six-year period described above; or
B. There has been a termination, dispute, or allegation of fraud or similar fault against the WISeR Participant in which case the records shall be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

Article XIII. Remedial Action and Termination

Section 13.1 Grounds for Remedial Action

A. CMS may take remedial action against the WISeR Participant if CMS determines that the WISeR Participant:
    1. Has failed to comply with any applicable term of the Agreement or any Medicare program requirement, rule, or regulation;
    2. Has failed to comply with the American with Disabilities Act of 1990, 42 U.S.C. § 12101 *et seq*. (1990);
    3. Has failed to comply with the WISeR Participant's Corrective Action Plan (CAP), the monitoring or auditing plan, or both, developed by CMS for the WISeR Participant, or other remedial action imposed by CMS, if applicable;
    4. Has taken any action that threatens the health or safety of a Beneficiary, including a WISeR Beneficiary;
    5. Has failed to rectify deficiencies following any remedial action;
    6. Has undergone a Change in Control that renders it ineligible for participation in the Model or presents a program integrity risk;
    7. Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model or any requirement of the Medicare program;
    8. Has failed to pay amounts owed to CMS by the date specified in a demand letter;
    9. Has failed to pay a WISeR Recoupment;

10. Has a conflict of interest; or
11. Poses significant program integrity risks, including but not limited to:
    i. Is subject to sanctions or other actions of a federal, state, or local government agency;
    ii. Is subject to investigation or action by HHS (including, but not limited to OIG and CMS) or the Department of Justice due to an allegation of fraud or similar misconduct, including but not limited to being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

Section 13.2 Types of Remedial Action

A. If grounds for remedial action exist, CMS may take one or more of the following actions:
    1. Notify the WISeR Participant of the violation;
    2. Require the WISeR Participant to provide additional information to CMS or its designees;
    3. Conduct site visits, interview WISeR Providers and/or WISeR Suppliers, interview Beneficiaries, or take other actions to gather information;
    4. Place the WISeR Participant on a monitoring and/or auditing plan developed by CMS;
    5. Require the WISeR Participant to not use a WISeR Clinician or WISeR Clinical Reviewer for Medical Review, immediately or within a timeframe specified by CMS;
    6. Withhold, deny, or recoup WISeR Payments;
    7. Withhold, deny, or recoup any Advance WISeR Payments;
    8. Suspend or terminate the WISeR Participant's ability to perform its Prior Authorization Process on new requests;
    9. Require a CAP from the WISeR Participant that is acceptable to CMS. If CMS requires a CAP from the WISeR Participant, the following requirements apply:
        i. The WISeR Participant shall submit a CAP to CMS for approval by a deadline established by CMS:
        ii. CMS must approve the WISeR Participant's CAP;
        iii. The CAP must address what actions the WISeR Participant will take within a specified time period to ensure that all deficiencies will be corrected and that the WISeR Participant will be in compliance with the terms of this Agreement; and

iv. If the WISeR Participant does not comply with the terms of the CAP within the specified period of time, CMS may take additional remedial actions or terminate the Agreement or Agreement Performance Period in accordance with Section 13.3.

B. CMS may impose additional remedial actions, including but not limited to terminating the Agreement or Agreement Performance Period pursuant to Section 13.3, if CMS determines that the WISeR Participant's efforts to address noncompliance or other grounds for remedial action were insufficient.

Section 13.3 Termination by CMS

CMS may immediately or with advance notice terminate the Agreement or Agreement Performance Period if:

A. CMS determines that it no longer has the funds to support the Model;
B. CMS modifies or terminates the Model pursuant to section 1115A(b)(3)(B) of the Act;
C. CMS offers the WISeR Participant an amendment to this Agreement pursuant to Section 1.4, and the WISeR Participant does not sign such amendment by the date specified by CMS;
D. CMS determines that any grounds for remedial action exist;
E. CMS determines that the WISeR Participant has failed to submit, obtain approval for, implement, or fully comply with the terms of a CAP;
F. CMS determines that the WISeR Participant has failed to demonstrate improved performance following any remedial action imposed by CMS;
G. The WISeR Participant has a conflict of interest that cannot be resolved;
H. The WISeR Participant has not executed a valid BAA; or
I. The WISeR Participant assigns or purports to assign any of the rights or obligations under the Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

Section 13.4 Termination of the Agreement Performance Period by WISeR Participant

The WISeR Participant may terminate the Agreement Performance Period upon advance written notice to CMS. Such notice must specify the effective date of the termination, which must be at least 90 Days after the date of the notice.

Section 13.5 Financial Settlement Upon Termination

If CMS terminates the Agreement or the Agreement Performance Period is terminated by either party, CMS shall conduct settlement for the entire Performance Year in which the Agreement is terminated in accordance with Article VIII of the Agreement.

Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination

If the Agreement or Agreement Performance Period is terminated under Section 13.3 or Section 13.4, the WISeR Participant shall provide written notice of the termination to all WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction. The WISeR Participant shall deliver such written notice no later than 45 Days before the effective date of termination unless a different date is specified by CMS. The WISeR Participant shall include in such notices any content specified by CMS.

Article XIV. Limitation on Review and Dispute Resolution

Section 14.1 Limitations on Review

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

A. The selection of organizations, sites, or participants to test models selected for testing or expansion under section 1115A of the Act, including the decision by CMS to terminate the Agreement or Agreement Performance Period;
B. The elements, parameters, scope, and duration of such models for testing or dissemination;
C. Determinations regarding budget neutrality under section 1115A(b)(3);
D. The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B);
E. Determinations about expansion of the duration and scope of a model under section 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection (c);
F. The selection of quality performance standards by CMS;
G. The methodology applied to calculate Regional Benchmarks, WISeR Discount, AQS, and WISeR Payments;
H. The methodology used to calculate the WISeR Participant's WISeR Payment; and
I. The methodology used to calculate the WISeR Recoupment.

Section 14.2 Dispute Resolution

A. Right to Reconsideration. The WISeR Participant may request reconsideration of a determination made by CMS pursuant to the Agreement only if such reconsideration is not precluded by section 1115A(d)(2) of the Act or the Agreement.
    1. Such a request for reconsideration by the WISeR Participant must satisfy the following criteria:

i. The request must be submitted to a designee of CMS ("**Reconsideration Official**") who –
    a. Is authorized to receive such requests;
    b. Did not participate in the determination that is the subject of the reconsideration request; and
    c. May be, but does not have to be, an Inferior Officer.
ii. The request must include a copy of the initial determination issued by CMS and contain a detailed, written explanation of the basis for the dispute, including supporting documentation;
iii. The request must be made within 30 Days of the date of the initial determination for which reconsideration is being requested and
iv. The request must be delivered via email to CMS at InnovationModelsReconsideration@cms.hhs.gov or at such other address specified by CMS.

2. Requests that do not meet the requirements of Section 14.2.A.1 will be denied.
3. Within 15 Days of receiving a request for reconsideration, the parties will be sent a written acknowledgement of receipt of the reconsideration request. Such an acknowledgement will set forth:
    i. The review procedures; and
    ii. A briefing schedule that permits each party to submit written briefs, including any evidence or documentation in support of the party's position for consideration by the Reconsideration Official.

B. Standards for Reconsideration
1. The parties shall proceed diligently with the performance of this Agreement during the course of any dispute arising under the Agreement.
2. The reconsideration will consist of a review of documentation that is submitted timely and in accordance with the standards specified by the Reconsideration Official.
3. The burden of proof is on the WISeR Participant to demonstrate to the Reconsideration Official with clear and convincing evidence that the determination is inconsistent with the terms of the Agreement.

C. Reconsideration Determination
1. The reconsideration determination will be based only upon:
    i. Position papers and supporting documentation that are timely submitted to the Reconsideration Official and meet the standards for submission under Section 14.2.B.2; and

ii. Documents and data that were timely submitted to CMS in the required format before the agency made the determination that is the subject of the reconsideration request.

2. The Reconsideration Official will issue to CMS and the WISeR Participant a written notification of the reconsideration determination ("**Reconsideration Determination**"). Absent unusual circumstances, the Reconsideration Determination will be issued within 60 Days of receipt of timely filed position papers and supporting documentation.
3. The Reconsideration Determination is final and binding 30 Days after its issuance, unless the WISeR Participant or CMS timely requests review of the Reconsideration Determination in accordance with Sections 14.2.D.1 and 2.

D. CMS Administrator Review. The WISeR Participant or CMS may request CMS Administrator review of the Reconsideration Determination.

1. The request must be made via email to InnovationModelsReconsideration@cms.hhs.gov or such other address as specified by CMS within 30 Days after the date of the Reconsideration Determination.
2. The request must include a copy of the Reconsideration Determination and a detailed, written explanation of why the WISeR Participant or CMS disagrees with the Reconsideration Determination.
3. Within 30 business days after receiving a request for review, the CMS Administrator (or a delegate acting on behalf of the CMS Administrator) will determine whether the request for review is granted or denied. The CMS Administrator will promptly send the parties written acknowledgement of receipt of the request for review. Such an acknowledgement will set forth:
    i. Whether the request for review is granted or denied; and
    ii. If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.
4. If the request for review is denied, the Reconsideration Determination is final and binding as of the date the request for review is denied.
5. If the request for review is granted:
    i. The record for review will consist of timely submitted briefs and the evidence contained in the record of the proceedings before the Reconsideration Official. The CMS Administrator will not consider documentation submitted for review other than documents and date described in Section 14.2.B.2;

ii. The CMS Administrator will review the record and issue to CMS and to the WISeR Participant a written determination; and
iii. The written determination of the CMS Administrator is final and binding.

E. Effect of Dispute Resolution. The dispute resolution process under this Agreement shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

Article XV. Miscellaneous

Section 15.1 Agency Notifications and Submission of Reports

A. For a notice or other communication required under this Agreement to be valid, it must be in writing.
B. Unless otherwise specified in this Agreement or stated in writing after the Effective Date, all notifications and reports required under this Agreement must be submitted to the parties at the addresses set forth below:

CMS:
WISeR Model
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop: WB-06-05
Baltimore, MD 21244
Email: WISeR@cms.hhs.gov

WISeR Participant:
Genzeon Corporation
559 W Uwchlan Ave
Exton
PA
19341

Section 15.2 Notice of Bankruptcy

A. If the WISeR Participant has filed a bankruptcy petition, whether voluntary or involuntary, the WISeR Participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the WISeR Participant under the terms of each model tested under section 1115A of the Act in which the WISeR Participant is participating or has participated and all administrative or judicial review proceedings related to any payments under such models have been fully and finally resolved.

B. The notice of bankruptcy must be sent by certified mail no later than 5 Days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the WISeR Participant is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the WISeR Participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the WISeR Participant and CMS have been fully and finally resolved with respect to that model.

C. The notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3-01-24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices.

Section 15.3 Severability

In the event that any one or more of the provisions of this Agreement is, for any reason, held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had never been included in the Agreement, unless the deletion of such provision or provisions would result in such a material change to the Agreement so as to cause continued participation under the terms of this Agreement to be unreasonable.

Section 15.4 Entire Agreement; Amendment

This Agreement, including all appendices, constitutes the entire agreement between the parties. The parties may amend this Agreement or any appendix hereto at any time by mutual written consent; provided, however, that CMS may amend this Agreement or any appendix hereto in writing without the consent of the WISeR Participant as specified in this Agreement or any appendix hereto, or for good cause or as necessary to comply with applicable federal

or state law, regulatory requirements, accreditation standards, or licensing guidelines or rules. To the extent practicable, CMS shall provide the WISeR Participant with 30 Days' advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

Section 15.5 Survival

Expiration or termination of this Agreement by CMS shall not affect the rights and obligations of the parties accrued prior to the effective date of the expiration or termination of this Agreement, except as provided in this Agreement. The rights and duties under the following sections of this Agreement shall survive the expiration or termination of this Agreement and apply thereafter:

Article VIII. Payment;
Article IX. Data Sharing and Reports;
Section 10.1 Evaluation Requirements;
Section 10.4 Rights in Data and Intellectual Property;
Section 10.5 WISeR Participant Public Release of Information;
Section 11.3 Compliance with Monitoring and Oversight Activities;
Article XII. Audits and Record Retention;
Section 13.5 Financial Settlement Upon Termination;
Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination;
Section 14.1 Limitations on Review;
Section 15.2 Notice of Bankruptcy;
Section 15.5 Survival; and
Section 15.7 Prohibition on Assignment.

Section 15.6 Precedence

If any provision of this Agreement conflicts with a provision of any document incorporated herein by reference, the provision of this Agreement shall prevail.

Section 15.7 Prohibition on Assignment

Except with the prior written consent of CMS, the WISeR Participant shall not transfer, including by merger (whether the WISeR Participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under this Agreement; (2) any right that it has to satisfy a condition under this Agreement; (3) any remedy that it has under this Agreement; or (4) any obligation imposed on it under this Agreement. The WISeR Participant shall provide CMS 90 Days' advance written notice of any such proposed transfer. This obligation remains in effect until final payment by or to the WISeR Participant has been made under this Agreement. CMS may condition its consent to transfer on full payment of any amounts owed by the WISeR Participant under this Agreement or owed to CMS by the

proposed assignee. Any purported transfer in violation of this Section is voidable at the discretion of CMS.

Section 15.8 Certification

The WISeR Participant executive signing this Agreement certifies to the best of his or her knowledge, information, and belief that the WISeR Participant satisfies the requirements of Section 3.1.A, that all WISeR Clinicians and WISeR Clinical Reviewers satisfy the requirements of Section 3.4, and that he or she is authorized by the WISeR Participant to execute this Agreement and to legally bind the WISeR Participant to its terms and conditions.

Section 15.9 Execution in Counterpart

This Agreement and any amendments hereto may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof. This Agreement and any amendments hereto may be signed by autopen or electronic signature (e.g., DocuSign or similar electronic signature technology) and may be transmitted by electronic means. Copies of this Agreement and any amendments hereto that are so executed and delivered have the same force and effect as if executed with handwritten signatures and physically delivered.

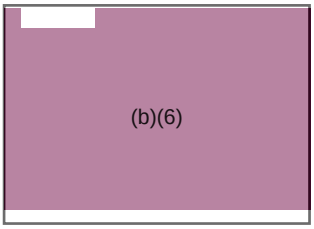
[SIGNATURE PAGE FOLLOWS]

Each party is signing this Agreement on the date stated opposite that party's signature. If a party signs but fails to date a signature, the date that the other party receives the signing party's signature will be deemed to be the date that the signing party signed the Agreement.

WISeR Participant: Genzeon Corporation

WISeR ID: WISeR-00145

Date: 2025-09-26 15:31:48

By: 

(b)(6)

Name of Authorized Signatory

(b)(6)

Title

CMS:

Date: 2025-10-01 14:14:13

By: _____

Arrah Tabe-Bedward

Name of Authorized Signatory

CMS Executive

Appendices

Appendix A: Select Items and Services

Appendix B: Quality Measures

Appendix C: WISeR Participant Proprietary and Confidential Information

Appendix A: Select Items and Services

CMS uses Covered Services that correspond to the LCDs and NCDs identified in the Table 1 below ("**Select Items and Services**") to determine whether the WISeR Provider's and/or WISeR Supplier's Medicare claim is subject to the Prior Authorization Process for Performance Year 1. The WISeR Participant performs its Prior Authorization Process for each Select Item or Service identified in a Prior Authorization request within its WISeR Jurisdiction.

CMS may unilaterally revise the Select Items and Services identified in Table 1 prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any revisions to the Select Items and Services for a Performance Period prior to the start of the Performance Period in which such change will take effect.

Table 1

Select Items and Services	Associated NCD/LCDs
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)	NCD 160.7 NCD 230.18 NCD 160.19 NCD 160.24 NCD 160.18
Induced Lesions of Nerve Tracts	NCD 160.1
Epidural Steroid Injections for Pain Management	L39015, L39242, L36920
Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L34106, L38201, L35130
Cervical Fusion Excluding codes already included in OPD	L39741, L39762, L39793
Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee	NCD 150.9

Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea	L38307, L38312, L38385
Incontinence Control Devices	NCD 230.10
Diagnosis and Treatment of Impotence	NCD 230.4
Percutaneous Image-Guided Lumbar Decompression for Spinal Stenosis	NCD 150.13
Skin and Tissue Substitutes • Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds • Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities	L35041 L36690

Appendix B: Quality Measures

Consistent with Article VII and the WISeR Data Reporting Guide, CMS shall use the following WISeR Performance Measure Set for purposes of calculating the AQS of the WISeR Participant for Performance Year 1. CMS will also use the following WISeR Performance Measure Set for purposes of monitoring and evaluating the overall performance of the WISeR Participant during the Model.

CMS may update the quality measures identified in the WISeR Performance Measure Set prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any updates for a Performance Period prior to the start of the Performance Period in which such change will take effect.

WISeR Performance Measure Set

Domain	First Applicable Performance Period	Data Source	Measurement Frequency
Timeliness of Determinations	PP1	WISeR Participant-Reported	Quarterly
Accuracy of Determinations	PP1	CMS Audit of WISeR Participant-Reported Data	Quarterly

Appendix C: WISeR Participant Proprietary and Confidential Information

The following are specific examples, without limitation, of what the WISeR Participant considers proprietary and confidential information currently maintained by the WISeR Participant that should not be publicly disclosed:

1) (b)(4)

2) (b)(4)

3) (b)(4)

4) (b)(4)

In accordance with Section 10.4 of the Agreement, this information shall not be released by CMS without the express written consent of the WISeR Participant except as required by federal law.

Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Patient Care Models Group
7500 Security Blvd
Baltimore, MD 21244

Wasteful and Inappropriate Service Reduction (WISeR) Model

Participation Agreement

Segment 1: January 1, 2026-December 31, 2028

August 29, 2025

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PARTICIPATION AGREEMENT

This Participation Agreement (the "**Agreement**") is between the CENTERS FOR MEDICARE & MEDICAID SERVICES ("**CMS**") and

Humata Health, Inc. , ("**WISeR Participant**").

CMS is the agency within the U.S. Department of Health and Human Services ("**HHS**") that is charged with administering the Medicare and Medicaid programs.

The WISeR Participant is a legal entity identified by a single TIN and has Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process and Pre-Payment Review for Select Items and Services on Medicare fee-for-service ("**FFS**") Claims.

CMS is implementing the Wasteful and Inappropriate Service Reduction Model ("**WISeR**" or "**Model**") under section 1115A of the Social Security Act ("**Act**"), which authorizes CMS through its Center for Medicare and Medicaid Innovation ("**Innovation Center**") to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program expenditures while preserving or enhancing the quality of care furnished to Beneficiaries.

The Model seeks to reduce or maintain Medicare FFS expenditures while improving the quality of care and health outcomes for Medicare FFS beneficiaries through the WISeR Participant's Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process for Select Items and Services that do not satisfy existing Medicare Coverage Criteria and may be fraudulent, wasteful, or of low-value to Medicare FFS beneficiaries.

The WISeR Participant applied to participate in WISeR, and CMS has approved the WISeR Participant for participation in the Model for the MAC Jurisdiction of JH Novitas and the state of Oklahoma. The designated state is the WISeR Participant's WISeR Jurisdiction.

The parties therefore agree as follows:

Article I. Agreement Term

Section 1.1 Effective Date

This Agreement will become effective when it is signed by the last party to sign it (as indicated by the date associated with that party's signature) ("**Effective Date**").

Section 1.2 Agreement Term

The term of this Agreement ("**Agreement Term**") begins on the Effective Date and expires two years after the last Day of the Agreement Performance Period, as defined in Section 1.3, unless the Agreement is sooner terminated by CMS in accordance with Section 13.3, in which case the Agreement Term ends on the effective date of such termination.

Section 1.3 Agreement Performance Period

A. The performance period of this Agreement ("**Agreement Performance Period**") begins on the Effective Date and ends at 11:59 PM ET on December 31, 2028, unless the Agreement Period or the Agreement is sooner terminated in accordance with Section 1.4.B or Article XIII, in which case the Agreement Performance Period ends on the date specified in the termination notice.

B. CMS may offer the WISeR Participant the option to participate in a second segment of this Model which would begin on January 1, 2029, and end at 11:59 PM ET on December 31, 2031. The WISeR Participant must execute a new agreement with CMS to participate in the Model during the second segment. Any such agreement will authorize CMS to take remedial action against the WISeR Participant for non-compliance with the terms of this Agreement, regardless of when the non-compliance is discovered by CMS.

Section 1.4 Amended and Restated Agreements

A. No later than 30 Days prior to the start of a calendar year during the Agreement Performance Period, CMS may offer the WISeR Participant the opportunity to sign an amendment to this Agreement, which may be in the form of an amended and restated version of this Agreement.

B. If the WISeR Participant fails to sign an amendment offered by CMS pursuant to Section 1.4.A by a date specified by CMS, CMS may terminate the Agreement Performance Period on December 31 of the year in which the amendment was offered.

Article II. Definitions

Advance WISeR Payment means the payment that meets the requirements in Section 8.4.

Aggregate Quality Score (AQS) means the score that is calculated from the WISeR Participant's quality data and used to determine the quality multiplier applied during the calculation of the WISeR Payment.

ARS stands for **CMS Acceptable Risk Safeguard** and means the standard to CMS and its contractors, including the WISeR Participant, as to the minimum level of required security and privacy controls. *See* https://security.cms.gov/policy-guidance/cms-acceptable-risk-safeguards-ars (last accessed August 2025).

ATO stands for **CMS Authority to Operate** and means the information systems operated by or on behalf of the U.S. federal government that meet FISMA standards.

BAA stands for **Business Associate Agreement** and means the legally binding contract required under HIPAA between CMS and the WISeR Participant that handles Protected Health Information.

Beneficiary means an individual who is entitled to Medicare FFS benefits under Part A or enrolled under Part B.

Change in Control means: (1) the acquisition by any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the WISeR Participant representing more than 50 percent of the WISeR Participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the WISeR Participant by any other individual or entity; (3) the sale, lease exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the WISeR Participant; or (4) the approval and completion of a plan of liquidation of the WISeR Participant, or an agreement for the sale or liquidation of the WISeR Participant.

Covered Services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Day(s) means calendar day(s) unless otherwise specified.

Electronic Submission of Medical Documentation (esMD) means a system used by CMS to enable providers, suppliers, and other entities to reduce or eliminate the need to mail or fax paper documents and instead electronically submit or request supporting medical documentation related to CMS claims and Prior Authorization.

Enhanced Technology means the WISeR Participant's technology that is intended to improve the accuracy and efficiency of the Prior Authorization Process and Pre-Payment Review.

Exemption Status means the status that a WISeR Provider or WISeR Supplier may earn to be exempt from requesting Prior Authorization for the Select Items and Services in accordance with Section 6.2 of this Agreement and the WISeR Participant Guide.

FedRAMP stands for **Federal Risk and Authorization Management Program** and means the government-wide program that standardizes security assessments for cloud services (44 U.S.C. § 3607).

Financial Settlement Report means the report that is defined in Section 8.9.

FISMA stands for **Federal Information Security Management Act of 2002, as amended by the Federal Information Security Modernization Act of 2014** and means the framework of guidelines and security standards to protect government information and operations as set forth in 44 U.S.C. § 3541, *et seq.* and 44 U.S.C. § 3551, *et seq*..

Initial Prior Authorization Determination means the communication to the WISeR Provider or WISeR Supplier detailing the Prior Authorization Affirmation or Prior Authorization Non-Affirmation for an initial Prior Authorization submission.

IS2P2 stands for **CMS Information Systems Security & Privacy Policy** and means the policy that defines how CMS protects and controls access to its information and systems as required under FISMA of 2014 (44 U.S.C. Chapter 35).

Locality means a CMS-defined geographic area within a MAC Jurisdiction (e.g., a state, or other geographic boundary) that CMS uses to determine Medicare payment rates for Covered Services.

LCDs stands for **Local Coverage Determinations** and has the meaning set forth in Section 1869(f)(2)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(2)(B)).

MAC stands for Medicare Administrative Contractor and means a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B medical claims or Durable Medical Equipment (DME) claims for Medicare fee-for-service beneficiaries, as further defined in Section 1874A(a)(3) of the Social Security Act (42 U.S.C. § 1395kk-1(a)(3) and 42 C.F.R. Subpart E).

MAC Jurisdiction means the defined geographic territory for the Medicare Part A and Part B Jurisdictions L, 15, H, and F selected for the WISeR Model and as depicted on the "A/B MAC

Jurisdictions" map at https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/who-are-macs (last accessed August 2025) (*see also* Section 911(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173).

Medical Review means the collection and clinical review of medical records and related information to ensure that Medicare payment is made only for services that meet all Medicare Coverage Criteria.

Medically Necessary means reasonable and necessary as determined in accordance with Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)).

Medicare Coverage Criteria means the existing Medicare coverage criteria as set forth in statute, regulation, NCD, or LCD.

Model Participant means a technology company that has signed an agreement with CMS to participate in WISeR and is not the WISeR Participant.

Model Performance Period means the period of time, regardless of the Agreement Performance Period, that begins on January 1, 2026 and ends on December 31, 2031, unless sooner terminated in accordance with Section 12.3.

Navigation Services means services and information including Medicare Coverage Criteria, Prior Authorization performance data, and such other services as detailed in the WISeR Participant Guide that are provided by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers, as applicable, to all WISeR Providers and WISeR Suppliers to increase clinically appropriate care.

NCDs stands for **National Coverage Determinations** and has the meaning set forth in Section 1869(f)(1)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(1)(B).

NPI stands for **National Provider Identifier**.

Payable Non-Affirmation means an Initial Prior Authorization Determination of Prior Authorization Non-Affirmation that qualifies for a WISeR Payment because there was no Resubmission within 120 Days that received a determination of Prior Authorization Affirmation and, at the time of Reconciliation, there was no associated claim paid by Medicare due to the successful appeal of a claim denial.

Performance Period means the three-month period in which the WISeR Participant issues Initial Prior Authorization Determinations for Prior Authorization requests and issues

determinations for Pre-Payment Reviews, including without limitation all associated Resubmissions submitted within 120 days of the Initial Prior Authorization Determination.

Performance Year or **PY** means the 12-month period beginning on January 1 of each year during the Model Performance Period.

Pre-Payment Review means the review by the WISeR Participant to verify consistency with Medicare Coverage Criteria for a claim for one or more Select Items and Services furnished in the MAC Jurisdiction that is submitted to Medicare without requesting Prior Authorization, consistent with 42 C.F.R. § 405.903.

Prior Authorization is a request by the WISeR Provider or WISeR Supplier for provisional affirmation of Medicare Coverage Criteria for one of the Select Items and Services prior to furnishing such items and services to the WISeR Beneficiary and before the claim is submitted for processing.

Prior Authorization Process means the process detailed in Article VI of the Agreement.

Prior Authorization Provisional Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Prior Authorization Non-Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is not accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Program Integrity Screening means a review of an individual's or entity's program integrity history and current status, which may include a review of the individual's or entity's eligibility, history of exclusion or other sanctions imposed with respect to participation in Medicare, Medicaid, or CHIP; history of failure to pay Medicare debts in a timely manner; current or prior law enforcement investigations or administrative actions regardless of whether such investigations or actions relate to participation in Medicare, Medicaid, or CHIP; affiliations with individuals or entities that have a history of program integrity issues; and other information pertaining to the trustworthiness of the individual or entity.

Reconciliation means the process by which CMS calculates the WISeR Payment amount owed to the WISeR Participant for a specific Performance Period as set forth in Article VIII.

Reconciliation Report means the report issued by CMS that details the Reconciliation calculations for the WISeR Participant and the amount of any WISeR Payment for one or more specified Performance Periods.

Regional Benchmark means a payment amount calculated by CMS for each of the Select Items and Services for a given Locality and Performance Period that CMS uses to calculate the WISeR Payment amount for a Payable Non-Affirmation as set forth in Section 8.3.

Resubmission means a Prior Authorization submitted to the WISeR Participant within 120 Days of an Initial Prior Authorization Determination for a Prior Authorization previously submitted by the same WISeR Provider or WISeR Supplier for the same WISeR Beneficiary and same Select Item or Service.

Resubmission Determination means the communication to the WISeR Provider and/or WISeR Supplier detailing the Prior Authorization Provisional Affirmation or Prior Authorization Non-Affirmation for a Resubmission.

Select Items and Services means the Covered Services detailed in Appendix A that are subject to the Prior Authorization Process. When used in its singular form this term is referred to as "**Select Item or Service**".

Start Date means January 1, 2026.

TIN stands for taxpayer identification number.

VDC stands for CMS Virtual Data Center and means the comprehensive information technology infrastructure designed to centralize and modernize CMS' digital operations.

WISeR Beneficiary means a Beneficiary that meets the requirements set forth in Section 4.1.

WISeR Clinician means an individual that satisfies the requirements of Section 3.6.

WISeR Clinical Reviewer means an individual that satisfies the requirements of Section 3.6.

WISeR Data Reporting Guide means the guidance paper that CMS publishes and provides to the WISeR Participant that sets forth the WISeR Participant's reporting obligations during the Model. CMS may modify the WISeR Data Reporting Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Data Reporting Guide at least 30 Days prior to the effective date of such revisions.

WISeR Discount means the discount specified in Section 8.3.C that CMS applies when calculating the WISeR Payment.

WISeR Jurisdiction means the defined geographic states of New Jersey (Jurisdiction L/Novitas Solutions, Inc.), Ohio (Jurisdiction 15/CGS Administrators, LLC), Oklahoma and Texas (JH/Novitas), and Arizona and Washington (JF/Noridian) selected for the WISeR Model

for which the WISeR Participant conducts Prior Authorization Process on claims for Select Items and Services from institutional providers, physicians, clinicians and suppliers.

WISeR Participant means the technology company that meets the requirements set forth in Article III and has signed this Agreement with CMS to participate in the Model.

WISeR Participant Guide means a guidance paper that CMS publishes and provides to the WISeR Participant that sets forth additional details to support the WISeR Participant's activities and obligations during the Model. CMS may modify the WISeR Participant Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Participant Guide at least 30 Days prior to the effective date of such revisions.

WISeR Payment means the Model specific payment made by CMS for a Payable Non-Affirmation or a Pre-Payment Review that qualifies for payment as set forth in Article VIII.

WISeR Performance Measure Set means the measures detailed in Appendix B, and as may be revised in the WISeR Data Reporting Guide, that CMS uses in calculating the AQS.

WISeR Provider means a provider, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction that furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

WISeR Recoupment means the amount owed to CMS if CMS pays a WISeR Payment to the WISeR Participant and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

WISeR Supplier means a supplier, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction and who furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

Article III. General Requirements

Section 3.1 WISeR Participant Requirements

A. During the Agreement Term, the WISeR Participant shall:
    1. Be a legal entity formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates for the purpose of carrying out the activities required by this Agreement;
    2. Have Enhanced Technology and be identified by a single TIN, to provide specified health insurance benefit administrative services, including

Medicare Prior Authorization and Pre-Payment Review services to interpret and apply Medicare Coverage Criteria and clinical coverage criteria derived from NCDs and LCDs, in support of the Medicare FFS program;

3. Use its Enhanced Technology for implementing and streamlining the Prior Authorization Process and Pre-Payment Review for Select Items and Services in its assigned WISeR Jurisdiction;
4. Have a valid Business Associate Agreement ("**BAA**") with CMS;
5. Support CMS in its efforts to make accurate and timely payments to WISeR Providers or WISeR Suppliers for Select Items and Services furnished to WISeR Beneficiaries;
6. Support CMS in its efforts to ensure care provided to Beneficiaries is Medically Necessary and adheres to Medicare Coverage Criteria, thus protecting Beneficiaries and the Medicare Trust Fund; and
7. Not have a conflict of interest as detailed in Section 3.3 of this Agreement.

The WISeR Participant states that it satisfies the requirements of this Section 3.1.A as of the Effective Date.

B. The WISeR Participant shall satisfy the requirements of this Section 3.1.B no later than 45 Days before the Start Date and throughout the remainder of the Agreement Term:
    1. Have access to Federal Risk and Authorization Management Program ("**FedRAMP**") certified workflows;
    2. Comply with all applicable Federal data protection and security requirements including Federal Information Security Management Act ("**FISMA**") requirements, CMS Information Systems Security & Privacy Policy ("**IS2P2**"), CMS Acceptable Risk Safeguard ("**ARS**");
    3. Follow CMS Authority to Operate ("**ATO**") guidelines for connections established between the Medicare Administrative Contractor ("**MAC**") and WISeR Participant; and
    4. Enter into a valid Joint Operating Agreement ("**JOA**") with the applicable MAC.
C. Changes to the WISeR Participant
    1. Change of WISeR Participant Name. The WISeR Participant shall provide written notice to CMS at least 60 Days before any change in the WISeR Participant's legal name becomes effective. The WISeR Participant shall forward to CMS a copy of the document effectuating the name change, authenticated by the appropriate state official (if applicable), and the parties shall execute an agreement reflecting the change of the WISeR Participant's name. This obligation shall remain in effect until the latter of the effective date

of termination of this Agreement or when the final payment by or to the WISeR Participant has been made under this Agreement.

2. Change in WISeR Participant TIN. The WISeR Participant shall provide at least 90 Days advanced written notice before the effective date of any change in the WISeR Participant's TIN. Such notice must be submitted in the form and manner specified by CMS. In response to a change in the WISeR Participant's TIN, CMS may terminate the Agreement or Agreement Performance Period, or take any other actions consistent with the terms of this Agreement. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
3. Change in Control.
    i. The WISeR Participant shall provide written notice to CMS at least 90 Days before the effective date of any Change in Control. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
    ii. Upon learning of a Change in Control, CMS may conduct a Program Integrity Screening and take other appropriate action to ensure compliance with the terms of the Model by the new controlling entity and may require the new controlling entity to execute a novation agreement with CMS or require the new controlling entity to execute a new Participation Agreement with CMS. CMS may also terminate the Participation Agreement between the former controlling entity and CMS.
    iii. If the WISeR Participant undergoes a Change in Control, CMS may take one or more of the following actions: terminate this Agreement; terminate the Agreement Performance Period; or immediately conduct financial settlement in accordance with Section 8.9.
4. Change in Primary Point of Contact. The WISeR Participant shall provide written notice to CMS of any changes to the contact information for the WISeR Participant's primary point of contact no later than 15 Days after the change.

D. Information for Electronic Funds Transfer

1. The WISeR Participant shall submit to CMS a completed Electronic Funds Transfer Authorization Agreement in the form and manner and by the date(s) specified by CMS.

2. The WISeR Participant shall promptly update its Electronic Funds Transfer Authorization Agreement if there are account or bank changes, or any change to the WISeR Participant set forth in Section 3.1.C.
3. If the WISeR Participant fails to submit or accurately complete the Electronic Funds Transfer Authorization Agreement, CMS may withhold any WISeR Payment owed to the WISeR Participant until the WISeR Participant has submitted and CMS has processed an Electronic Funds Transfer Authorization Agreement with the correct information. In addition, the failure to submit or accurately complete an Electronic Funds Transfer Authorization Agreement could delay the WISeR Participant's receipt and timely payment of a demand for payment under this Agreement, and thereby cause the WISeR Participant to be liable for interest on the amount owed to CMS.

E. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, the WISeR Participant fails to meet any requirements set forth in Section 3.1. The WISeR Participant shall provide such written notice to CMS at least 30 Days before failing to satisfy any requirements in Section 3.1.A, or within 5 Days of becoming aware that the WISeR Participant has failed to satisfy any requirements in Section 3.1(B)-(D).

Section 3.2 WISeR Participant Governance

A. General.
   1. The WISeR Participant shall maintain an identifiable governing body with sole and exclusive authority to execute the functions of the WISeR Participant and make final decisions on behalf of the WISeR Participant. The WISeR Participant shall have a governing body that satisfies the following criteria:
      i. The governing body has responsibility for oversight and strategic direction of the WISeR Participant and is responsible for holding the WISeR Participant management accountable for the WISeR Participant's activities;
      ii. The governing body has a transparent governing process;
      iii. When acting as a member of the governing body of the WISeR Participant, each governing body member has a fiduciary duty to the WISeR Participant and to CMS for actions relating to the terms of this Agreement, the Model and the terms set forth in the Business Associate Agreement, including the duty of loyalty, and shall act consistent with that fiduciary duty; and

iv. The governing body shall receive regular reports from the designated compliance official of the WISeR Participant who satisfies the requirements of Section 11.1.

2. The WISeR Participant shall provide each member of the governing body with a copy of the Agreement and any amendments hereto.
3. If CMS determines that the composition of the WISeR Participant's governing body, executive leadership, or parent organization(s) (as applicable) compromises the WISeR Participant's ability to participate in the Model or to comply with the terms of the Agreement, CMS may take one or more of the remedial actions specified in Section 13.2.
4. The WISeR Participant shall ensure that its governing body implements a process for documenting governing body composition, meetings and decisions, and shall retain such documentation in accordance with Section 12.2.

B. Composition and Control of the Governing Body.

1. The WISeR Participant's governing body shall not include any individual with pending or open investigations, or a history of convictions or sanctions, including without limitation:
    i. Investigations or actions related to participation in Medicare, Medicaid, or Children's Health Insurance Program;
    ii. A history of failure to pay Medicare debts in a timely manner;
    iii. Affiliations with individuals or entities that have a history of program integrity issues;
    iv. Conduct that a reasonable person would deem to be unfit conduct; or
    v. A history of legal or monetary sanctions.
2. The WISeR Participant shall routinely monitor each individual on its governing body to ensure compliance with the provisions of this Section 3.2.
3. The WISeR Participant shall immediately remove from its governing body any individual that becomes subject to a conviction or sanction.
4. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, it removes an individual from its governing body. The WISeR Participant shall provide such written notice to CMS within 5 Days of such removal.
5. The governing body members may serve in similar or complementary roles or positions, subject to Section 3.3.

Section 3.3 Conflict of Interest

A. The WISeR Participant shall have a conflict of interest policy that applies to members of the governing body and satisfies the following criteria:
    1. Requires each member of the governing body to disclose relevant financial interests and other interests that could prevent impartiality;
    2. Requires each member of the governing body to update its disclosure statement whenever the member's personal or financial circumstances change in such a way that a new conflict of interest might occur;
    3. Provides a procedure to determine whether a conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses remedial actions for members of the governing body that fail to comply with the policy.

B. Notwithstanding the obligations set forth in Section 3.3.A, the WISeR Participant shall have a conflict of interest policy that applies to its business operations and satisfies the following criteria:
    1. Requires that the WISeR Participant refrain from engaging in activities that would lead to the preferential or non-preferential treatment of any WISeR Provider, WISeR Supplier, WISeR Clinician, WISeR Clinical Reviewer, individual clinician, medical group, medical practice, Beneficiary, or any other individual or entity with an interest in the Prior Authorization Process or Pre-Payment Review;
    2. Requires that the WISeR Participant prohibit WISeR Clinicians and WISeR Clinical Reviewers from participating in the Prior Authorization Process and Pre-Payment Review associated with a provider or supplier under the same TIN as the reviewing WISeR Clinician or WISeR Clinical Reviewer;
    3. Provides a procedure to determine whether such conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses plans of action to correct instances that fail to comply with the policy.

C. The WISeR Participant shall ensure that its conflict of interest policy sets forth a process to address situations where an individual employed by or contracted by the WISeR Participant and has a financial interest, personal activity, or relationship that could impair that individual's ability to act impartially and in the best interest of CMS when performing under the terms of this Agreement, the Business Associate Agreement, or the Model.

D. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Prior Authorization request not participate in the review of that request or any associated Resubmissions related to that Prior Authorization request.
E. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Pre-Payment Review not participate in the review of that claim or any associated Resubmissions related to that Pre-Payment Review.
F. The WISeR Participant shall de-identify Prior Authorization requests, Resubmissions, and Pre-Payment Review claims prior to permitting its WISeR Clinicians and WISeR Clinical Reviewers to conduct a Medical Review or peer-to-peer review.
G. The WISeR Participant shall designate a committee or group responsible for evaluating disclosed potential conflicts of interest and determine whether they pose a risk to the fairness of the Prior Authorization review or the Pre-Payment Review.
    1. The WISeR Participant shall provide immediate written notice of disclosed potential conflicts of interest to CMS. Such written notice shall be made within 5 Days of becoming aware of the potential conflicts of interest.
    2. The WISeR Participant shall include CMS in the determination process associated with the disclosed potential conflicts of interest.

Section 3.4 Required Prior Authorization Activities

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.
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.
C. The WISeR Participant shall review Prior Authorizations in its WISeR Jurisdiction submitted by all WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).
D. Consistent with Section 3.4.C, the WISeR Participant shall perform its Prior Authorization Process on Prior Authorizations received.
E. Consistent with the terms of this Agreement and the requirements set forth in the WISeR Participant Guide, the WISeR Participant shall issue Prior Authorization determinations to the requesting WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction with a copy to the applicable WISeR Beneficiary.

Section 3.5 WISeR Providers and WISeR Suppliers

A. WISeR Providers and WISeR Suppliers may submit Prior Authorization requests directly to the WISeR Participant and receive a determination for Select Items and Services.

B. If the WISeR Provider or WISeR Supplier submits a Prior Authorization request to its MAC for a Select Item or Service, then:

   1. CMS, through the applicable MAC, will re-route the Prior Authorization request to the WISeR Participant;
   2. The WISeR Participant must perform its Prior Authorization Process on the re-routed Prior Authorization from the MAC for the Select Item or Service and issue a determination directly to the WISeR Provider or WISeR Supplier with copy to the MAC and the WISeR Beneficiary identified on the Prior Authorization request; and
   3. Perform any additional requirements as described in the WISeR Participant Guide.

C. CMS, through the applicable MAC, will notify the WISeR Participant if a WISeR Provider or WISeR Supplier submits a claim to Medicare for one or more Select Items and Services furnished to a WISeR Beneficiary in the WISeR Jurisdiction without requesting Prior Authorization.

D. The WISeR Participant must conduct Pre-Payment Review in accordance with Section 6.5 of this Agreement for each Select Item or Service that does not have a Prior Authorization request from the WISeR Provider or WISeR Supplier.

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.

F. CMS will provide written notice, which may be in the form of the WISeR Participant Guide, to the WISeR Participant regarding additional determination letter requirements.

G. The WISeR Participant shall provide to its WISeR Providers and WISeR Suppliers prior authorization criteria and relevant evidence-based clinical practice guidelines for Select Items and Services in a form and manner and by the date(s) determined by CMS. Such compliance assistance information shall include examples of documentation that would support approval of a Prior Authorization request for each Select Item or Service, as well as examples of common mistakes, omissions, and evidence that would result in a denial of Prior Authorization.

Section 3.6 WISeR Clinicians and WISeR Clinical Reviewers

A. General.

1. The WISeR Participant may choose to:
    i. Directly employ clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinicians**"); or
    ii. Subcontract with a separate entity that provides appropriate clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinical Reviewers**"); or
    iii. Do both (i) and (ii).
2. The WISeR Participant must provide to its subcontractor, if applicable, necessary and appropriate WISeR Participant Guide provisions to ensure that each WISeR Clinical Reviewer meets the Medical Review requirements to ensure proper coverage determinations that adheres to Medicare Coverage Criteria and CMS coverage policy.
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.

B. <u>WISeR Clinicians</u>.
1. The WISeR Participant shall ensure that each WISeR Clinician:
    i. Be a board-certified clinician, including a:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;

iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;

vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and

vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinician performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant shall ensure that each WISeR Clinician performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers in a form and manner determined by CMS, as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that the WISeR Clinician has an active, valid and unrestricted license.

C. Record of WISeR Clinicians. The WISeR Participant shall maintain, in accordance with Article XII, a record of all its WISeR Clinicians.
   1. The WISeR Participant shall retain current and historical records of all its WISeR Clinicians in accordance with Section 12.2 of this Agreement.
   2. CMS may request and the WISeR Participant must provide to CMS a certified copy of all WISeR Clinicians at any given time during the Agreement Term.

D. Monitoring and Compliance of WISeR Clinicians.
   1. CMS will monitor the program integrity history of the WISeR Participant's WISeR Clinicians. CMS may require the WISeR Participant to exclude an individual WISeR Clinician or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
   2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinician be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure that each WISeR Clinician conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks, and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that each WISeR Clinician uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items and Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Items and Services;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

E. WISeR Clinical Reviewers.

1. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer:
    i. Be a board-certified clinician, including:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;
    iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;
vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and
vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinical Reviewer performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall require its subcontractor to ensure that the WISeR Clinical Reviewer has an active, valid and unrestricted license.

F. Record of WISeR Clinical Reviewers. The WISeR Participant must require its subcontractor to maintain, in accordance with Article XII of this Agreement, a record of all WISeR Clinical Reviewers performing activities related to this Model.
1. The WISeR Participant shall require the subcontractor to retain current and historical records of all WISeR Clinical Reviewers consistent with Section 12.2 of this Agreement.
2. The WISeR Participant shall require its subcontractor to provide the WISeR Participant with a certified copy of all WISeR Clinical Reviewers at any given time during the Agreement Term. The WISeR Participant shall provide such information to CMS in a form and manner and by the date(s) specified by CMS.

G. Monitoring and Compliance of WISeR Clinical Reviewers.
1. CMS will monitor the program integrity history of the WISeR Participant's use of WISeR Clinical Reviewers. CMS may require the WISeR Participant to exclude an individual WISeR Clinical Reviewer or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinical Reviewer be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items or Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Item or Service;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

Section 3.7 Customer Service

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.
B. The WISeR Participant shall provide an overall environment where WISeR Providers and WISeR Suppliers understand the Prior Authorization Process and Pre-Payment Review process for Select Items and Services.
C. The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.
D. The WISeR Participant shall maintain effective WISeR Provider and WISeR Supplier education that helps ensure complete Prior Authorization submissions for Select Items and Services and reduces the need for re-submissions, requests for appeal, and overturn of coverage determinations on appeal.
E. The WISeR Participant shall educate WISeR Providers and WISeR Suppliers on how to submit Prior Authorization requests and provide its WISeR Providers and WISeR Suppliers with information related to the Medicare Coverage Criteria associated with

the Select Items and Services. Such educational activities shall be conducted in a form and manner determined or approved by CMS, and as may be detailed in the WISeR Participant Guide.

F. The WISeR Participant must educate WISeR Providers and WISeR Suppliers within its assigned WISeR Jurisdiction about the Prior Authorization Process consistent with the provisions of this Agreement and the WISeR Participant Guide.

Section 3.8 Operational Requirements

A. The WISeR Participant shall promote corporate integrity and establish internal controls and an effective compliance program to achieve Agreement goals and objectives.

B. The WISeR Participant shall work collaboratively with CMS, WISeR Providers, WISeR Suppliers, Medicare Administrative Contractors, and other CMS contractors to foster integration of Medicare operations.

C. The WISeR Participant shall develop and continually refine business processes to foster excellence and quality in the administration of the Medicare program.

D. The WISeR Participant shall foster efficiencies in the administration of the Medicare FFS program to promote best value for the government.

E. The WISeR Participant shall use innovative and creative solutions to improve program operations.

Section 3.9 Overlap with Other CMS Programs and Initiatives

A. The parties agree that the WISeR Model is not a shared savings model and there is no Beneficiary alignment in this Model.

B. The WISeR Participant may simultaneously participate in the WISeR Model and any other Innovation Center model.

C. CMS reserves the right to unilaterally update this overlaps policy upon written notice to the WISeR Participant.

Article IV. Beneficiary Eligibility, Engagement, Verification, and Protections

Section 4.1 Beneficiary Eligibility

A. To be considered a WISeR Beneficiary, a Beneficiary must meet the following criteria:

1. Be identified on a Prior Authorization request or a claim subject to Pre-Payment Review for a Select Item or Service from a WISeR Provider or WISeR Supplier in the WISeR Participant's WISeR Jurisdiction;

2. Is eligible for Medicare Part A and enrolled in Medicare Part B at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review;
3. Is a legal adult aged 18 years or older;
4. Is not enrolled in Medicare Advantage at the time of the Prior Authorization request or the date of service on the claim subject to Pre-Payment Review;
5. Has Medicare as the primary payer at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review; and
6. Is not covered under the United Mine Worker Health and Retirement Funds.

Section 4.2 Beneficiary Engagement and Beneficiary Verification

A. The WISeR Participant does not have Beneficiaries aligned or assigned to it for this Model.
B. CMS may require the WISeR Participant to educate Beneficiaries, including WISeR Beneficiaries, within its WISeR Jurisdiction on the Prior Authorization Process for Select Items and Services.
C. The WISeR Participant must ensure that each Prior Authorization request submitted by a WISeR Provider, WISeR Supplier, or a MAC is for a Select Item or Service that will be furnished to a WISeR Beneficiary within the WISeR Jurisdiction.

Section 4.3 Beneficiary Protections and Non-Affirmed Decisions

A. The WISeR Participant shall provide written Prior Authorization Process decisions to the WISeR Provider and/or WISeR Supplier with a copy to the applicable WISeR Beneficiary and appropriate MAC.
B. The WISeR Participant's Prior Authorization Non-Affirmation decision for the Select Item or Service that is determined to not be Medically Necessary must require the WISeR Provider or WISeR Supplier to notify the WISeR Beneficiary and issue an Advance Beneficiary Notice of Non-coverage (ABN) prior to performing such item(s) or service(s) if it is expected that payment would be denied.
C. For purposes of the WISeR Provider and WISeR Supplier notifications required under Sections 4.3.A and 4.3.B, the WISeR Participant shall use a template letter provided by CMS, in which CMS will designate letter content that the WISeR Participant shall not change, as well as places in which the WISeR Participant may insert its own original content.
D. Beneficiaries continue to have all applicable administrative appeal rights under Original Medicare.

Section 4.4 Prohibition on Beneficiary Inducements

Except as otherwise permitted by applicable law, the WISeR Participant shall not provide gifts or other remuneration to Beneficiaries to induce them to receive or to continue to receive items or services from one or more of the following: WISeR Providers, WISeR Suppliers, WISeR Clinicians, or WISeR Clinical Reviewers.

Section 4.5 HIPAA Requirements

A. The WISeR Participant acknowledges that it is either a covered entity or business associate, as those terms are defined in 45 C.F.R. § 160.103, of CMS that is a covered entity.
B. The WISeR Participant shall have all appropriate administrative, technical, and physical safeguards in place before the Start Date to protect the privacy and security of protected health information ("**PHI**") in accordance with 45 C.F.R. § 164.530(c).
C. The WISeR Participant shall maintain the privacy and security of all Model-related information that identifies individual Beneficiaries in accordance with the Health Insurance Portability and Accountability Act ("**HIPAA**") Privacy and Security Rules and all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of PHI by covered entities and their business associates, as well as all other applicable federal and state laws and regulations.

Article V. Functional Requirements

Section 5.1 Functional and Infrastructure Requirements

A. The WISeR Participant shall develop, execute, and maintain a risk management plan that includes:
    1. WISeR Jurisdiction-wide risks, including without limitation risks related to cybersecurity issues;
    2. Periodic assessment, conducted monthly at a minimum, of new risks; and
    3. Mitigation and contingency planning.
B. The WISeR Participant shall provide and use infrastructure to fulfill the requirements of this Agreement.
C. The WISeR Participant shall provide the infrastructure required to integrate and interact with the assigned CMS Virtual Data Center ("**VDC**") and to accomplish services not provided by the VDC to fulfill the requirements of this Agreement.
    1. The WISeR Participant shall work with all Base Function entities, including the VDC, to interface and/or facilitate the receipt or transmission of files, programs or other such products.

2. **Base Functions** are functions provided either by the shared system or the VDC and include interfaces that are part of the base system processing such as the Common Working File (CWF), Comprehensive Error Rate Testing (CERT), Correct Coding Initiative (CCI), BDRD, PECOS, PIMR, Pricer, PULSE, etc.
3. **Non-base/Non-core applications or interfaces** refers to any applications or interfaces that are not part of the base system processing or are not provided or maintained as part of the Medicare Shared Systems (FISS or MCS).
    i. Non-base/non-core applications or interfaces may involve an outside vendor, a Medicare Data Center, or any entity with which the WISeR Participant communicates or shares information through a software application (not including commercial word processing or spreadsheet programs) in processing Medicare claims.
    ii. Examples of non-base/non-core processes include but are not limited to the following:
        a. Print mail;
        b. American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N Transaction Translation Services (via Commercial Off the Shelf (COTS) products);
        c. Workload Management reports;
        d. Scanning Administration;
        e. ICR/OCR Imaging;
        f. Fraud, Waste, or Abuse reporting;
        g. Data Analysis (Easytrieve, SAS extracts, etc.); and
        h. Data files the WISeR Participant routinely receives.

D. The WISeR Participant shall provide translation software that is HIPAA-compliant and strictly adheres to the ASC X12N Technical Report Type 3 (TR3s) for inbound transactions (e.g., ASC X12N claim, ASC X12N 276 claim status request) and outbound transactions (e.g., ASC X12N 835 remittance advice, ASC X123N 277 claim status response, ASC X12N TA1 interchange acknowledgement, ASC X12N 999 implementation acknowledgment, ASC X12N 277 claim acknowledgment).

E. In the event of termination by CMS or the WISeR Participant pursuant to Article XIII, the WISeR Participant shall be required to perform certain closeout activities detailed by CMS in a form and manner and by the date(s) specified by CMS.

Section 5.2 Telecommunications

A. Unless directed to use another connection by CMS, the WISeR Participant shall use only the CMS-supplied telecommunications network to transmit Medicare data to ensure the privacy and security of this protected information for:
    1. Medicare communications between the WISeR Participant and Medicare Administrative Contractor(s), if any;
    2. Communications between the WISeR Participant and subcontractors, if any; and
    3. Communications between the WISeR Participant and CMS.
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.
C. As applicable, the WISeR Participant shall interact with CMS' current enterprise identity access management systems, or any future enterprise identity access management system as directed by CMS, to ensure that the electronic data interchange (EDI) submitter/receiver is an authorized EDI submitter for each transaction.
D. As applicable, the WISeR Participant shall be responsible for the verification/validation of the WISeR Providers and WISeR Suppliers that will be exchanging EDI with the WISeR Participant.

Section 5.3 CMS Audits and Reviews of Software

A. The WISeR Participant shall allow CMS the use of provided software and software documentation, tools, and equipment to conduct audit reviews, tests, and assessments of the WISeR Participant at its facility, its data center and/or in its data cloud.
B. Consistent with Section 5.3.A, the WISeR Participant shall allow CMS use and access to, without limitation, the WISeR Participant's Enhanced Technology, artificial intelligence, machine learning technology, and other similar technologies.

Article VI. Prior Authorization Process

Section 6.1 General

A. The WISeR Participant shall use its Enhanced Technology to review and assess Prior Authorization requests within its assigned WISeR Jurisdiction ("**Prior Authorization Process**").

B. The WISeR Participant must review and assess each Prior Authorization request to ensure that the request meets the following criteria:
    1. Include all documentation necessary to show that the Select Items and Services meet applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The Prior Authorization request is submitted before the Select Items and Services are provided to the WISeR Beneficiary and before the claim is submitted.
C. The WISeR Participant reviews and assesses each expedited Prior Authorization request to ensure that the expedited request meets the following criteria:
    1. Includes all documentation necessary to show that the Select Item or Service meets applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The expedited Prior Authorization request is submitted before the Select Item or Service is provided to the WISeR Beneficiary and before the claim is submitted.
    3. Includes documentation showing that the processing of the Prior Authorization must be expedited due to the WISeR Beneficiary's life, health, or ability to regain maximum function being in serious jeopardy.
D. The WISeR Participant shall evaluate and refine its Prior Authorization Process to ensure accuracy in its Prior Authorization determinations and to prevent harm to Beneficiaries, including WISeR Beneficiaries.
E. The WISeR Participant shall engage in activities such as Navigation Services to reduce clinically inappropriate care and promote clinically appropriate care with its WISeR Providers and WISeR Suppliers in a form and manner and by the date(s) specified by CMS.
F. The WISeR Participant shall report Prior Authorization Process related activities and metrics to CMS through monthly, yearly, and ad hoc reports in a form and manner and by the date(s) specified by CMS.

Section 6.2 Prior Authorization Process and Exemption Status

A. General. 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).
B. Upon receipt of a Prior Authorization, the WISeR Participant shall review the request for compliance with applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act.

1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to the Select Items and Services detailed in Table 1 of Appendix A of this Agreement.
2. The WISeR Participant shall verify that the Prior Authorization is for a Select Item or Service as detailed in Table 1 of Appendix A.
3. The WISeR Participant must further verify that the Prior Authorization request is from a WISeR Provider or WISeR Supplier within the WISeR Jurisdiction.
4. The WISeR Participant shall verify that the requested Select Item or Service would be furnished to an individual that is a WISeR Beneficiary.

C. The WISeR Participant, its WISeR Clinician(s) and its WISeR Clinical Reviewers shall conduct Medical Review of the Prior Authorization, any Resubmissions, render determinations, and communicate decisions to the WISeR Providers, WISeR Suppliers, and WISeR Beneficiaries in accordance with the terms of this Agreement and the applicable requirements detailed in the WISeR Participant Guide.

D. Resubmission. The WISeR Participant shall accept Resubmissions from a WISeR Provider or WISeR Supplier for a Select Item or Service.
1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to each Resubmission; or
2. At the request of the WISeR Provider or WISeR Supplier through its Resubmission, the WISeR Participant shall require its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, to perform peer-to-peer review of the Resubmission. Such peer-to-peer review activities and requirements are detailed in the WISeR Participant Guide and the WISeR Participant acknowledges and agrees that its WISeR Clinicians and WISeR Clinical Reviewers will comply with such requirements.

E. Exemption Status. The WISeR Participant shall provide Exemption Status to a WISeR Provider or WISeR Supplier that has:
1. Submitted the minimum number of Prior Authorization requests for Select Items and Services furnished to WISeR Beneficiaries within the WISeR Jurisdiction as detailed in the WISeR Participant Guide;
2. Has met the CMS threshold percentage of Prior Authorization Provisional Affirmations as detailed in the WISeR Participant Guide; and
3. Met any additional criteria set forth by CMS in the WISeR Participant Guide.

F. Exemption Status List. The WISeR Participant shall retain current and historical lists of WISeR Providers and WISeR Suppliers that have earned Exemption Status.
1. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it has earned Exemption Status and has been added to the Exemption Status list.

i. The WISeR Participant shall specify in its notice to the WISeR Provider or WISeR Supplier the effective date of its Exemption Status, the process for retaining Exemption Status, and provide such other details as described in the WISeR Participant Guide.

2. The WISeR Participant shall provide current and historical Exemption Status lists to CMS in a form and manner and by the date(s) specified by CMS in accordance with the terms of this Agreement and applicable requirements set forth in the WISeR Participant Guide.
3. The WISeR Participant may remove a WISeR Provider or WISeR Supplier from the Exemption Status list if it fails to meet the requirements for Exemption Status as described in the WISeR Participant Guide.
4. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it is removed from the Exemption Status list and such notice shall specify the effective date of removal, the process for re-earning Exemption Status, and provide such other details as described in the WISeR Participant Guide.

Section 6.3 Prior Authorization Determinations

A. Determination Letters.

1. CMS may develop and provide to the WISeR Participant and Model Participants template determination letters.
2. Upon request of the WISeR Participant to CMS, and at the discretion of CMS, the WISeR Participant may create its own template determination letter(s), and such template(s) must be submitted to CMS for review and written approval prior to use and include at a minimum the following information and any other information as specified in the WISeR Participant Guide:
    i. A Unique Tracking Number (UTN);
    ii. For Prior Authorization Non-Affirmation decisions:
        a. A detailed explanation for the decision;
        b. The availability of unlimited resubmissions by the WISeR Provider or WISeR Supplier;
        c. Instructions for how the WISeR Provider or WISeR Supplier may request peer-to-peer review; and
        d. The opportunity to forego the resubmission process, provide one or more of the Select Items and Services, submit the claim for payment and:
            1. The claim will be denied; and
            2. All Medicare appeal rights will be available.
    iii. For re-routed Prior Authorization decisions:

a. Contact information for the WISeR Participant;
b. Instructions to the requesting WISeR Provider and/or WISeR Supplier on how it may choose to submit future Prior Authorization requests for Select Items and Services directly to the WISeR Participant; and
c. Any additional information that CMS may require through written notification to the WISeR Participant.

3. If CMS determines that the template(s) submitted by the WISeR Participant contains misinformation or is otherwise inconsistent with the terms of this Agreement or the WISeR Participant Guide, CMS may reject the template(s) or require the WISeR Participant to amend the template(s) and resubmit such amended template(s) to CMS for review and approval prior to use.

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.

C. Resubmission of Prior Authorization.
1. The WISeR Participant shall issue a Resubmission Determination to the WISeR Provider or WISeR Supplier within 3 Days of the WISeR Participant's receipt of the Prior Authorization resubmission.
2. The WISeR Participant shall ensure the Resubmission Determination is delivered to the WISeR Provider or WISeR Supplier in the same manner it was submitted via postmark, fax, or electronic delivery.

D. Expedited Circumstances. The WISeR Participant may only consider an expedited review of a Prior Authorization request upon receipt of request for expedited review by the WISeR Provider or WISeR Supplier.
1. If the WISeR Participant, in consultation with its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, determines that delays in receipt of a Prior Authorization decision could jeopardize the life, health, or ability to regain maximum function of the WISeR Beneficiary, then the WISeR Participant will process the Prior Authorization under an expedited timeframe, upon request.
i. The WISeR Participant will communicate a determination within 2 business days of receipt of the expedited request.

ii. WISeR Providers and WISeR Suppliers, and their MAC(s) when applicable, are encouraged to use fax, Electronic Submission of Medical Documentation (esMD), or any other CMS approved electronic portal to avoid delays with mailing.

E. Prior Authorization Provisional Affirmation. The WISeR Participant will issue a Prior Authorization Provisional Affirmation of coverage to a WISeR Provider or WISeR Supplier, with a copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and any applicable criteria in the WISeR Participant Guide are met to support the rendering of such item or service to a WISeR Beneficiary.

1. The WISeR Participant's Prior Authorization Provisional Affirmation decision is valid for 120 days from the date the determination was made.

F. Prior Authorization Non-Affirmation.

1. Consistent with Section 3.6.B.2 and Section 3.6.E.2, the WISeR Participant must require its WISeR Clinician(s) and WISeR Clinical Reviewer(s), as applicable, to perform a Medical Review of each Prior Authorization request that may not meet Medicare Coverage Criteria.
    i. The Medical Review of a Prior Authorization request by a WISeR Clinician or WISeR Clinical Reviewer, as applicable, must be performed before the WISeR Participant issues a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier.
2. The WISeR Participant will issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier, with copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and applicable criteria in the WISeR Participant Guide are not met and do not support the rendering of such item or service to a WISeR Beneficiary.
3. The WISeR Participant may issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier for a Select Item or Service via the same method it was requested if the Prior Authorization request contains technical errors or is otherwise insufficient to meet the requirements for Prior Authorization Provisional Affirmation.

G. Appeals. The WISeR Participant acknowledges and agrees that nothing in this Agreement nor in the WISeR Participant Guide shall be construed to limit or otherwise prevent a WISeR Provider, WISeR Supplier, WISeR Beneficiary or Beneficiary from

engaging in the Medicare appeals process permitted by applicable law, regulations, or Medicare program requirements.

Section 6.4 Prior Authorization Non-Affirmation and Resubmissions

A. The WISeR Participant shall provide written notice consistent with Section 6.3.A of this Agreement to the WISeR Provider or WISeR Supplier that the WISeR Provider or WISeR Supplier may resubmit a Prior Authorization upon receipt of a Prior Authorization Non-Affirmation.
B. The WISeR Participant shall provide written notice, consistent with Section 6.3.A, to the WISeR Provider or WISeR Supplier that it may resubmit a Prior Authorization for expedited review consistent with the requirements in Section 6.3.D of this Agreement.
C. The WISeR Participant shall consider all Resubmissions for Prior Authorization received within 120 Days of the Initial Prior Authorization Determination.
D. The WISeR Participant shall review a Resubmission for Prior Authorization received after 120 Days of the Initial Prior Authorization Determination as an Initial Prior Authorization request.

Section 6.5 Pre-Payment Review

A. The WISeR Participant acknowledges that Prior Authorization is not a condition of payment to the WISeR Provider or WISeR Supplier.
B. The WISeR Participant agrees that the WISeR Provider or WISeR Supplier may elect not to submit a Prior Authorization before furnishing one or more of the Select Items and Services to a WISeR Beneficiary.
C. If the WISeR Provider or WISeR Supplier elects not to submit a Prior Authorization for one or more Select Items and Services it furnishes to a WISeR Beneficiary, then the WISeR Participant shall coordinate with the appropriate MAC to subject the claim to Pre-Payment Review consistent with the terms of this Agreement, Sections 6.5.C.1 and 6.5.C.2, and the requirements detailed in the WISeR Participant Guide.
    1. CMS, through its appropriate MAC, will flag claims submitted by the WISeR Provider or WISeR Supplier for Select Items and Services without a Prior Authorization request.
    2. CMS, through its appropriate MAC, will re-route flagged claims to the WISeR Participant for Pre-Payment Review.
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.

Article VII. Quality Performance

Section 7.1 Quality Score

CMS shall use the quality score in determining the WISeR Participant's Aggregate Quality Score ("**AQS**") according to the methodology described in this Article VII and the WISeR Data Reporting Guide.

Section 7.2 Quality Measures

A. General
   1. The WISeR Participant shall complete reporting for all quality measures and for all Prior Authorizations received, Prior Authorization Provisional Affirmations, Prior Authorization Non-Affirmations, and Resubmissions in accordance with the WISeR Data Reporting Guide.
   2. CMS will publish, at least annually, a WISeR Data Reporting Guide, detailing the WISeR quality reporting requirements.
   3. CMS may modify the WISeR Performance Measure Set, or the number of measures that the WISeR Participant must report, or both. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Performance Measure Set at least 30 Days prior to the effective date of the change.
      i. If CMS removes a quality measure from the WISeR Performance Measure Set in advance of a Performance Period, CMS will not use the removed quality measure to evaluate the WISeR Participant, and the WISeR Participant will not be accountable for performance on such quality measures during the relevant Performance Period.

B. WISeR Performance Measure Set
   1. The WISeR Participant shall report all measures to CMS that are listed in the WISeR Performance Measure Set as described in Appendix B to this Agreement and the WISeR Data Reporting Guide. CMS shall use these measures for the purposes of calculating the WISeR Participant's AQS, the monitoring and evaluation of the overall efficiency and accuracy in WISeR, and to evaluate the WISeR Participant's performance during the Model.
   2. CMS will determine what version of specifications will be used for each measure included in the WISeR Performance Measure Set for the applicable Performance Period. CMS will notify the WISeR Participant of the version of specifications that will be used for each measure included in the WISeR Performance Measure Set as early as possible after such information becomes available.

3. The WISeR Participant must report all required measures from the WISeR Performance Measure Set in order to be eligible to earn the WISeR Payment for a Performance Period in accordance with Section 8.3.

C. Quality Measure Reporting
   1. The WISeR Participant must submit all quality measures that are listed in the WISeR Performance Measure Set to CMS during the defined reporting period for quality measures as communicated in the WISeR Data Reporting Guide.
   2. CMS reserves the right to require submission via any other format, including the Fast Healthcare Interoperability Resources ("**FHIR®**") standard, at any time during the Agreement Term without the consent of the WISeR Participant. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the reporting format of measures at least 90 Days prior to the measurement period.
   3. The WISeR Participant shall comply with the requirements described in this Article VII and Appendix B of this Agreement, and the requirements detailed in the WISeR Data Reporting Guide.

Section 7.3 Collection of Data and Purpose

A. Pursuant to 42 C.F.R. § 403.1110(b), the WISeR Participant must collect and report data described in Section 7.2 to CMS for CMS' Model monitoring and evaluation purposes.
B. The WISeR Participant, at CMS' request, will administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
C. CMS reserves the right to administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
D. CMS may require the WISeR Participant to implement surveys of WISeR Providers, WISeR Suppliers, and/or WISeR Beneficiaries in the WISeR Participant's designated WISeR Jurisdiction and report any survey measures included in the WISeR Data Reporting Guide to CMS.

Section 7.4 Quality Performance Scoring

A. CMS will calculate the WISeR Participant's AQS for each Performance Period at the time of Reconciliation.
B. CMS will calculate the AQS based on quality measures specified in the WISeR Data Reporting Guide.

C. CMS will calculate the AQS by totaling the quality points for all quality measures included in the AQS calculation for a given Performance Period and dividing by the maximum quality points available for these included quality measures.
D. CMS may modify the methodology for Quality Performance Scoring and shall notify the WISeR Participant in writing at least 30 Days before the start of the Performance Period in which such change would take effect. Modifications to the Quality Performance Scoring methodology may include, but are not limited to:
    1. Modifications to the set of quality measures included in the AQS;
    2. Modifications to the point values and point distributions for one or more quality measures included in the AQS;
    3. Modifications to the benchmark for one or more quality measures included in the AQS; and
    4. Modifications to the metrics for one or more quality measures included in the AQS.
E. CMS will convert the AQS to a quality multiplier that will be applied to each WISeR payment for the applicable Performance Period, as detailed in the WISeR Data Reporting Guide.

Article VIII. Financial Management and Payment

Section 8.1 General

A. CMS shall make, adjust, settle, and seek repayment of WISeR Payments in accordance with this Article VIII and Article XIII.
B. CMS may unilaterally amend Article VIII and to the extent practicable will issue advance written notice to the WISeR Participant 30 Days before the start of the Performance Period in which the amendment would take effect.

Section 8.2 Financial Management Requirements

A. The WISeR Participant shall promote the fiscal integrity of the Medicare FFS program and be an accountable steward of public funds.
B. The WISeR Participant shall adhere to the CMS Medicare integrity program.

Section 8.3 WISeR Payments

A. General.
    1. CMS pays the WISeR Payment to the WISeR Participant, as set forth in this Article VIII, subject to initial Reconciliation, financial settlement, and recoupment.

2. The WISeR Participant may receive a WISeR Payment for each Pre-Payment Review that results in a denied claim for a Select Item or Service and for each Payable Non-Affirmation.
3. CMS shall not pay the WISeR Participant a WISeR Payment if the WISeR Participant conducts a Prior Authorization or a Pre-Payment Review and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
4. The WISeR Participant owes a WISeR Recoupment and shall remit all WISeR Recoupments to CMS if Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to a WISeR Beneficiary due to the successful appeal of a claim denial.
5. CMS calculates the WISeR Payment as set forth in Section 8.3.D.

B. Calculation of Regional Benchmark.

1. For each Performance Period and each Locality within the WISeR Participant's designated WISeR Jurisdiction, CMS determines a Locality-specific Regional Benchmark for each of the Select Items and Services identified in Table 1 of Appendix A of this Agreement.
2. Except as specified in Section 8.3.B.3, CMS calculates the Regional Benchmark by:
    i. Identifying all claims that were submitted within the state that include the applicable Locality, were submitted by a WISeR Provider or a WISeR Supplier, include the applicable Select Item or Service, and have a date of service in the 12 months preceding the start of the applicable Performance Period;
    ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the Locality and applicable to the calendar year that includes the Performance Period being reconciled; and
    iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.
3. In the event change in law or Medicare policy changes effective during the Agreement Performance Period and applicable to a Select Item(s) or Service(s), CMS may, at its sole discretion, calculate the Regional Benchmark for the applicable Select Item or Service for one or more Performance Periods by:

i. Identifying all claims for the Select Item or Service that were submitted by Medicare-enrolled providers or suppliers within the WISeR Participant's designated MAC Jurisdiction with a date of service that is:
    a. No earlier than the effective date of the applicable legislation or Medicare policy change;
    b. No earlier than 9 months before the start of the applicable Performance Period; and
    c. No later than the final Day of the applicable Performance Period; and
ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the calendar year that includes the Performance Period being reconciled; and
iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.

4. When calculating the average claim-level payment as set forth in Section 8.3.B.2.iii and Section 8.3.B.3.iii, CMS may exclude payments for certain items or services billed on the same claim as the applicable Select Item or Service. CMS will maintain a list of such exclusions in the WISeR Participant Guide.

C. WISeR Discount. CMS calculates the WISeR Discount separately by state for each of the Select Items and Services as the percentage of claims with a medical necessity denial among all claims submitted by WISeR Providers and WISeR Suppliers within the state for that Select Item or Service with a date of service in 12 months preceding the start of the Model Performance Period. CMS may modify the WISeR Discount, including the dates of service for claims included in the calculation of the WISeR Discount, and to the extent practicable will provide 30 Days' advance written notice before the effective date of such modifications.

D. WISeR Payment. The WISeR Participant may earn a WISeR Payment for each Payable Non-Affirmation and for each Pre-Payment Review resulting in a denied claim for a Select Item or Service.

1. CMS calculates the WISeR Payment for each Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state;
    ii. Multiplying by the WISeR payment rate of 25 percent; and
    iii. Applying the quality adjustment determined by the WISeR Participant's AQS.

2. CMS calculates the WISeR Payment for each Pre-Payment Review resulting in a denied claim for a Select Item or Service by:
    i. Calculating the amount billed on the claim, less any approved payments for services other than the Select Item or Service that were billed on the same claim and less any denied payments billed on the same claim for one or more excluded service(s) noted in the WISeR Participant Guide;
    ii. Reducing the amount set forth in Section 8.3.D.2.i by the WISeR Discount applicable to the Select Item or Service and state;
    iii. Multiplying by the WISeR payment rate of 25 percent; and
    iv. Applying the quality adjustment determined by the WISeR Participant's AQS.

E. WISeR Recoupment. CMS will recoup a WISeR Recoupment from the WISeR Participant if CMS pays the WISeR Participant a WISeR Payment and Medicare subsequently pays the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
    1. The amount of the WISeR Recoupment will equal the amount of the previous WISeR Payment that CMS paid to the WISeR Participant for the applicable Payable Non-Affirmation or Pre-Payment Review.
    2. CMS will identify any WISeR Recoupments on a quarterly basis.
    3. To the extent possible, CMS will net any WISeR Recoupments against the total of WISeR Payments for a future Performance Period as set forth in Section 8.5.
    4. If CMS cannot collect WISeR Recoupments for claims appeals adjudicated after the Reconciliation of the final Performance Period under the Agreement or any other CMS program or initiative, CMS shall issue a demand letter to the WISeR Participant and the WISeR Participant shall pay CMS the amount owed within 30 Days of the date of demand letter.
    5. If CMS does not timely receive payment in full, the remaining amount owed will be considered a delinquent debt subject to the provisions of Section 8.8.D.

Section 8.4 Advance WISeR Payment

A. At the sole discretion of CMS, CMS may pay the WISeR Participant an Advance WISeR Payment prior to completing Reconciliation for a given Performance Period.

B. Eligibility Criteria.
    1. At the sole discretion of CMS, CMS may provide an Advance WISeR Payment to the WISeR Participant for an applicable Performance Period.

2. The WISeR Participant may be eligible to receive an Advance WISeR Payment during an applicable Performance Year if:
    i. CMS has notified the WISeR Participant of the availability of an Advance WISeR Payment for a specified Performance Period;
    ii. CMS has detailed specific data elements that the WISeR Participant must report to CMS in a form and manner and by the date(s) specified by CMS ("**Preliminary Data**");
    iii. The WISeR Participant timely reports the required data elements to CMS; and
    iv. CMS has approved the WISeR Participant's reported data elements and eligibility for an Advance WISeR Payment for the specified Performance Period.
3. If CMS determines that the WISeR Participant has not timely or accurately reported all required data elements, then CMS may deem the WISeR Participant ineligible for an Advance WISeR Payment for the applicable Performance Period.
4. If CMS has approved the WISeR Participant's eligibility for an Advance WISeR Payment for the applicable Performance Period, then CMS calculates the Advance WISeR Payment as set forth in Section 8.4.D.
5. In applicable Performance Periods, CMS will calculate the Advance WISeR Payment no earlier than the first Day after the end of the Performance Period.

C. Adjustments to Future WISeR Payment(s). If CMS determines that the WISeR Participant is eligible to receive an Advance WISeR Payment, CMS will net the amount of the Advance WISeR Payment against future WISeR Payments, including as applicable:
    1. Any WISeR Payments that CMS calculates for the applicable Performance Period during Reconciliation; and
    2. Any WISeR Payments that CMS calculates for subsequent Performance Periods.

D. Calculation of an Advance WISeR Payment. CMS calculates an Advance WISeR Payment using Preliminary Data for the Performance Period submitted by the WISeR Participant as set forth in Section 8.4.B. CMS calculates the Advance WISeR Payment for the applicable Performance Period as follows:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will provisionally determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will provisionally identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will estimate the WISeR Payment for each provisionally identified Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state; and
    ii. Multiplying by the WISeR payment rate of 25 percent.
5. CMS will estimate the WISeR Payment for each provisionally identified Pre-Payment Review qualifying for a WISeR Payment by:
    i. Calculating the amount billed on the claim, less any payments for services other than the Select Item or Service that were billed on the same claim;
    ii. Reducing this amount by the WISeR Discount applicable to the Select Item or Service and state; and
    iii. Multiplying by the WISeR payment rate of 25 percent.
6. CMS will total the estimated WISeR Payments as set forth in Section 8.4.E.4 and Section 8.4.E.5 and multiply this total by 50 percent to obtain the Advance WISeR Payment.

Section 8.5 Reconciliation Process

A. CMS will perform Reconciliation for a Performance Period by completing the following calculations:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will calculate the AQS for the WISeR Participant as set forth in Section 7.4 and in the WISeR Data Reporting Guide.
5. CMS will calculate the WISeR Payment as set forth in Section 8.3.D.
6. CMS will identify any pending WISeR Recoupments as set forth in Section 8.3.E. and will net these WISeR Recoupments against the total of WISeR Payments for the Performance Period.

B. CMS will perform Reconciliation for a Performance Period no earlier than the Day after the last Day on which a Resubmission for a Prior Authorization may be submitted, except as otherwise provided in Section 8.5.C.
    1. After calculating the WISeR Payment amount for the Reconciliation for a Performance Period, CMS will compare this amount against any WISeR Payment that was calculated in the initial Reconciliation for the same Performance Period and already paid or recouped by CMS, to determine the net amount of any WISeR Payment still owed for that Performance Period.
    2. If CMS issues a Reconciliation Report detailing the results of the Reconciliation, as described in Section 8.6, simultaneously with the Reconciliation Report detailing the results of the initial Reconciliation for a subsequent Performance Period, CMS may net any WISeR Payment amount specified in the Reconciliation Report for the initial Reconciliation against the net WISeR Payment amount that CMS calculates for the Reconciliation in accordance with Section 8.5.B.1.
C. If the Agreement or Agreement Performance Period is terminated pursuant to Article XIII, CMS shall conduct an initial Reconciliation and a final financial settlement, in accordance with Section 8.9, for the WISeR Participant's final Performance Period, which shall include all Prior Authorizations and Pre-Payment Reviews conducted by the WISeR Participant through the effective date of termination or expiration of this Agreement.

Section 8.6 Reconciliation Report

A. After performing Reconciliation for a given Performance Period as set forth in Section 8.5, CMS shall issue a Reconciliation Report to the WISeR Participant.
B. The Reconciliation Report will set forth the calculation of the WISeR Participant's Regional Benchmarks, AQS, Payable Non-Affirmations, and any applicable WISeR Payment for that Performance Period. In accordance with Section 8.5, the Reconciliation Report for any subsequent Reconciliation for a given Performance Period will also set forth any necessary adjustments to the WISeR Payment amount, if applicable, calculated in the initial Reconciliation for that Performance Period.
C. CMS shall make reasonable efforts to issue the initial Reconciliation Report for each Performance Period within 6 months after the last Day of that Performance Period.
D. Unless CMS receives a timely calculation error notice in accordance with Section 8.7, the Reconciliation Report shall be deemed final 30 Days from the date of issuance by CMS.

Section 8.7 Reconciliation Report Calculation Error

A. The WISeR Participant may contest a Reconciliation Report in accordance with this Section 8.7.
B. The WISeR Participant shall have 30 Days from the date the Reconciliation Report is issued to provide written notice to CMS of an error in the calculation of the WISeR Payment specified in that Reconciliation Report. The calculation error notice must contain a detailed, written explanation of the basis for the calculation error, including any supporting documentation.
C. If CMS receives a timely calculation error notice, CMS shall issue a written determination within 30 Days to either confirm or revise the calculation error, although CMS may extend the deadline for its determination upon written notice to the WISeR Participant.
    1. If CMS issues a written determination that the amount was calculated in error, CMS shall issue a revised Reconciliation Report, which is final on the date of issuance. The WISeR Participant may dispute the revised Reconciliation Report in accordance with Article XIV if the dispute is not precluded from review.
    2. If CMS issues a written determination that the amount is correct, the Reconciliation Report is final on the date the determination is issued.
    3. The WISeR Participant may dispute the determination issued by CMS in accordance with Article XIV if the dispute is not precluded from review.

D. If the WISeR Participant does not submit a timely calculation error notice to CMS in accordance with this Section 8.7, the WISeR Participant is precluded from later contesting the WISeR Payment amounts specified in that Reconciliation Report.
E. If as a result of any later inspection, evaluation, investigation, or audit, it is determined that any WISeR Payment amounts have been calculated in error, CMS may adjust such amounts, issue a revised Reconciliation Report, and make or demand payment of any additional amounts owed in accordance with this Section 8.7.

Section 8.8 Payment of Amounts Owed

A. CMS will pay the WISeR Participant any WISeR Payment amount owed to the WISeR Participant that is specified in Reconciliation Report within 30 Days after the date the Reconciliation Report is deemed final, as set forth in this Section 8.8.
B. CMS shall issue to the WISeR Participant a demand letter for any WISeR Payment owed pursuant to a Reconciliation Report that has been deemed final. The demand letter will be sent to the WISeR Participant at the address specified on the most recent Electronic Funds Transfer Authorization Agreement submitted by the WISeR Participant in accordance with Section 3.1.E.
C. The WISeR Participant shall pay any WISeR Payment amount owed to CMS within 30 Days of the date of a demand letter.
D. Delinquent Debt
    i. If the WISeR Participant fails to pay amounts due to CMS in full by the date specified in any demand letter, CMS shall assess simple interest on the unpaid balance at the rate applicable to other Medicare debts under 42 C.F.R. § 405.378. Interest shall be calculated in 30-Day periods and shall be assessed for each 30-Day period that payment is not made in full. Any payments received by CMS first shall be applied toward accrued interest and then to any outstanding principal balance due.
    ii. If CMS does not receive payment in full by the date the payment is due, CMS shall invoke all legal means to collect the debt and will use any applicable debt collection tools, including referral of the debt to the United States Department of Treasury, pursuant to 31 U.S.C. § 3711(g).

Section 8.9 Financial Settlement Report

A. Upon the expiration or termination of the Agreement Performance Period, CMS will issue to the WISeR Participant a financial settlement report that sets forth the amount of any WISeR Recoupments that the WISeR Participant must repay to CMS

or the amount of any WISeR Payment that CMS must make to the WISeR Participant, in accordance with this Agreement ("**Financial Settlement Report**").

B. If the Financial Settlement Report indicates that CMS owes the WISeR Participant additional payment, CMS shall make such payment within 30 Days after the Financial Settlement Report is deemed final.

C. If the Financial Settlement Report indicates that the WISeR Participant owes CMS a WISeR Recoupment, CMS will issue the WISeR Participant a demand letter for such monies owed to CMS. The WISeR Participant shall pay CMS any WISeR Recoupment within 30 Days of the date of a demand letter. If CMS does not timely receive payment in full, the remaining monies owed shall be considered a delinquent debt in accordance with Section 8.8.D.

Section 8.10 Extreme and Uncontrollable Circumstances

A. CMS may, in its sole discretion, provide Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers if the WISeR Providers and WISeR Suppliers:

   1. Are located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act; and
   2. Are located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

B. CMS has the sole discretion to determine the time period during which Prior Authorization flexibilities are provided to the WISeR Participant's WISeR Providers and WISeR Suppliers.

C. In the event that CMS provides Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers, CMS will provide written notice to the WISeR Participant of any impact such flexibilities have on the terms of this Agreement.

D. The WISeR Participant shall identify, develop, and coordinate prevention, response, and recovery procedures to ensure the availability of critical resources, and facilitate the continuity of essential business functions in an emergency situation, including natural disasters, manmade incidents, catastrophic emergencies, and public health emergencies ("**Continuity of Operations (COOP) Plan**").

E. The WISeR Participant shall maintain a COOP Plan that addresses protection of the physical infrastructure and business continuity (with or without system availability) of mission essential functions, to include without limitation the Prior Authorization Process, and communicating to WISeR Providers and WISeR Suppliers.

F. The WISeR Participant's COOP Plan shall include an information technology (IT) contingency and disaster recovery plan that addresses identified IT risks and vulnerabilities including, without limitation, cybersecurity issues.

Article IX. Business Associate Agreement, Data Sharing and Reports

Section 9.1 Business Associate Agreement

A. The WISeR Participant agrees to execute a valid Business Associate Agreement ("**BAA**") with CMS no later than 5 Days after the Effective Date of this Agreement.
B. If the WISeR Participant fails to execute a valid BAA pursuant to Section 9.1.A by the date specified by CMS, CMS will terminate the Agreement or the Agreement Performance Period or both in accordance with Section 13.3.
C. The WISeR Participant's BAA with CMS shall be active and valid for the duration of the Agreement Term.
D. The WISeR Participant shall comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") Privacy, Security, and Breach Notification Rules (45 C.F.R. Part 160 & Part 164, subparts A through E) ("**HIPAA Rules**").
E. The parties agree that the terms and conditions of the executed BAA between the WISeR Participant and CMS are hereby incorporated by reference into this Agreement as if fully set forth herein.

Section 9.2 Data Sharing and Reports – General

A. The WISeR Participant shall implement information technology (IT) systems security controls in order to maintain the confidentiality, integrity, and availability of the Medicare systems operations in the event of computer incidents or physical disasters.
B. Subject to the limitations discussed in this Agreement, and in accordance with applicable law, including HIPAA and the regulations in 42 C.F.R. Part 2, in advance of the Start Date of this Agreement, during the Agreement Performance Period, and any other time deemed necessary by CMS, CMS will offer the WISeR Participant an opportunity to request certain Beneficiary-identifiable data and reports in accordance with the terms and conditions set forth in this Agreement and in the BAA.
C. The Beneficiary-identifiable data available for request are described in Section 9.3 of this Agreement and in the BAA between CMS and the WISeR Participant.
D. Consistent with 42 C.F.R. § 403.1110(b), the WISeR Participant shall report data metrics for monitoring and evaluation purposes related to the WISeR Participant's Prior Authorization Process that include without limitation:

1. The total number of Prior Authorizations received during the data reporting period with a detailed description of:
    i. The number of Prior Authorization Provisional Affirmations during the data reporting period; and
    ii. The number of Prior Authorization Non-Affirmations during the data reportion period; and
2. The time (e.g., Days, weeks, hours, etc.) taken for the WISeR Participant's Prior Authorization Process to reach a determination;
    i. The total number of Resubmissions for each Prior Authorization received during the data reporting window or for a previous data reporting window;
    ii. The number of reversals of the Initial Prior Authorization Determination.

Section 9.3 Provision of Certain Beneficiary-Identifiable Claims Data

A. At CMS' sole discretion based on CMS' available resources, the limitations in this Agreement, the limitations in the BAA, and applicable law, CMS and the WISeR Participant may share certain Beneficiary-identifiable data for Beneficiaries in the WISeR Jurisdiction subject to the Prior Authorization Process.
B. The Beneficiary-identifiable data includes the data and reports described in this Section 9.3.B.
    1. Detailed Beneficiary Claims Data. These data will include individual Beneficiary-identifiable Medicare FFS claims data for Select Items and Services provided to Beneficiaries within the WISeR Jurisdiction. This includes without limitation data on Medicare FFS expenditures and utilization, and Prior Authorization Process metrics (e.g., timing, Prior Authorization request determinations, Resubmissions of Prior Authorizations, etc.).
    2. Quality Performance Scoring Data. These data will include Beneficiary-identifiable data and quality performance data specific to the Prior Authorization Process.
C. The parties mutually agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by CMS.
D. The parties further agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by the WISeR Participant as it relates to the Prior Authorization Process.

E. The WISeR Participant represents, and in furnishing the data files specified in Section 9.3.B of this Agreement and the BAA CMS relies upon such representation, that such data files will be used solely for the purpose of carrying out the provisions of this Agreement to improve the efficiency and accuracy of Prior Authorizations, quality improvement activities, reducing health care costs for the Medicare FFS program without causing harm to Beneficiaries, identifying or reducing fraud, waste, and abuse in Medicare FFS, and such other purposes described int his Agreement. The WISeR Participant agrees not to disclosure, use, or reuse the data excepts as specified in this Agreement, the BAA, or except as CMS shall authorize in writing or as otherwise required by law. The WISeR Participant further agrees not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement and the BAA.

F. Information derived from the CMS data specified in Section 9.3.B of this Agreement and in the BAA may be shared and used within the legal confines of the WISeR Participant and its WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers and WISeR Suppliers in a manner consistent with the provisions of this Agreement and the BAA to improve the Prior Authorization Process and Beneficiary care.

G. The WISeR Participant may reuse original or derivative data without prior written authorization from CMS for quality improvement activities relating to improving health or reducing health care costs through the Prior Authorization Process, but shall not disseminate (unless required by law) any individually identifiable original or derived information from the data specified in Section 9.3.B of this Agreement to anyone who is not a HIPAA Covered Entity, a HIPAA Business Associate, a WISeR Clinician or WISeR Clinical Reviewer performing activities related to this Model, or a WISeR Provider or WISeR Supplier in treatment relationship with the subject WISeR Beneficiary. When using or disclosing PHI or personally identifiable information ("**PII**"), obtained from data specified in Section 9.3.B, the WISeR Participant must make "reasonable efforts to limit" the information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure, or request.

H. The WISeR Participant shall establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget ("**OMB**") in OMB Circular No. A-130, Appendix I – Responsibilities for Protecting and Managing Federal Information Resources (https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A130/a130revised.pdf) as well as Federal Information Processing Standard 200 entitled

"Minimum Security Requirement for Federal Information and Information Systems" (http:// (http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf); and, NIST Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" (http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf). The WISeR Participant acknowledges that the use of unsecured telecommunications, including the Internet, to transmit directly or indirectly identifiable information from the files specified in Section 9.2.B or any such derivative data files is strictly prohibited.

I. The WISeR Participant shall grant access to the data and/or the facility(ies) in which the data is maintained to the authorized representatives of CMS or Office of Inspector General of the Department of Health and Human Services ("**OIG**") for the purpose of inspecting to confirm compliance with the terms of this Agreement and the BAA.

J. The WISeR Participant agrees that any use of CMS data in the creation of any document concerning the purpose specified in this section must adhere to CMS' current cell size suppression policy. The policy stipulates that no cell (e.g., patients, services) representing 10 or fewer Beneficiaries may be displayed. Also, no percentages or other mathematical formulas may be used if they result in the display of a cell representing 10 or fewer Beneficiaries. A cell that represents or uses percentages or other mathematical formulas to represent zero Beneficiaries must be displayed.

Article X. Participation in Evaluation, Shared Learning Activities, and Site Visits

Section 10.1 Evaluation Requirement

A. General. The WISeR Participant shall participate and cooperate in any independent evaluation activities conducted by or on behalf of CMS aimed at assessing the impact of the Model on the goals of improving quality of care and reducing fraud, waste, and abuse expenditures for the Medicare program. The WISeR Participant shall require its WISeR Clinicians and WISeR Clinical Reviewers to participate and cooperate in any such independent evaluation activities conducted by or on behalf of CMS. Termination or expiration of this Agreement shall not affect the right of CMS to evaluate WISeR.

B. Primary Data. In its evaluation activities, CMS or its designee(s) may collect qualitative and quantitative data. These data may include, but are not limited to the following sources:

1. Site visits with the WISeR Participant;
2. Surveys or interviews with WISeR Providers and WISeR Suppliers;
3. Surveys or interviews with Beneficiaries and their caregivers;
4. Focus groups of WISeR Providers and WISeR Suppliers;
5. Focus groups of Beneficiaries and their caregivers;
6. Interviews with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
7. Focus groups with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
8. Direct observation of WISeR Provider and/or WISeR Supplier interactions with the WISeR Participant and its staff, and other activities related to the WISeR Participant's participation in the Model;
9. Review of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates; and
10. Surveys.

C. Secondary Data. In its evaluation activities, CMS may use data or information submitted by the WISeR Participant as well as claims submitted to CMS for Select Items and Services furnished to Beneficiaries. These data may include, but are not limited to:
    1. Claims data;
    2. Survey data from Patient Experience surveys;
    3. Medical records;
    4. Clinical data;
    5. Monitoring data (e.g., audit results, etc.); and
    6. Quality and clinical data submitted to CMS.
D. Reporting Requirements. CMS may add or modify evaluation-related reporting requirements during the Agreement Term. CMS will notify the WISeR Participant of any additions or modifications as soon as practicable or at least 30 Days prior to the Day on which such change would take effect.

Section 10.2 Shared Learning Activities

A. The WISeR Participant shall participate in CMS-sponsored learning activities designed to drive improvement and foster innovations in using technology-assisted decision-making through sharing best practices or new knowledge that emerges from participation in the Model.
B. The WISeR Participant shall actively engage in a variety of learning events, learning communities, and sharing promising tools and ideas, as well as their lessons learned.

Section 10.3 Site Visits

A. The WISeR Participant shall cooperate and require its staff to cooperate in any site visits conducted by or on behalf of CMS.
B. CMS or its designee(s) shall, to the extent practicable, schedule any site visits to the WISeR Participant no fewer than 15 Days in advance. To the extent practicable, CMS will attempt to accommodate the WISeR Participant's request for particular dates in scheduling site visits. However, the WISeR Participant may not request a date that is more than 60 Days after the date of the initial site visit notice from CMS.
C. The WISeR Participant shall ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during the site visit.
D. Notwithstanding the foregoing, CMS or its designee(s) may perform unannounced site visits at any of the WISeR Participant's office locations at any time to investigate concerns or other program integrity issues.
E. Nothing in this Agreement shall be construed to limit or otherwise prevent CMS from performing site visits permitted by applicable law or regulations.

Section 10.4 Rights in Data and Intellectual Property

A. CMS may use any data obtained pursuant to the Model to evaluate the Model and to disseminate quantitative results and successful care management techniques to other providers and suppliers and to the public. Data to be disseminated may include results of WISeR Provider and WISeR Supplier surveys, results of patient experience of care and quality of life surveys as well as measures based upon claims, medical records, and other data sources. The WISeR Participant will be permitted to comment on evaluation reports when the WISeR Participant has been specifically cited to ensure factual accuracy but may not edit conclusions or control the dissemination of reports.
B. The parties agree that by participating in the Model, the WISeR Participant grants to CMS and its designees a limited, royalty-free, worldwide, non-sublicensable, non-exclusive license on a warranty-free basis during the term of this Agreement (and for any agreed to extension thereof) in, to and under all intellectual property and information technology owned or licensable (without the consent of, or payment to, any third party) by the WISeR Participant or any of its affiliates, solely for CMS or any of its designees or affiliates to receive and use such information technology.
C. Notwithstanding any other provision in the Agreement, the parties agree that any intellectual property or information technology developed as a result of the collaborative activity under the terms of this Agreement and the requirements associated with this Model will be dealt with by appropriate written agreements

D. Notwithstanding any other provision in the Agreement, all proprietary trade secret information and technology of the WISeR Participant that existed prior to the Effective Date of this Agreement is and shall remain the sole property of the WISeR Participant, and, except as required by federal law, shall not be released by CMS without express written consent. The regulation at 48 C.F.R. § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into the Agreement. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property right or other rights to the WISeR Participant's proprietary information or technology.

E. If the WISeR Participant maintains any information that should not be publicly disclosed because the WISeR Participant considers such information to be proprietary and confidential, the WISeR Participant acknowledges that it may submit to CMS a form, using either the template attached as Appendix C, or a form substantially the same as Appendix C, identifying specific examples of information the WISeR Participant considers to be proprietary and confidential. The WISeR Participant must notify CMS, in a form and manner to be specified by CMS, of any updates to this form. If the WISeR Participant does not submit such a form, the WISeR Participant will be deemed to have confirmed that it has no information it considers proprietary and confidential.

Section 10.5 WISeR Participant Public Release of Information

A. The WISeR Participant shall obtain prior approval from CMS during the Agreement Term and for 6 months thereafter for the publication or release of any press release, external report or statistical/analytical material that materially and substantially references the WISeR Participant's participation in the Model. External reports and statistical/analytical material may include but are not limited to papers, articles, professional publications, speeches, and testimony.

B. All external reports and statistical/analytical material that are subject to this Section 10.5 must include the following statement on the first page: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

Article XI. Compliance and Oversight

Section 11.1 WISeR Participant Compliance Plan

A. The WISeR Participant shall have a compliance plan that includes at least the following elements:

1. A designated compliance official or individual who is not legal counsel to the WISeR Participant and reports directly to the WISeR Participant's governing body;
2. Mechanisms for identifying and addressing compliance problems related to the WISeR Participant's operations and performance;
3. A method for employees or contractors of the WISeR Participant performing functions or services related to this Model to anonymously report suspected problems related to the WISeR Participant's compliance official;
4. Compliance training for the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers; and
5. A requirement for the WISeR Participant to report probable violations of law to an appropriate law enforcement agency.

B. The WISeR Participant shall ensure that its compliance plan is in compliance with all applicable laws and regulations. The WISeR Participant shall periodically update its compliance plan to reflect changes in those laws and regulations.

Section 11.2 CMS Monitoring and Oversight Activities

A. CMS shall conduct monitoring activities to assess compliance by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers with the terms of this Agreement. Such monitoring activities may include, but are not limited to:
   1. Claims analyses to identify fraudulent behavior or program integrity risks such as efforts to manipulate Prior Authorization Process accuracy and efficiency;
   2. Claims and appeals data to identify fraudulent behavior or program integrity risks, including data between the WISeR Participant and any MAC;
   3. Review of documents from the WISeR Participant, WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers, and WISeR Suppliers, including surveys and questionnaires;
   4. Review and audits of the WISeR Participant's Enhanced Technology, including without limitation, reliance on artificial intelligence, machine learning capabilities, and its impact on the timing and accuracy of Prior Authorization determinations, denial rates, affirmation rates, resubmission rates, and other data related to such Enhanced Technology;
   5. Review and audits of the WISeR Participant's Pre-Payment Review processes performed by its WISeR Clinicians and WISeR Clinical Reviewers, and the impact on the timing and accuracy of Pre-Payment Review determinations, denial rates, affirmation rates, resubmission rates, and other data related to such reviews;
   6. Interviews with Beneficiaries and their caregivers;

7. Audits of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant;
8. Audits of data related to Pre-Payment Review, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant; and
9. Site visits to the WISeR Participant.

B. In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including, without limitation, all Medicare claims submitted for items and/or services furnished to Beneficiaries.

C. In conducting monitoring and oversight activities, CMS or its designee(s) may use any relevant data or information including, without limitation, all Prior Authorization requests, Pre-Payment Review activities, determinations, and resubmissions submitted for items and/or services furnished to Beneficiaries.

D. Nothing in this Agreement limits or otherwise prevents CMS from monitoring the WISeR Participant for compliance as permitted by applicable law or regulations.

E. CMS may conduct monitoring activities pursuant to this Article XI for up to two calendar years after the effective date of termination or expiration of this Agreement.

Section 11.3 Compliance with Monitoring and Oversight Activities

A. The WISeR Participant shall cooperate with, and require its WISeR Clinicians and WISeR Clinical Reviewers to cooperate with, all CMS monitoring and oversight requests and activities.

B. The WISeR Participant shall ensure it has sufficient access to all records, data, and information necessary to comply with the monitoring activities described in this Agreement. As necessary, the WISeR Participant shall request this information from any WISeR Clinician, or any WISeR Clinical Reviewer, or individual performing functions or providing services related to WISeR.

Section 11.4 Compliance with Laws

A. Agreement to Comply

1. The WISeR Participant shall comply with, and shall require all WISeR Clinicians and WISeR Clinical Reviewers to comply with, the applicable terms of the Agreement and all applicable statutes, regulations, and guidance, including without limitation: (a) federal criminal laws; (b) the Social Security Act (Public Law 74-271); (c) Title XVIII of the Act; (d) the False Claims Act (31 U.S.C. § 3729 et seq.); (e) the antikickback statute (42 U.S.C. § 1320a-7b(b)); (f) the civil monetary penalties law (42 U.S.C. § 1320a-7a); (g) the federal

physician self-referral law (42 U.S.C. § 1395nn); and (h) any applicable State laws.

2. This Agreement does not waive any obligation of the WISeR Participant to comply with the terms of any other CMS contract, agreement, model, or demonstration.

B. Reservation of Rights

1. Nothing contained in this Agreement or in the application process for WISeR constitutes a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS Office of the Inspector General, or CMS of any right to institute any proceeding or action for violations of any statutes, rules, or regulations administered by the government, or to prevent or limit the rights of the government to obtain relief under any other federal statutes or regulations, or on account of any violation of the Agreement or any other provision of law. This Agreement does not bind any government agency except CMS and the Agreement binds CMS only to the extent provided in this Agreement.
2. The failure by CMS to require performance of any provision of this Agreement does not affect CMS' right to require performance at any time thereafter, nor does a waiver of any breach or default of the Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

C. Office of Inspector General of the Department of Health and Human Services (OIG) Authority. None of the provisions of this Agreement limit or restrict the OIG's authority to audit, evaluate, investigate, or inspect the WISeR Participant or its WISeR Clinicians or its WISeR Clinical Reviewers.

D. Other Government Authority. None of the provisions of this Agreement limit or restrict any other government authority that is permitted by law to audit, evaluate, investigate, or inspect the WISeR Participant.

Section 11.5 Applicable Statutes, Regulations, Manuals, and Documents

In addition to all referenced statutes, regulations, manuals, and documents, the following statutes, regulations, manuals, and documents apply to this Agreement and are hereby incorporated by reference.

A. Financial management and internal controls (e.g., the Federal Managers' Financial Integrity Act of 1982 (FMFIA), the Chief Financial Officers' Act of 1990, etc.);
B. Federal Information Security Management Act of 2014 (FISMA);
C. Privacy and information technology requirements (Privacy Act of 1974, Information Technology Management Reform Act of 1996);

D. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191);
E. Rehabilitation Act of 1973 (including section 508, Accessibility Standards);
F. Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248);
G. Administrative Simplification Compliance Act of 2002 (Public Law 107-105);
H. Benefit Improvement and Protection Act of 2000 (Public Law 106-554);
I. Executive Order 13410, to the extent practicable, Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs;

Medicare manuals (e.g., internet only manuals – IOMs) to administer CMS programs. In the event of any conflict, this Agreement shall have precedence over the IOMs located at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index;

Article XII. Audits and Record Retention

Section 12.1 Right to Audit and Inspect

The WISeR Participant agrees that the government (including CMS, HHS, and the Comptroller General or their designees) has the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the WISeR Participant that pertain to the following:

A. The WISeR Participant's compliance with the terms of this Agreement, including provisions that require the WISeR Participant to impose duties or requirements on its WISeR Clinicians and its WISeR Clinical Reviewers;
B. Whether the WISeR Clinicians and WISeR Clinical Reviewers complied with the duties and requirements imposed on them by the WISeR Participant pursuant to the terms of this Agreement;
C. The quality of services performed under this Agreement;
D. Any activity by the WISeR Participant that may pose a potential risk of harm to Beneficiaries or a vulnerability to the integrity of the Model test;
E. The WISeR Participant's right to WISeR Payments;
F. The ability of the WISeR Participant to repay amounts owed to CMS under this Agreement;
G. The WISeR Participant's financial arrangements.

Section 12.2 Maintenance of Records

The WISeR Participant shall maintain and shall give the government (including CMS, HHS, and the Comptroller General or their designees) access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs,

quality performance measures, and financial arrangements) sufficient to enable the audit, evaluation, inspection, or investigation of the Model, including the subjects identified in Section 11.2. The WISeR Participant shall maintain such books, contracts, records, documents, and other evidence for a period of six years from the expiration or termination of this Agreement or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:

A. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the WISeR Participant at least 30 Days before expiration of the six-year period described above; or
B. There has been a termination, dispute, or allegation of fraud or similar fault against the WISeR Participant in which case the records shall be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

Article XIII. Remedial Action and Termination

Section 13.1 Grounds for Remedial Action

A. CMS may take remedial action against the WISeR Participant if CMS determines that the WISeR Participant:
    1. Has failed to comply with any applicable term of the Agreement or any Medicare program requirement, rule, or regulation;
    2. Has failed to comply with the American with Disabilities Act of 1990, 42 U.S.C. § 12101 *et seq*. (1990);
    3. Has failed to comply with the WISeR Participant's Corrective Action Plan (CAP), the monitoring or auditing plan, or both, developed by CMS for the WISeR Participant, or other remedial action imposed by CMS, if applicable;
    4. Has taken any action that threatens the health or safety of a Beneficiary, including a WISeR Beneficiary;
    5. Has failed to rectify deficiencies following any remedial action;
    6. Has undergone a Change in Control that renders it ineligible for participation in the Model or presents a program integrity risk;
    7. Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model or any requirement of the Medicare program;
    8. Has failed to pay amounts owed to CMS by the date specified in a demand letter;
    9. Has failed to pay a WISeR Recoupment;

10. Has a conflict of interest; or
11. Poses significant program integrity risks, including but not limited to:
    i. Is subject to sanctions or other actions of a federal, state, or local government agency;
    ii. Is subject to investigation or action by HHS (including, but not limited to OIG and CMS) or the Department of Justice due to an allegation of fraud or similar misconduct, including but not limited to being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

Section 13.2 Types of Remedial Action

A. If grounds for remedial action exist, CMS may take one or more of the following actions:
    1. Notify the WISeR Participant of the violation;
    2. Require the WISeR Participant to provide additional information to CMS or its designees;
    3. Conduct site visits, interview WISeR Providers and/or WISeR Suppliers, interview Beneficiaries, or take other actions to gather information;
    4. Place the WISeR Participant on a monitoring and/or auditing plan developed by CMS;
    5. Require the WISeR Participant to not use a WISeR Clinician or WISeR Clinical Reviewer for Medical Review, immediately or within a timeframe specified by CMS;
    6. Withhold, deny, or recoup WISeR Payments;
    7. Withhold, deny, or recoup any Advance WISeR Payments;
    8. Suspend or terminate the WISeR Participant's ability to perform its Prior Authorization Process on new requests;
    9. Require a CAP from the WISeR Participant that is acceptable to CMS. If CMS requires a CAP from the WISeR Participant, the following requirements apply:
        i. The WISeR Participant shall submit a CAP to CMS for approval by a deadline established by CMS:
        ii. CMS must approve the WISeR Participant's CAP;
        iii. The CAP must address what actions the WISeR Participant will take within a specified time period to ensure that all deficiencies will be corrected and that the WISeR Participant will be in compliance with the terms of this Agreement; and

iv. If the WISeR Participant does not comply with the terms of the CAP within the specified period of time, CMS may take additional remedial actions or terminate the Agreement or Agreement Performance Period in accordance with Section 13.3.

B. CMS may impose additional remedial actions, including but not limited to terminating the Agreement or Agreement Performance Period pursuant to Section 13.3, if CMS determines that the WISeR Participant's efforts to address noncompliance or other grounds for remedial action were insufficient.

Section 13.3 Termination by CMS

CMS may immediately or with advance notice terminate the Agreement or Agreement Performance Period if:

A. CMS determines that it no longer has the funds to support the Model;
B. CMS modifies or terminates the Model pursuant to section 1115A(b)(3)(B) of the Act;
C. CMS offers the WISeR Participant an amendment to this Agreement pursuant to Section 1.4, and the WISeR Participant does not sign such amendment by the date specified by CMS;
D. CMS determines that any grounds for remedial action exist;
E. CMS determines that the WISeR Participant has failed to submit, obtain approval for, implement, or fully comply with the terms of a CAP;
F. CMS determines that the WISeR Participant has failed to demonstrate improved performance following any remedial action imposed by CMS;
G. The WISeR Participant has a conflict of interest that cannot be resolved;
H. The WISeR Participant has not executed a valid BAA; or
I. The WISeR Participant assigns or purports to assign any of the rights or obligations under the Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

Section 13.4 Termination of the Agreement Performance Period by WISeR Participant

The WISeR Participant may terminate the Agreement Performance Period upon advance written notice to CMS. Such notice must specify the effective date of the termination, which must be at least 90 Days after the date of the notice.

Section 13.5 Financial Settlement Upon Termination

If CMS terminates the Agreement or the Agreement Performance Period is terminated by either party, CMS shall conduct settlement for the entire Performance Year in which the Agreement is terminated in accordance with Article VIII of the Agreement.

Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination

If the Agreement or Agreement Performance Period is terminated under Section 13.3 or Section 13.4, the WISeR Participant shall provide written notice of the termination to all WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction. The WISeR Participant shall deliver such written notice no later than 45 Days before the effective date of termination unless a different date is specified by CMS. The WISeR Participant shall include in such notices any content specified by CMS.

Article XIV. Limitation on Review and Dispute Resolution

Section 14.1 Limitations on Review

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

A. The selection of organizations, sites, or participants to test models selected for testing or expansion under section 1115A of the Act, including the decision by CMS to terminate the Agreement or Agreement Performance Period;
B. The elements, parameters, scope, and duration of such models for testing or dissemination;
C. Determinations regarding budget neutrality under section 1115A(b)(3);
D. The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B);
E. Determinations about expansion of the duration and scope of a model under section 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection (c);
F. The selection of quality performance standards by CMS;
G. The methodology applied to calculate Regional Benchmarks, WISeR Discount, AQS, and WISeR Payments;
H. The methodology used to calculate the WISeR Participant's WISeR Payment; and
I. The methodology used to calculate the WISeR Recoupment.

Section 14.2 Dispute Resolution

A. Right to Reconsideration. The WISeR Participant may request reconsideration of a determination made by CMS pursuant to the Agreement only if such reconsideration is not precluded by section 1115A(d)(2) of the Act or the Agreement.
    1. Such a request for reconsideration by the WISeR Participant must satisfy the following criteria:

i. The request must be submitted to a designee of CMS ("**Reconsideration Official**") who –
    a. Is authorized to receive such requests;
    b. Did not participate in the determination that is the subject of the reconsideration request; and
    c. May be, but does not have to be, an Inferior Officer.
ii. The request must include a copy of the initial determination issued by CMS and contain a detailed, written explanation of the basis for the dispute, including supporting documentation;
iii. The request must be made within 30 Days of the date of the initial determination for which reconsideration is being requested and
iv. The request must be delivered via email to CMS at InnovationModelsReconsideration@cms.hhs.gov or at such other address specified by CMS.

2. Requests that do not meet the requirements of Section 14.2.A.1 will be denied.
3. Within 15 Days of receiving a request for reconsideration, the parties will be sent a written acknowledgement of receipt of the reconsideration request. Such an acknowledgement will set forth:
    i. The review procedures; and
    ii. A briefing schedule that permits each party to submit written briefs, including any evidence or documentation in support of the party's position for consideration by the Reconsideration Official.

B. Standards for Reconsideration
1. The parties shall proceed diligently with the performance of this Agreement during the course of any dispute arising under the Agreement.
2. The reconsideration will consist of a review of documentation that is submitted timely and in accordance with the standards specified by the Reconsideration Official.
3. The burden of proof is on the WISeR Participant to demonstrate to the Reconsideration Official with clear and convincing evidence that the determination is inconsistent with the terms of the Agreement.

C. Reconsideration Determination
1. The reconsideration determination will be based only upon:
    i. Position papers and supporting documentation that are timely submitted to the Reconsideration Official and meet the standards for submission under Section 14.2.B.2; and

ii. Documents and data that were timely submitted to CMS in the required format before the agency made the determination that is the subject of the reconsideration request.

2. The Reconsideration Official will issue to CMS and the WISeR Participant a written notification of the reconsideration determination ("**Reconsideration Determination**"). Absent unusual circumstances, the Reconsideration Determination will be issued within 60 Days of receipt of timely filed position papers and supporting documentation.
3. The Reconsideration Determination is final and binding 30 Days after its issuance, unless the WISeR Participant or CMS timely requests review of the Reconsideration Determination in accordance with Sections 14.2.D.1 and 2.

D. CMS Administrator Review. The WISeR Participant or CMS may request CMS Administrator review of the Reconsideration Determination.

1. The request must be made via email to InnovationModelsReconsideration@cms.hhs.gov or such other address as specified by CMS within 30 Days after the date of the Reconsideration Determination.
2. The request must include a copy of the Reconsideration Determination and a detailed, written explanation of why the WISeR Participant or CMS disagrees with the Reconsideration Determination.
3. Within 30 business days after receiving a request for review, the CMS Administrator (or a delegate acting on behalf of the CMS Administrator) will determine whether the request for review is granted or denied. The CMS Administrator will promptly send the parties written acknowledgement of receipt of the request for review. Such an acknowledgement will set forth:
    i. Whether the request for review is granted or denied; and
    ii. If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.
4. If the request for review is denied, the Reconsideration Determination is final and binding as of the date the request for review is denied.
5. If the request for review is granted:
    i. The record for review will consist of timely submitted briefs and the evidence contained in the record of the proceedings before the Reconsideration Official. The CMS Administrator will not consider documentation submitted for review other than documents and date described in Section 14.2.B.2;

ii. The CMS Administrator will review the record and issue to CMS and to the WISeR Participant a written determination; and
iii. The written determination of the CMS Administrator is final and binding.

E. Effect of Dispute Resolution. The dispute resolution process under this Agreement shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

Article XV. Miscellaneous

Section 15.1 Agency Notifications and Submission of Reports

A. For a notice or other communication required under this Agreement to be valid, it must be in writing.
B. Unless otherwise specified in this Agreement or stated in writing after the Effective Date, all notifications and reports required under this Agreement must be submitted to the parties at the addresses set forth below:

CMS:
WISeR Model
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop: WB-06-05
Baltimore, MD 21244
Email: WISeR@cms.hhs.gov

WISeR Participant:
Humata Health, Inc.
382 NE 191 St #15349
Miami
FL
33179

Section 15.2 Notice of Bankruptcy

A. If the WISeR Participant has filed a bankruptcy petition, whether voluntary or involuntary, the WISeR Participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the WISeR Participant under the terms of each model tested under section 1115A of the Act in which the WISeR Participant is participating or has participated and all administrative or judicial review proceedings related to any payments under such models have been fully and finally resolved.

B. The notice of bankruptcy must be sent by certified mail no later than 5 Days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the WISeR Participant is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the WISeR Participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the WISeR Participant and CMS have been fully and finally resolved with respect to that model.

C. The notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3-01-24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices.

Section 15.3 Severability

In the event that any one or more of the provisions of this Agreement is, for any reason, held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had never been included in the Agreement, unless the deletion of such provision or provisions would result in such a material change to the Agreement so as to cause continued participation under the terms of this Agreement to be unreasonable.

Section 15.4 Entire Agreement; Amendment

This Agreement, including all appendices, constitutes the entire agreement between the parties. The parties may amend this Agreement or any appendix hereto at any time by mutual written consent; provided, however, that CMS may amend this Agreement or any appendix hereto in writing without the consent of the WISeR Participant as specified in this Agreement or any appendix hereto, or for good cause or as necessary to comply with applicable federal

or state law, regulatory requirements, accreditation standards, or licensing guidelines or rules. To the extent practicable, CMS shall provide the WISeR Participant with 30 Days' advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

Section 15.5 Survival

Expiration or termination of this Agreement by CMS shall not affect the rights and obligations of the parties accrued prior to the effective date of the expiration or termination of this Agreement, except as provided in this Agreement. The rights and duties under the following sections of this Agreement shall survive the expiration or termination of this Agreement and apply thereafter:

Article VIII. Payment;
Article IX. Data Sharing and Reports;
Section 10.1 Evaluation Requirements;
Section 10.4 Rights in Data and Intellectual Property;
Section 10.5 WISeR Participant Public Release of Information;
Section 11.3 Compliance with Monitoring and Oversight Activities;
Article XII. Audits and Record Retention;
Section 13.5 Financial Settlement Upon Termination;
Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination;
Section 14.1 Limitations on Review;
Section 15.2 Notice of Bankruptcy;
Section 15.5 Survival; and
Section 15.7 Prohibition on Assignment.

Section 15.6 Precedence

If any provision of this Agreement conflicts with a provision of any document incorporated herein by reference, the provision of this Agreement shall prevail.

Section 15.7 Prohibition on Assignment

Except with the prior written consent of CMS, the WISeR Participant shall not transfer, including by merger (whether the WISeR Participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under this Agreement; (2) any right that it has to satisfy a condition under this Agreement; (3) any remedy that it has under this Agreement; or (4) any obligation imposed on it under this Agreement. The WISeR Participant shall provide CMS 90 Days' advance written notice of any such proposed transfer. This obligation remains in effect until final payment by or to the WISeR Participant has been made under this Agreement. CMS may condition its consent to transfer on full payment of any amounts owed by the WISeR Participant under this Agreement or owed to CMS by the

proposed assignee. Any purported transfer in violation of this Section is voidable at the discretion of CMS.

Section 15.8 Certification

The WISeR Participant executive signing this Agreement certifies to the best of his or her knowledge, information, and belief that the WISeR Participant satisfies the requirements of Section 3.1.A, that all WISeR Clinicians and WISeR Clinical Reviewers satisfy the requirements of Section 3.4, and that he or she is authorized by the WISeR Participant to execute this Agreement and to legally bind the WISeR Participant to its terms and conditions.

Section 15.9 Execution in Counterpart

This Agreement and any amendments hereto may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof. This Agreement and any amendments hereto may be signed by autopen or electronic signature (e.g., DocuSign or similar electronic signature technology) and may be transmitted by electronic means. Copies of this Agreement and any amendments hereto that are so executed and delivered have the same force and effect as if executed with handwritten signatures and physically delivered.

[SIGNATURE PAGE FOLLOWS]

Each party is signing this Agreement on the date stated opposite that party's signature. If a party signs but fails to date a signature, the date that the other party receives the signing party's signature will be deemed to be the date that the signing party signed the Agreement.

WISeR Participant: Humata Health, Inc.

WISeR ID: WISeR-00039

Date: 2025-09-26 10:34:59

By: (b)(6)

(b)(6)

Name of Authorized Signatory

(b)(6)

Title

CMS:

Date: 2025-10-01 14:14:13

By: _____

Arrah Tabe-Bedward

Name of Authorized Signatory

CMS Executive

Appendices

Appendix A: Select Items and Services

Appendix B: Quality Measures

Appendix C: WISeR Participant Proprietary and Confidential Information

Appendix A: Select Items and Services

CMS uses Covered Services that correspond to the LCDs and NCDs identified in the Table 1 below ("**Select Items and Services**") to determine whether the WISeR Provider's and/or WISeR Supplier's Medicare claim is subject to the Prior Authorization Process for Performance Year 1. The WISeR Participant performs its Prior Authorization Process for each Select Item or Service identified in a Prior Authorization request within its WISeR Jurisdiction.

CMS may unilaterally revise the Select Items and Services identified in Table 1 prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any revisions to the Select Items and Services for a Performance Period prior to the start of the Performance Period in which such change will take effect.

Table 1

Select Items and Services	Associated NCD/LCDs
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)	NCD 160.7 NCD 230.18 NCD 160.19 NCD 160.24 NCD 160.18
Induced Lesions of Nerve Tracts	NCD 160.1
Epidural Steroid Injections for Pain Management	L39015, L39242, L36920
Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L34106, L38201, L35130
Cervical Fusion Excluding codes already included in OPD	L39741, L39762, L39793
Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee	NCD 150.9

Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea	L38307, L38312, L38385
Incontinence Control Devices	NCD 230.10
Diagnosis and Treatment of Impotence	NCD 230.4
Percutaneous Image-Guided Lumbar Decompression for Spinal Stenosis	NCD 150.13
Skin and Tissue Substitutes • Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds • Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities	L35041 L36690

Appendix B: Quality Measures

Consistent with Article VII and the WISeR Data Reporting Guide, CMS shall use the following WISeR Performance Measure Set for purposes of calculating the AQS of the WISeR Participant for Performance Year 1. CMS will also use the following WISeR Performance Measure Set for purposes of monitoring and evaluating the overall performance of the WISeR Participant during the Model.

CMS may update the quality measures identified in the WISeR Performance Measure Set prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any updates for a Performance Period prior to the start of the Performance Period in which such change will take effect.

WISeR Performance Measure Set

Domain	First Applicable Performance Period	Data Source	Measurement Frequency
Timeliness of Determinations	PP1	WISeR Participant-Reported	Quarterly
Accuracy of Determinations	PP1	CMS Audit of WISeR Participant-Reported Data	Quarterly

Appendix C: WISeR Participant Proprietary and Confidential Information

The following are specific examples, without limitation, of what the WISeR Participant considers proprietary and confidential information currently maintained by the WISeR Participant that should not be publicly disclosed:

1) (b)(4)

2) (b)(4)

3) (b)(4)

4)

In accordance with Section 10.4 of the Agreement, this information shall not be released by CMS without the express written consent of the WISeR Participant except as required by federal law.

Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Patient Care Models Group
7500 Security Blvd
Baltimore, MD 21244

Wasteful and Inappropriate Service Reduction (WISeR) Model

Participation Agreement

Segment 1: January 1, 2026-December 31, 2028

August 29, 2025

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PARTICIPATION AGREEMENT

This Participation Agreement (the "**Agreement**") is between the CENTERS FOR MEDICARE & MEDICAID SERVICES ("**CMS**") and

Innovaccer Inc. , ("**WISeR Participant**").

CMS is the agency within the U.S. Department of Health and Human Services ("**HHS**") that is charged with administering the Medicare and Medicaid programs.

The WISeR Participant is a legal entity identified by a single TIN and has Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process and Pre-Payment Review for Select Items and Services on Medicare fee-for-service ("**FFS**") Claims.

CMS is implementing the Wasteful and Inappropriate Service Reduction Model ("**WISeR**" or "**Model**") under section 1115A of the Social Security Act ("**Act**"), which authorizes CMS through its Center for Medicare and Medicaid Innovation ("**Innovation Center**") to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program expenditures while preserving or enhancing the quality of care furnished to Beneficiaries.

The Model seeks to reduce or maintain Medicare FFS expenditures while improving the quality of care and health outcomes for Medicare FFS beneficiaries through the WISeR Participant's Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process for Select Items and Services that do not satisfy existing Medicare Coverage Criteria and may be fraudulent, wasteful, or of low-value to Medicare FFS beneficiaries.

The WISeR Participant applied to participate in WISeR, and CMS has approved the WISeR Participant for participation in the Model for the MAC Jurisdiction of J15 CGS and the state of Ohio. The designated state is the WISeR Participant's WISeR Jurisdiction.

The parties therefore agree as follows:

Article I. Agreement Term

Section 1.1 Effective Date

This Agreement will become effective when it is signed by the last party to sign it (as indicated by the date associated with that party's signature) ("**Effective Date**").

Section 1.2 Agreement Term

The term of this Agreement ("**Agreement Term**") begins on the Effective Date and expires two years after the last Day of the Agreement Performance Period, as defined in Section 1.3, unless the Agreement is sooner terminated by CMS in accordance with Section 13.3, in which case the Agreement Term ends on the effective date of such termination.

Section 1.3 Agreement Performance Period

A. The performance period of this Agreement ("**Agreement Performance Period**") begins on the Effective Date and ends at 11:59 PM ET on December 31, 2028, unless the Agreement Period or the Agreement is sooner terminated in accordance with Section 1.4.B or Article XIII, in which case the Agreement Performance Period ends on the date specified in the termination notice.

B. CMS may offer the WISeR Participant the option to participate in a second segment of this Model which would begin on January 1, 2029, and end at 11:59 PM ET on December 31, 2031. The WISeR Participant must execute a new agreement with CMS to participate in the Model during the second segment. Any such agreement will authorize CMS to take remedial action against the WISeR Participant for non-compliance with the terms of this Agreement, regardless of when the non-compliance is discovered by CMS.

Section 1.4 Amended and Restated Agreements

A. No later than 30 Days prior to the start of a calendar year during the Agreement Performance Period, CMS may offer the WISeR Participant the opportunity to sign an amendment to this Agreement, which may be in the form of an amended and restated version of this Agreement.

B. If the WISeR Participant fails to sign an amendment offered by CMS pursuant to Section 1.4.A by a date specified by CMS, CMS may terminate the Agreement Performance Period on December 31 of the year in which the amendment was offered.

Article II. Definitions

Advance WISeR Payment means the payment that meets the requirements in Section 8.4.

Aggregate Quality Score (AQS) means the score that is calculated from the WISeR Participant's quality data and used to determine the quality multiplier applied during the calculation of the WISeR Payment.

ARS stands for **CMS Acceptable Risk Safeguard** and means the standard to CMS and its contractors, including the WISeR Participant, as to the minimum level of required security and privacy controls. *See* https://security.cms.gov/policy-guidance/cms-acceptable-risk-safeguards-ars (last accessed August 2025).

ATO stands for **CMS Authority to Operate** and means the information systems operated by or on behalf of the U.S. federal government that meet FISMA standards.

BAA stands for **Business Associate Agreement** and means the legally binding contract required under HIPAA between CMS and the WISeR Participant that handles Protected Health Information.

Beneficiary means an individual who is entitled to Medicare FFS benefits under Part A or enrolled under Part B.

Change in Control means: (1) the acquisition by any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the WISeR Participant representing more than 50 percent of the WISeR Participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the WISeR Participant by any other individual or entity; (3) the sale, lease exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the WISeR Participant; or (4) the approval and completion of a plan of liquidation of the WISeR Participant, or an agreement for the sale or liquidation of the WISeR Participant.

Covered Services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Day(s) means calendar day(s) unless otherwise specified.

Electronic Submission of Medical Documentation (esMD) means a system used by CMS to enable providers, suppliers, and other entities to reduce or eliminate the need to mail or fax paper documents and instead electronically submit or request supporting medical documentation related to CMS claims and Prior Authorization.

Enhanced Technology means the WISeR Participant's technology that is intended to improve the accuracy and efficiency of the Prior Authorization Process and Pre-Payment Review.

Exemption Status means the status that a WISeR Provider or WISeR Supplier may earn to be exempt from requesting Prior Authorization for the Select Items and Services in accordance with Section 6.2 of this Agreement and the WISeR Participant Guide.

FedRAMP stands for **Federal Risk and Authorization Management Program** and means the government-wide program that standardizes security assessments for cloud services (44 U.S.C. § 3607).

Financial Settlement Report means the report that is defined in Section 8.9.

FISMA stands for **Federal Information Security Management Act of 2002, as amended by the Federal Information Security Modernization Act of 2014** and means the framework of guidelines and security standards to protect government information and operations as set forth in 44 U.S.C. § 3541, *et seq.* and 44 U.S.C. § 3551, *et seq*..

Initial Prior Authorization Determination means the communication to the WISeR Provider or WISeR Supplier detailing the Prior Authorization Affirmation or Prior Authorization Non-Affirmation for an initial Prior Authorization submission.

IS2P2 stands for **CMS Information Systems Security & Privacy Policy** and means the policy that defines how CMS protects and controls access to its information and systems as required under FISMA of 2014 (44 U.S.C. Chapter 35).

Locality means a CMS-defined geographic area within a MAC Jurisdiction (e.g., a state, or other geographic boundary) that CMS uses to determine Medicare payment rates for Covered Services.

LCDs stands for **Local Coverage Determinations** and has the meaning set forth in Section 1869(f)(2)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(2)(B)).

MAC stands for Medicare Administrative Contractor and means a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B medical claims or Durable Medical Equipment (DME) claims for Medicare fee-for-service beneficiaries, as further defined in Section 1874A(a)(3) of the Social Security Act (42 U.S.C. § 1395kk-1(a)(3) and 42 C.F.R. Subpart E).

MAC Jurisdiction means the defined geographic territory for the Medicare Part A and Part B Jurisdictions L, 15, H, and F selected for the WISeR Model and as depicted on the "A/B MAC

Jurisdictions" map at https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/who-are-macs (last accessed August 2025) (*see also* Section 911(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173).

Medical Review means the collection and clinical review of medical records and related information to ensure that Medicare payment is made only for services that meet all Medicare Coverage Criteria.

Medically Necessary means reasonable and necessary as determined in accordance with Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)).

Medicare Coverage Criteria means the existing Medicare coverage criteria as set forth in statute, regulation, NCD, or LCD.

Model Participant means a technology company that has signed an agreement with CMS to participate in WISeR and is not the WISeR Participant.

Model Performance Period means the period of time, regardless of the Agreement Performance Period, that begins on January 1, 2026 and ends on December 31, 2031, unless sooner terminated in accordance with Section 12.3.

Navigation Services means services and information including Medicare Coverage Criteria, Prior Authorization performance data, and such other services as detailed in the WISeR Participant Guide that are provided by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers, as applicable, to all WISeR Providers and WISeR Suppliers to increase clinically appropriate care.

NCDs stands for **National Coverage Determinations** and has the meaning set forth in Section 1869(f)(1)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(1)(B).

NPI stands for **National Provider Identifier**.

Payable Non-Affirmation means an Initial Prior Authorization Determination of Prior Authorization Non-Affirmation that qualifies for a WISeR Payment because there was no Resubmission within 120 Days that received a determination of Prior Authorization Affirmation and, at the time of Reconciliation, there was no associated claim paid by Medicare due to the successful appeal of a claim denial.

Performance Period means the three-month period in which the WISeR Participant issues Initial Prior Authorization Determinations for Prior Authorization requests and issues

determinations for Pre-Payment Reviews, including without limitation all associated Resubmissions submitted within 120 days of the Initial Prior Authorization Determination.

Performance Year or **PY** means the 12-month period beginning on January 1 of each year during the Model Performance Period.

Pre-Payment Review means the review by the WISeR Participant to verify consistency with Medicare Coverage Criteria for a claim for one or more Select Items and Services furnished in the MAC Jurisdiction that is submitted to Medicare without requesting Prior Authorization, consistent with 42 C.F.R. § 405.903.

Prior Authorization is a request by the WISeR Provider or WISeR Supplier for provisional affirmation of Medicare Coverage Criteria for one of the Select Items and Services prior to furnishing such items and services to the WISeR Beneficiary and before the claim is submitted for processing.

Prior Authorization Process means the process detailed in Article VI of the Agreement.

Prior Authorization Provisional Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Prior Authorization Non-Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is not accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Program Integrity Screening means a review of an individual's or entity's program integrity history and current status, which may include a review of the individual's or entity's eligibility, history of exclusion or other sanctions imposed with respect to participation in Medicare, Medicaid, or CHIP; history of failure to pay Medicare debts in a timely manner; current or prior law enforcement investigations or administrative actions regardless of whether such investigations or actions relate to participation in Medicare, Medicaid, or CHIP; affiliations with individuals or entities that have a history of program integrity issues; and other information pertaining to the trustworthiness of the individual or entity.

Reconciliation means the process by which CMS calculates the WISeR Payment amount owed to the WISeR Participant for a specific Performance Period as set forth in Article VIII.

Reconciliation Report means the report issued by CMS that details the Reconciliation calculations for the WISeR Participant and the amount of any WISeR Payment for one or more specified Performance Periods.

Regional Benchmark means a payment amount calculated by CMS for each of the Select Items and Services for a given Locality and Performance Period that CMS uses to calculate the WISeR Payment amount for a Payable Non-Affirmation as set forth in Section 8.3.

Resubmission means a Prior Authorization submitted to the WISeR Participant within 120 Days of an Initial Prior Authorization Determination for a Prior Authorization previously submitted by the same WISeR Provider or WISeR Supplier for the same WISeR Beneficiary and same Select Item or Service.

Resubmission Determination means the communication to the WISeR Provider and/or WISeR Supplier detailing the Prior Authorization Provisional Affirmation or Prior Authorization Non-Affirmation for a Resubmission.

Select Items and Services means the Covered Services detailed in Appendix A that are subject to the Prior Authorization Process. When used in its singular form this term is referred to as "**Select Item or Service**".

Start Date means January 1, 2026.

TIN stands for taxpayer identification number.

VDC stands for CMS Virtual Data Center and means the comprehensive information technology infrastructure designed to centralize and modernize CMS' digital operations.

WISeR Beneficiary means a Beneficiary that meets the requirements set forth in Section 4.1.

WISeR Clinician means an individual that satisfies the requirements of Section 3.6.

WISeR Clinical Reviewer means an individual that satisfies the requirements of Section 3.6.

WISeR Data Reporting Guide means the guidance paper that CMS publishes and provides to the WISeR Participant that sets forth the WISeR Participant's reporting obligations during the Model. CMS may modify the WISeR Data Reporting Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Data Reporting Guide at least 30 Days prior to the effective date of such revisions.

WISeR Discount means the discount specified in Section 8.3.C that CMS applies when calculating the WISeR Payment.

WISeR Jurisdiction means the defined geographic states of New Jersey (Jurisdiction L/Novitas Solutions, Inc.), Ohio (Jurisdiction 15/CGS Administrators, LLC), Oklahoma and Texas (JH/Novitas), and Arizona and Washington (JF/Noridian) selected for the WISeR Model

for which the WISeR Participant conducts Prior Authorization Process on claims for Select Items and Services from institutional providers, physicians, clinicians and suppliers.

WISeR Participant means the technology company that meets the requirements set forth in Article III and has signed this Agreement with CMS to participate in the Model.

WISeR Participant Guide means a guidance paper that CMS publishes and provides to the WISeR Participant that sets forth additional details to support the WISeR Participant's activities and obligations during the Model. CMS may modify the WISeR Participant Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Participant Guide at least 30 Days prior to the effective date of such revisions.

WISeR Payment means the Model specific payment made by CMS for a Payable Non-Affirmation or a Pre-Payment Review that qualifies for payment as set forth in Article VIII.

WISeR Performance Measure Set means the measures detailed in Appendix B, and as may be revised in the WISeR Data Reporting Guide, that CMS uses in calculating the AQS.

WISeR Provider means a provider, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction that furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

WISeR Recoupment means the amount owed to CMS if CMS pays a WISeR Payment to the WISeR Participant and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

WISeR Supplier means a supplier, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction and who furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

Article III. General Requirements

Section 3.1 WISeR Participant Requirements

A. During the Agreement Term, the WISeR Participant shall:
    1. Be a legal entity formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates for the purpose of carrying out the activities required by this Agreement;
    2. Have Enhanced Technology and be identified by a single TIN, to provide specified health insurance benefit administrative services, including

Medicare Prior Authorization and Pre-Payment Review services to interpret and apply Medicare Coverage Criteria and clinical coverage criteria derived from NCDs and LCDs, in support of the Medicare FFS program;

3. Use its Enhanced Technology for implementing and streamlining the Prior Authorization Process and Pre-Payment Review for Select Items and Services in its assigned WISeR Jurisdiction;
4. Have a valid Business Associate Agreement ("**BAA**") with CMS;
5. Support CMS in its efforts to make accurate and timely payments to WISeR Providers or WISeR Suppliers for Select Items and Services furnished to WISeR Beneficiaries;
6. Support CMS in its efforts to ensure care provided to Beneficiaries is Medically Necessary and adheres to Medicare Coverage Criteria, thus protecting Beneficiaries and the Medicare Trust Fund; and
7. Not have a conflict of interest as detailed in Section 3.3 of this Agreement.

The WISeR Participant states that it satisfies the requirements of this Section 3.1.A as of the Effective Date.

B. The WISeR Participant shall satisfy the requirements of this Section 3.1.B no later than 45 Days before the Start Date and throughout the remainder of the Agreement Term:
    1. Have access to Federal Risk and Authorization Management Program ("**FedRAMP**") certified workflows;
    2. Comply with all applicable Federal data protection and security requirements including Federal Information Security Management Act ("**FISMA**") requirements, CMS Information Systems Security & Privacy Policy ("**IS2P2**"), CMS Acceptable Risk Safeguard ("**ARS**");
    3. Follow CMS Authority to Operate ("**ATO**") guidelines for connections established between the Medicare Administrative Contractor ("**MAC**") and WISeR Participant; and
    4. Enter into a valid Joint Operating Agreement ("**JOA**") with the applicable MAC.
C. Changes to the WISeR Participant
    1. Change of WISeR Participant Name. The WISeR Participant shall provide written notice to CMS at least 60 Days before any change in the WISeR Participant's legal name becomes effective. The WISeR Participant shall forward to CMS a copy of the document effectuating the name change, authenticated by the appropriate state official (if applicable), and the parties shall execute an agreement reflecting the change of the WISeR Participant's name. This obligation shall remain in effect until the latter of the effective date

of termination of this Agreement or when the final payment by or to the WISeR Participant has been made under this Agreement.

2. Change in WISeR Participant TIN. The WISeR Participant shall provide at least 90 Days advanced written notice before the effective date of any change in the WISeR Participant's TIN. Such notice must be submitted in the form and manner specified by CMS. In response to a change in the WISeR Participant's TIN, CMS may terminate the Agreement or Agreement Performance Period, or take any other actions consistent with the terms of this Agreement. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
3. Change in Control.
    i. The WISeR Participant shall provide written notice to CMS at least 90 Days before the effective date of any Change in Control. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
    ii. Upon learning of a Change in Control, CMS may conduct a Program Integrity Screening and take other appropriate action to ensure compliance with the terms of the Model by the new controlling entity and may require the new controlling entity to execute a novation agreement with CMS or require the new controlling entity to execute a new Participation Agreement with CMS. CMS may also terminate the Participation Agreement between the former controlling entity and CMS.
    iii. If the WISeR Participant undergoes a Change in Control, CMS may take one or more of the following actions: terminate this Agreement; terminate the Agreement Performance Period; or immediately conduct financial settlement in accordance with Section 8.9.
4. Change in Primary Point of Contact. The WISeR Participant shall provide written notice to CMS of any changes to the contact information for the WISeR Participant's primary point of contact no later than 15 Days after the change.

D. Information for Electronic Funds Transfer

1. The WISeR Participant shall submit to CMS a completed Electronic Funds Transfer Authorization Agreement in the form and manner and by the date(s) specified by CMS.

2. The WISeR Participant shall promptly update its Electronic Funds Transfer Authorization Agreement if there are account or bank changes, or any change to the WISeR Participant set forth in Section 3.1.C.
3. If the WISeR Participant fails to submit or accurately complete the Electronic Funds Transfer Authorization Agreement, CMS may withhold any WISeR Payment owed to the WISeR Participant until the WISeR Participant has submitted and CMS has processed an Electronic Funds Transfer Authorization Agreement with the correct information. In addition, the failure to submit or accurately complete an Electronic Funds Transfer Authorization Agreement could delay the WISeR Participant's receipt and timely payment of a demand for payment under this Agreement, and thereby cause the WISeR Participant to be liable for interest on the amount owed to CMS.

E. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, the WISeR Participant fails to meet any requirements set forth in Section 3.1. The WISeR Participant shall provide such written notice to CMS at least 30 Days before failing to satisfy any requirements in Section 3.1.A, or within 5 Days of becoming aware that the WISeR Participant has failed to satisfy any requirements in Section 3.1(B)-(D).

Section 3.2 WISeR Participant Governance

A. General.
   1. The WISeR Participant shall maintain an identifiable governing body with sole and exclusive authority to execute the functions of the WISeR Participant and make final decisions on behalf of the WISeR Participant. The WISeR Participant shall have a governing body that satisfies the following criteria:
      i. The governing body has responsibility for oversight and strategic direction of the WISeR Participant and is responsible for holding the WISeR Participant management accountable for the WISeR Participant's activities;
      ii. The governing body has a transparent governing process;
      iii. When acting as a member of the governing body of the WISeR Participant, each governing body member has a fiduciary duty to the WISeR Participant and to CMS for actions relating to the terms of this Agreement, the Model and the terms set forth in the Business Associate Agreement, including the duty of loyalty, and shall act consistent with that fiduciary duty; and

iv. The governing body shall receive regular reports from the designated compliance official of the WISeR Participant who satisfies the requirements of Section 11.1.

2. The WISeR Participant shall provide each member of the governing body with a copy of the Agreement and any amendments hereto.
3. If CMS determines that the composition of the WISeR Participant's governing body, executive leadership, or parent organization(s) (as applicable) compromises the WISeR Participant's ability to participate in the Model or to comply with the terms of the Agreement, CMS may take one or more of the remedial actions specified in Section 13.2.
4. The WISeR Participant shall ensure that its governing body implements a process for documenting governing body composition, meetings and decisions, and shall retain such documentation in accordance with Section 12.2.

B. Composition and Control of the Governing Body.

1. The WISeR Participant's governing body shall not include any individual with pending or open investigations, or a history of convictions or sanctions, including without limitation:
    i. Investigations or actions related to participation in Medicare, Medicaid, or Children's Health Insurance Program;
    ii. A history of failure to pay Medicare debts in a timely manner;
    iii. Affiliations with individuals or entities that have a history of program integrity issues;
    iv. Conduct that a reasonable person would deem to be unfit conduct; or
    v. A history of legal or monetary sanctions.
2. The WISeR Participant shall routinely monitor each individual on its governing body to ensure compliance with the provisions of this Section 3.2.
3. The WISeR Participant shall immediately remove from its governing body any individual that becomes subject to a conviction or sanction.
4. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, it removes an individual from its governing body. The WISeR Participant shall provide such written notice to CMS within 5 Days of such removal.
5. The governing body members may serve in similar or complementary roles or positions, subject to Section 3.3.

Section 3.3 Conflict of Interest

A. The WISeR Participant shall have a conflict of interest policy that applies to members of the governing body and satisfies the following criteria:
    1. Requires each member of the governing body to disclose relevant financial interests and other interests that could prevent impartiality;
    2. Requires each member of the governing body to update its disclosure statement whenever the member's personal or financial circumstances change in such a way that a new conflict of interest might occur;
    3. Provides a procedure to determine whether a conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses remedial actions for members of the governing body that fail to comply with the policy.

B. Notwithstanding the obligations set forth in Section 3.3.A, the WISeR Participant shall have a conflict of interest policy that applies to its business operations and satisfies the following criteria:
    1. Requires that the WISeR Participant refrain from engaging in activities that would lead to the preferential or non-preferential treatment of any WISeR Provider, WISeR Supplier, WISeR Clinician, WISeR Clinical Reviewer, individual clinician, medical group, medical practice, Beneficiary, or any other individual or entity with an interest in the Prior Authorization Process or Pre-Payment Review;
    2. Requires that the WISeR Participant prohibit WISeR Clinicians and WISeR Clinical Reviewers from participating in the Prior Authorization Process and Pre-Payment Review associated with a provider or supplier under the same TIN as the reviewing WISeR Clinician or WISeR Clinical Reviewer;
    3. Provides a procedure to determine whether such conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses plans of action to correct instances that fail to comply with the policy.

C. The WISeR Participant shall ensure that its conflict of interest policy sets forth a process to address situations where an individual employed by or contracted by the WISeR Participant and has a financial interest, personal activity, or relationship that could impair that individual's ability to act impartially and in the best interest of CMS when performing under the terms of this Agreement, the Business Associate Agreement, or the Model.

D. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Prior Authorization request not participate in the review of that request or any associated Resubmissions related to that Prior Authorization request.
E. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Pre-Payment Review not participate in the review of that claim or any associated Resubmissions related to that Pre-Payment Review.
F. The WISeR Participant shall de-identify Prior Authorization requests, Resubmissions, and Pre-Payment Review claims prior to permitting its WISeR Clinicians and WISeR Clinical Reviewers to conduct a Medical Review or peer-to-peer review.
G. The WISeR Participant shall designate a committee or group responsible for evaluating disclosed potential conflicts of interest and determine whether they pose a risk to the fairness of the Prior Authorization review or the Pre-Payment Review.
    1. The WISeR Participant shall provide immediate written notice of disclosed potential conflicts of interest to CMS. Such written notice shall be made within 5 Days of becoming aware of the potential conflicts of interest.
    2. The WISeR Participant shall include CMS in the determination process associated with the disclosed potential conflicts of interest.

Section 3.4 Required Prior Authorization Activities

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.
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.
C. The WISeR Participant shall review Prior Authorizations in its WISeR Jurisdiction submitted by all WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).
D. Consistent with Section 3.4.C, the WISeR Participant shall perform its Prior Authorization Process on Prior Authorizations received.
E. Consistent with the terms of this Agreement and the requirements set forth in the WISeR Participant Guide, the WISeR Participant shall issue Prior Authorization determinations to the requesting WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction with a copy to the applicable WISeR Beneficiary.

Section 3.5 WISeR Providers and WISeR Suppliers

A. WISeR Providers and WISeR Suppliers may submit Prior Authorization requests directly to the WISeR Participant and receive a determination for Select Items and Services.

B. If the WISeR Provider or WISeR Supplier submits a Prior Authorization request to its MAC for a Select Item or Service, then:

   1. CMS, through the applicable MAC, will re-route the Prior Authorization request to the WISeR Participant;
   2. The WISeR Participant must perform its Prior Authorization Process on the re-routed Prior Authorization from the MAC for the Select Item or Service and issue a determination directly to the WISeR Provider or WISeR Supplier with copy to the MAC and the WISeR Beneficiary identified on the Prior Authorization request; and
   3. Perform any additional requirements as described in the WISeR Participant Guide.

C. CMS, through the applicable MAC, will notify the WISeR Participant if a WISeR Provider or WISeR Supplier submits a claim to Medicare for one or more Select Items and Services furnished to a WISeR Beneficiary in the WISeR Jurisdiction without requesting Prior Authorization.

D. The WISeR Participant must conduct Pre-Payment Review in accordance with Section 6.5 of this Agreement for each Select Item or Service that does not have a Prior Authorization request from the WISeR Provider or WISeR Supplier.

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.

F. CMS will provide written notice, which may be in the form of the WISeR Participant Guide, to the WISeR Participant regarding additional determination letter requirements.

G. The WISeR Participant shall provide to its WISeR Providers and WISeR Suppliers prior authorization criteria and relevant evidence-based clinical practice guidelines for Select Items and Services in a form and manner and by the date(s) determined by CMS. Such compliance assistance information shall include examples of documentation that would support approval of a Prior Authorization request for each Select Item or Service, as well as examples of common mistakes, omissions, and evidence that would result in a denial of Prior Authorization.

Section 3.6 WISeR Clinicians and WISeR Clinical Reviewers

A. General.

1. The WISeR Participant may choose to:
    i. Directly employ clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinicians**"); or
    ii. Subcontract with a separate entity that provides appropriate clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinical Reviewers**"); or
    iii. Do both (i) and (ii).
2. The WISeR Participant must provide to its subcontractor, if applicable, necessary and appropriate WISeR Participant Guide provisions to ensure that each WISeR Clinical Reviewer meets the Medical Review requirements to ensure proper coverage determinations that adheres to Medicare Coverage Criteria and CMS coverage policy.
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.

B. <u>WISeR Clinicians</u>.
1. The WISeR Participant shall ensure that each WISeR Clinician:
    i. Be a board-certified clinician, including a:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;

iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;

vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and

vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinician performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant shall ensure that each WISeR Clinician performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers in a form and manner determined by CMS, as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that the WISeR Clinician has an active, valid and unrestricted license.

C. Record of WISeR Clinicians. The WISeR Participant shall maintain, in accordance with Article XII, a record of all its WISeR Clinicians.
   1. The WISeR Participant shall retain current and historical records of all its WISeR Clinicians in accordance with Section 12.2 of this Agreement.
   2. CMS may request and the WISeR Participant must provide to CMS a certified copy of all WISeR Clinicians at any given time during the Agreement Term.

D. Monitoring and Compliance of WISeR Clinicians.
   1. CMS will monitor the program integrity history of the WISeR Participant's WISeR Clinicians. CMS may require the WISeR Participant to exclude an individual WISeR Clinician or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
   2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinician be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure that each WISeR Clinician conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks, and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that each WISeR Clinician uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items and Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Items and Services;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

E. WISeR Clinical Reviewers.

1. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer:
    i. Be a board-certified clinician, including:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;
    iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;
vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and
vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinical Reviewer performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall require its subcontractor to ensure that the WISeR Clinical Reviewer has an active, valid and unrestricted license.

F. Record of WISeR Clinical Reviewers. The WISeR Participant must require its subcontractor to maintain, in accordance with Article XII of this Agreement, a record of all WISeR Clinical Reviewers performing activities related to this Model.
1. The WISeR Participant shall require the subcontractor to retain current and historical records of all WISeR Clinical Reviewers consistent with Section 12.2 of this Agreement.
2. The WISeR Participant shall require its subcontractor to provide the WISeR Participant with a certified copy of all WISeR Clinical Reviewers at any given time during the Agreement Term. The WISeR Participant shall provide such information to CMS in a form and manner and by the date(s) specified by CMS.

G. Monitoring and Compliance of WISeR Clinical Reviewers.
1. CMS will monitor the program integrity history of the WISeR Participant's use of WISeR Clinical Reviewers. CMS may require the WISeR Participant to exclude an individual WISeR Clinical Reviewer or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinical Reviewer be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items or Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Item or Service;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

Section 3.7 Customer Service

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.
B. The WISeR Participant shall provide an overall environment where WISeR Providers and WISeR Suppliers understand the Prior Authorization Process and Pre-Payment Review process for Select Items and Services.
C. The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.
D. The WISeR Participant shall maintain effective WISeR Provider and WISeR Supplier education that helps ensure complete Prior Authorization submissions for Select Items and Services and reduces the need for re-submissions, requests for appeal, and overturn of coverage determinations on appeal.
E. The WISeR Participant shall educate WISeR Providers and WISeR Suppliers on how to submit Prior Authorization requests and provide its WISeR Providers and WISeR Suppliers with information related to the Medicare Coverage Criteria associated with

the Select Items and Services. Such educational activities shall be conducted in a form and manner determined or approved by CMS, and as may be detailed in the WISeR Participant Guide.

F. The WISeR Participant must educate WISeR Providers and WISeR Suppliers within its assigned WISeR Jurisdiction about the Prior Authorization Process consistent with the provisions of this Agreement and the WISeR Participant Guide.

Section 3.8 Operational Requirements

A. The WISeR Participant shall promote corporate integrity and establish internal controls and an effective compliance program to achieve Agreement goals and objectives.

B. The WISeR Participant shall work collaboratively with CMS, WISeR Providers, WISeR Suppliers, Medicare Administrative Contractors, and other CMS contractors to foster integration of Medicare operations.

C. The WISeR Participant shall develop and continually refine business processes to foster excellence and quality in the administration of the Medicare program.

D. The WISeR Participant shall foster efficiencies in the administration of the Medicare FFS program to promote best value for the government.

E. The WISeR Participant shall use innovative and creative solutions to improve program operations.

Section 3.9 Overlap with Other CMS Programs and Initiatives

A. The parties agree that the WISeR Model is not a shared savings model and there is no Beneficiary alignment in this Model.

B. The WISeR Participant may simultaneously participate in the WISeR Model and any other Innovation Center model.

C. CMS reserves the right to unilaterally update this overlaps policy upon written notice to the WISeR Participant.

Article IV. Beneficiary Eligibility, Engagement, Verification, and Protections

Section 4.1 Beneficiary Eligibility

A. To be considered a WISeR Beneficiary, a Beneficiary must meet the following criteria:

1. Be identified on a Prior Authorization request or a claim subject to Pre-Payment Review for a Select Item or Service from a WISeR Provider or WISeR Supplier in the WISeR Participant's WISeR Jurisdiction;

2. Is eligible for Medicare Part A and enrolled in Medicare Part B at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review;
3. Is a legal adult aged 18 years or older;
4. Is not enrolled in Medicare Advantage at the time of the Prior Authorization request or the date of service on the claim subject to Pre-Payment Review;
5. Has Medicare as the primary payer at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review; and
6. Is not covered under the United Mine Worker Health and Retirement Funds.

Section 4.2 Beneficiary Engagement and Beneficiary Verification

A. The WISeR Participant does not have Beneficiaries aligned or assigned to it for this Model.
B. CMS may require the WISeR Participant to educate Beneficiaries, including WISeR Beneficiaries, within its WISeR Jurisdiction on the Prior Authorization Process for Select Items and Services.
C. The WISeR Participant must ensure that each Prior Authorization request submitted by a WISeR Provider, WISeR Supplier, or a MAC is for a Select Item or Service that will be furnished to a WISeR Beneficiary within the WISeR Jurisdiction.

Section 4.3 Beneficiary Protections and Non-Affirmed Decisions

A. The WISeR Participant shall provide written Prior Authorization Process decisions to the WISeR Provider and/or WISeR Supplier with a copy to the applicable WISeR Beneficiary and appropriate MAC.
B. The WISeR Participant's Prior Authorization Non-Affirmation decision for the Select Item or Service that is determined to not be Medically Necessary must require the WISeR Provider or WISeR Supplier to notify the WISeR Beneficiary and issue an Advance Beneficiary Notice of Non-coverage (ABN) prior to performing such item(s) or service(s) if it is expected that payment would be denied.
C. For purposes of the WISeR Provider and WISeR Supplier notifications required under Sections 4.3.A and 4.3.B, the WISeR Participant shall use a template letter provided by CMS, in which CMS will designate letter content that the WISeR Participant shall not change, as well as places in which the WISeR Participant may insert its own original content.
D. Beneficiaries continue to have all applicable administrative appeal rights under Original Medicare.

Section 4.4 Prohibition on Beneficiary Inducements

Except as otherwise permitted by applicable law, the WISeR Participant shall not provide gifts or other remuneration to Beneficiaries to induce them to receive or to continue to receive items or services from one or more of the following: WISeR Providers, WISeR Suppliers, WISeR Clinicians, or WISeR Clinical Reviewers.

Section 4.5 HIPAA Requirements

A. The WISeR Participant acknowledges that it is either a covered entity or business associate, as those terms are defined in 45 C.F.R. § 160.103, of CMS that is a covered entity.
B. The WISeR Participant shall have all appropriate administrative, technical, and physical safeguards in place before the Start Date to protect the privacy and security of protected health information ("**PHI**") in accordance with 45 C.F.R. § 164.530(c).
C. The WISeR Participant shall maintain the privacy and security of all Model-related information that identifies individual Beneficiaries in accordance with the Health Insurance Portability and Accountability Act ("**HIPAA**") Privacy and Security Rules and all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of PHI by covered entities and their business associates, as well as all other applicable federal and state laws and regulations.

Article V. Functional Requirements

Section 5.1 Functional and Infrastructure Requirements

A. The WISeR Participant shall develop, execute, and maintain a risk management plan that includes:
    1. WISeR Jurisdiction-wide risks, including without limitation risks related to cybersecurity issues;
    2. Periodic assessment, conducted monthly at a minimum, of new risks; and
    3. Mitigation and contingency planning.
B. The WISeR Participant shall provide and use infrastructure to fulfill the requirements of this Agreement.
C. The WISeR Participant shall provide the infrastructure required to integrate and interact with the assigned CMS Virtual Data Center ("**VDC**") and to accomplish services not provided by the VDC to fulfill the requirements of this Agreement.
    1. The WISeR Participant shall work with all Base Function entities, including the VDC, to interface and/or facilitate the receipt or transmission of files, programs or other such products.

2. **Base Functions** are functions provided either by the shared system or the VDC and include interfaces that are part of the base system processing such as the Common Working File (CWF), Comprehensive Error Rate Testing (CERT), Correct Coding Initiative (CCI), BDRD, PECOS, PIMR, Pricer, PULSE, etc.
3. **Non-base/Non-core applications or interfaces** refers to any applications or interfaces that are not part of the base system processing or are not provided or maintained as part of the Medicare Shared Systems (FISS or MCS).
    i. Non-base/non-core applications or interfaces may involve an outside vendor, a Medicare Data Center, or any entity with which the WISeR Participant communicates or shares information through a software application (not including commercial word processing or spreadsheet programs) in processing Medicare claims.
    ii. Examples of non-base/non-core processes include but are not limited to the following:
        a. Print mail;
        b. American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N Transaction Translation Services (via Commercial Off the Shelf (COTS) products);
        c. Workload Management reports;
        d. Scanning Administration;
        e. ICR/OCR Imaging;
        f. Fraud, Waste, or Abuse reporting;
        g. Data Analysis (Easytrieve, SAS extracts, etc.); and
        h. Data files the WISeR Participant routinely receives.

D. The WISeR Participant shall provide translation software that is HIPAA-compliant and strictly adheres to the ASC X12N Technical Report Type 3 (TR3s) for inbound transactions (e.g., ASC X12N claim, ASC X12N 276 claim status request) and outbound transactions (e.g., ASC X12N 835 remittance advice, ASC X123N 277 claim status response, ASC X12N TA1 interchange acknowledgement, ASC X12N 999 implementation acknowledgment, ASC X12N 277 claim acknowledgment).

E. In the event of termination by CMS or the WISeR Participant pursuant to Article XIII, the WISeR Participant shall be required to perform certain closeout activities detailed by CMS in a form and manner and by the date(s) specified by CMS.

Section 5.2 Telecommunications

A. Unless directed to use another connection by CMS, the WISeR Participant shall use only the CMS-supplied telecommunications network to transmit Medicare data to ensure the privacy and security of this protected information for:
    1. Medicare communications between the WISeR Participant and Medicare Administrative Contractor(s), if any;
    2. Communications between the WISeR Participant and subcontractors, if any; and
    3. Communications between the WISeR Participant and CMS.
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.
C. As applicable, the WISeR Participant shall interact with CMS' current enterprise identity access management systems, or any future enterprise identity access management system as directed by CMS, to ensure that the electronic data interchange (EDI) submitter/receiver is an authorized EDI submitter for each transaction.
D. As applicable, the WISeR Participant shall be responsible for the verification/validation of the WISeR Providers and WISeR Suppliers that will be exchanging EDI with the WISeR Participant.

Section 5.3 CMS Audits and Reviews of Software

A. The WISeR Participant shall allow CMS the use of provided software and software documentation, tools, and equipment to conduct audit reviews, tests, and assessments of the WISeR Participant at its facility, its data center and/or in its data cloud.
B. Consistent with Section 5.3.A, the WISeR Participant shall allow CMS use and access to, without limitation, the WISeR Participant's Enhanced Technology, artificial intelligence, machine learning technology, and other similar technologies.

Article VI. Prior Authorization Process

Section 6.1 General

A. The WISeR Participant shall use its Enhanced Technology to review and assess Prior Authorization requests within its assigned WISeR Jurisdiction ("**Prior Authorization Process**").

B. The WISeR Participant must review and assess each Prior Authorization request to ensure that the request meets the following criteria:
    1. Include all documentation necessary to show that the Select Items and Services meet applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The Prior Authorization request is submitted before the Select Items and Services are provided to the WISeR Beneficiary and before the claim is submitted.
C. The WISeR Participant reviews and assesses each expedited Prior Authorization request to ensure that the expedited request meets the following criteria:
    1. Includes all documentation necessary to show that the Select Item or Service meets applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The expedited Prior Authorization request is submitted before the Select Item or Service is provided to the WISeR Beneficiary and before the claim is submitted.
    3. Includes documentation showing that the processing of the Prior Authorization must be expedited due to the WISeR Beneficiary's life, health, or ability to regain maximum function being in serious jeopardy.
D. The WISeR Participant shall evaluate and refine its Prior Authorization Process to ensure accuracy in its Prior Authorization determinations and to prevent harm to Beneficiaries, including WISeR Beneficiaries.
E. The WISeR Participant shall engage in activities such as Navigation Services to reduce clinically inappropriate care and promote clinically appropriate care with its WISeR Providers and WISeR Suppliers in a form and manner and by the date(s) specified by CMS.
F. The WISeR Participant shall report Prior Authorization Process related activities and metrics to CMS through monthly, yearly, and ad hoc reports in a form and manner and by the date(s) specified by CMS.

Section 6.2 Prior Authorization Process and Exemption Status

A. General. 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).
B. Upon receipt of a Prior Authorization, the WISeR Participant shall review the request for compliance with applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act.

1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to the Select Items and Services detailed in Table 1 of Appendix A of this Agreement.
2. The WISeR Participant shall verify that the Prior Authorization is for a Select Item or Service as detailed in Table 1 of Appendix A.
3. The WISeR Participant must further verify that the Prior Authorization request is from a WISeR Provider or WISeR Supplier within the WISeR Jurisdiction.
4. The WISeR Participant shall verify that the requested Select Item or Service would be furnished to an individual that is a WISeR Beneficiary.

C. The WISeR Participant, its WISeR Clinician(s) and its WISeR Clinical Reviewers shall conduct Medical Review of the Prior Authorization, any Resubmissions, render determinations, and communicate decisions to the WISeR Providers, WISeR Suppliers, and WISeR Beneficiaries in accordance with the terms of this Agreement and the applicable requirements detailed in the WISeR Participant Guide.

D. Resubmission. The WISeR Participant shall accept Resubmissions from a WISeR Provider or WISeR Supplier for a Select Item or Service.
1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to each Resubmission; or
2. At the request of the WISeR Provider or WISeR Supplier through its Resubmission, the WISeR Participant shall require its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, to perform peer-to-peer review of the Resubmission. Such peer-to-peer review activities and requirements are detailed in the WISeR Participant Guide and the WISeR Participant acknowledges and agrees that its WISeR Clinicians and WISeR Clinical Reviewers will comply with such requirements.

E. Exemption Status. The WISeR Participant shall provide Exemption Status to a WISeR Provider or WISeR Supplier that has:
1. Submitted the minimum number of Prior Authorization requests for Select Items and Services furnished to WISeR Beneficiaries within the WISeR Jurisdiction as detailed in the WISeR Participant Guide;
2. Has met the CMS threshold percentage of Prior Authorization Provisional Affirmations as detailed in the WISeR Participant Guide; and
3. Met any additional criteria set forth by CMS in the WISeR Participant Guide.

F. Exemption Status List. The WISeR Participant shall retain current and historical lists of WISeR Providers and WISeR Suppliers that have earned Exemption Status.
1. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it has earned Exemption Status and has been added to the Exemption Status list.

i. The WISeR Participant shall specify in its notice to the WISeR Provider or WISeR Supplier the effective date of its Exemption Status, the process for retaining Exemption Status, and provide such other details as described in the WISeR Participant Guide.

2. The WISeR Participant shall provide current and historical Exemption Status lists to CMS in a form and manner and by the date(s) specified by CMS in accordance with the terms of this Agreement and applicable requirements set forth in the WISeR Participant Guide.
3. The WISeR Participant may remove a WISeR Provider or WISeR Supplier from the Exemption Status list if it fails to meet the requirements for Exemption Status as described in the WISeR Participant Guide.
4. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it is removed from the Exemption Status list and such notice shall specify the effective date of removal, the process for re-earning Exemption Status, and provide such other details as described in the WISeR Participant Guide.

Section 6.3 Prior Authorization Determinations

A. Determination Letters.

1. CMS may develop and provide to the WISeR Participant and Model Participants template determination letters.
2. Upon request of the WISeR Participant to CMS, and at the discretion of CMS, the WISeR Participant may create its own template determination letter(s), and such template(s) must be submitted to CMS for review and written approval prior to use and include at a minimum the following information and any other information as specified in the WISeR Participant Guide:
    i. A Unique Tracking Number (UTN);
    ii. For Prior Authorization Non-Affirmation decisions:
        a. A detailed explanation for the decision;
        b. The availability of unlimited resubmissions by the WISeR Provider or WISeR Supplier;
        c. Instructions for how the WISeR Provider or WISeR Supplier may request peer-to-peer review; and
        d. The opportunity to forego the resubmission process, provide one or more of the Select Items and Services, submit the claim for payment and:
            1. The claim will be denied; and
            2. All Medicare appeal rights will be available.
    iii. For re-routed Prior Authorization decisions:

a. Contact information for the WISeR Participant;
b. Instructions to the requesting WISeR Provider and/or WISeR Supplier on how it may choose to submit future Prior Authorization requests for Select Items and Services directly to the WISeR Participant; and
c. Any additional information that CMS may require through written notification to the WISeR Participant.

3. If CMS determines that the template(s) submitted by the WISeR Participant contains misinformation or is otherwise inconsistent with the terms of this Agreement or the WISeR Participant Guide, CMS may reject the template(s) or require the WISeR Participant to amend the template(s) and resubmit such amended template(s) to CMS for review and approval prior to use.

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.

C. Resubmission of Prior Authorization.
1. The WISeR Participant shall issue a Resubmission Determination to the WISeR Provider or WISeR Supplier within 3 Days of the WISeR Participant's receipt of the Prior Authorization resubmission.
2. The WISeR Participant shall ensure the Resubmission Determination is delivered to the WISeR Provider or WISeR Supplier in the same manner it was submitted via postmark, fax, or electronic delivery.

D. Expedited Circumstances. The WISeR Participant may only consider an expedited review of a Prior Authorization request upon receipt of request for expedited review by the WISeR Provider or WISeR Supplier.
1. If the WISeR Participant, in consultation with its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, determines that delays in receipt of a Prior Authorization decision could jeopardize the life, health, or ability to regain maximum function of the WISeR Beneficiary, then the WISeR Participant will process the Prior Authorization under an expedited timeframe, upon request.
i. The WISeR Participant will communicate a determination within 2 business days of receipt of the expedited request.

ii. WISeR Providers and WISeR Suppliers, and their MAC(s) when applicable, are encouraged to use fax, Electronic Submission of Medical Documentation (esMD), or any other CMS approved electronic portal to avoid delays with mailing.

E. Prior Authorization Provisional Affirmation. The WISeR Participant will issue a Prior Authorization Provisional Affirmation of coverage to a WISeR Provider or WISeR Supplier, with a copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and any applicable criteria in the WISeR Participant Guide are met to support the rendering of such item or service to a WISeR Beneficiary.

1. The WISeR Participant's Prior Authorization Provisional Affirmation decision is valid for 120 days from the date the determination was made.

F. Prior Authorization Non-Affirmation.

1. Consistent with Section 3.6.B.2 and Section 3.6.E.2, the WISeR Participant must require its WISeR Clinician(s) and WISeR Clinical Reviewer(s), as applicable, to perform a Medical Review of each Prior Authorization request that may not meet Medicare Coverage Criteria.
    i. The Medical Review of a Prior Authorization request by a WISeR Clinician or WISeR Clinical Reviewer, as applicable, must be performed before the WISeR Participant issues a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier.
2. The WISeR Participant will issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier, with copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and applicable criteria in the WISeR Participant Guide are not met and do not support the rendering of such item or service to a WISeR Beneficiary.
3. The WISeR Participant may issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier for a Select Item or Service via the same method it was requested if the Prior Authorization request contains technical errors or is otherwise insufficient to meet the requirements for Prior Authorization Provisional Affirmation.

G. Appeals. The WISeR Participant acknowledges and agrees that nothing in this Agreement nor in the WISeR Participant Guide shall be construed to limit or otherwise prevent a WISeR Provider, WISeR Supplier, WISeR Beneficiary or Beneficiary from

engaging in the Medicare appeals process permitted by applicable law, regulations, or Medicare program requirements.

Section 6.4 Prior Authorization Non-Affirmation and Resubmissions

A. The WISeR Participant shall provide written notice consistent with Section 6.3.A of this Agreement to the WISeR Provider or WISeR Supplier that the WISeR Provider or WISeR Supplier may resubmit a Prior Authorization upon receipt of a Prior Authorization Non-Affirmation.
B. The WISeR Participant shall provide written notice, consistent with Section 6.3.A, to the WISeR Provider or WISeR Supplier that it may resubmit a Prior Authorization for expedited review consistent with the requirements in Section 6.3.D of this Agreement.
C. The WISeR Participant shall consider all Resubmissions for Prior Authorization received within 120 Days of the Initial Prior Authorization Determination.
D. The WISeR Participant shall review a Resubmission for Prior Authorization received after 120 Days of the Initial Prior Authorization Determination as an Initial Prior Authorization request.

Section 6.5 Pre-Payment Review

A. The WISeR Participant acknowledges that Prior Authorization is not a condition of payment to the WISeR Provider or WISeR Supplier.
B. The WISeR Participant agrees that the WISeR Provider or WISeR Supplier may elect not to submit a Prior Authorization before furnishing one or more of the Select Items and Services to a WISeR Beneficiary.
C. If the WISeR Provider or WISeR Supplier elects not to submit a Prior Authorization for one or more Select Items and Services it furnishes to a WISeR Beneficiary, then the WISeR Participant shall coordinate with the appropriate MAC to subject the claim to Pre-Payment Review consistent with the terms of this Agreement, Sections 6.5.C.1 and 6.5.C.2, and the requirements detailed in the WISeR Participant Guide.
    1. CMS, through its appropriate MAC, will flag claims submitted by the WISeR Provider or WISeR Supplier for Select Items and Services without a Prior Authorization request.
    2. CMS, through its appropriate MAC, will re-route flagged claims to the WISeR Participant for Pre-Payment Review.
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.

Article VII. Quality Performance

Section 7.1 Quality Score

CMS shall use the quality score in determining the WISeR Participant's Aggregate Quality Score ("**AQS**") according to the methodology described in this Article VII and the WISeR Data Reporting Guide.

Section 7.2 Quality Measures

A. General
   1. The WISeR Participant shall complete reporting for all quality measures and for all Prior Authorizations received, Prior Authorization Provisional Affirmations, Prior Authorization Non-Affirmations, and Resubmissions in accordance with the WISeR Data Reporting Guide.
   2. CMS will publish, at least annually, a WISeR Data Reporting Guide, detailing the WISeR quality reporting requirements.
   3. CMS may modify the WISeR Performance Measure Set, or the number of measures that the WISeR Participant must report, or both. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Performance Measure Set at least 30 Days prior to the effective date of the change.
      i. If CMS removes a quality measure from the WISeR Performance Measure Set in advance of a Performance Period, CMS will not use the removed quality measure to evaluate the WISeR Participant, and the WISeR Participant will not be accountable for performance on such quality measures during the relevant Performance Period.

B. WISeR Performance Measure Set
   1. The WISeR Participant shall report all measures to CMS that are listed in the WISeR Performance Measure Set as described in Appendix B to this Agreement and the WISeR Data Reporting Guide. CMS shall use these measures for the purposes of calculating the WISeR Participant's AQS, the monitoring and evaluation of the overall efficiency and accuracy in WISeR, and to evaluate the WISeR Participant's performance during the Model.
   2. CMS will determine what version of specifications will be used for each measure included in the WISeR Performance Measure Set for the applicable Performance Period. CMS will notify the WISeR Participant of the version of specifications that will be used for each measure included in the WISeR Performance Measure Set as early as possible after such information becomes available.

3. The WISeR Participant must report all required measures from the WISeR Performance Measure Set in order to be eligible to earn the WISeR Payment for a Performance Period in accordance with Section 8.3.

C. Quality Measure Reporting
   1. The WISeR Participant must submit all quality measures that are listed in the WISeR Performance Measure Set to CMS during the defined reporting period for quality measures as communicated in the WISeR Data Reporting Guide.
   2. CMS reserves the right to require submission via any other format, including the Fast Healthcare Interoperability Resources ("**FHIR®**") standard, at any time during the Agreement Term without the consent of the WISeR Participant. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the reporting format of measures at least 90 Days prior to the measurement period.
   3. The WISeR Participant shall comply with the requirements described in this Article VII and Appendix B of this Agreement, and the requirements detailed in the WISeR Data Reporting Guide.

Section 7.3 Collection of Data and Purpose

A. Pursuant to 42 C.F.R. § 403.1110(b), the WISeR Participant must collect and report data described in Section 7.2 to CMS for CMS' Model monitoring and evaluation purposes.
B. The WISeR Participant, at CMS' request, will administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
C. CMS reserves the right to administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
D. CMS may require the WISeR Participant to implement surveys of WISeR Providers, WISeR Suppliers, and/or WISeR Beneficiaries in the WISeR Participant's designated WISeR Jurisdiction and report any survey measures included in the WISeR Data Reporting Guide to CMS.

Section 7.4 Quality Performance Scoring

A. CMS will calculate the WISeR Participant's AQS for each Performance Period at the time of Reconciliation.
B. CMS will calculate the AQS based on quality measures specified in the WISeR Data Reporting Guide.

C. CMS will calculate the AQS by totaling the quality points for all quality measures included in the AQS calculation for a given Performance Period and dividing by the maximum quality points available for these included quality measures.
D. CMS may modify the methodology for Quality Performance Scoring and shall notify the WISeR Participant in writing at least 30 Days before the start of the Performance Period in which such change would take effect. Modifications to the Quality Performance Scoring methodology may include, but are not limited to:
    1. Modifications to the set of quality measures included in the AQS;
    2. Modifications to the point values and point distributions for one or more quality measures included in the AQS;
    3. Modifications to the benchmark for one or more quality measures included in the AQS; and
    4. Modifications to the metrics for one or more quality measures included in the AQS.
E. CMS will convert the AQS to a quality multiplier that will be applied to each WISeR payment for the applicable Performance Period, as detailed in the WISeR Data Reporting Guide.

Article VIII. Financial Management and Payment

Section 8.1 General

A. CMS shall make, adjust, settle, and seek repayment of WISeR Payments in accordance with this Article VIII and Article XIII.
B. CMS may unilaterally amend Article VIII and to the extent practicable will issue advance written notice to the WISeR Participant 30 Days before the start of the Performance Period in which the amendment would take effect.

Section 8.2 Financial Management Requirements

A. The WISeR Participant shall promote the fiscal integrity of the Medicare FFS program and be an accountable steward of public funds.
B. The WISeR Participant shall adhere to the CMS Medicare integrity program.

Section 8.3 WISeR Payments

A. General.
    1. CMS pays the WISeR Payment to the WISeR Participant, as set forth in this Article VIII, subject to initial Reconciliation, financial settlement, and recoupment.

2. The WISeR Participant may receive a WISeR Payment for each Pre-Payment Review that results in a denied claim for a Select Item or Service and for each Payable Non-Affirmation.
3. CMS shall not pay the WISeR Participant a WISeR Payment if the WISeR Participant conducts a Prior Authorization or a Pre-Payment Review and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
4. The WISeR Participant owes a WISeR Recoupment and shall remit all WISeR Recoupments to CMS if Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to a WISeR Beneficiary due to the successful appeal of a claim denial.
5. CMS calculates the WISeR Payment as set forth in Section 8.3.D.

B. Calculation of Regional Benchmark.

1. For each Performance Period and each Locality within the WISeR Participant's designated WISeR Jurisdiction, CMS determines a Locality-specific Regional Benchmark for each of the Select Items and Services identified in Table 1 of Appendix A of this Agreement.
2. Except as specified in Section 8.3.B.3, CMS calculates the Regional Benchmark by:
    i. Identifying all claims that were submitted within the state that include the applicable Locality, were submitted by a WISeR Provider or a WISeR Supplier, include the applicable Select Item or Service, and have a date of service in the 12 months preceding the start of the applicable Performance Period;
    ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the Locality and applicable to the calendar year that includes the Performance Period being reconciled; and
    iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.
3. In the event change in law or Medicare policy changes effective during the Agreement Performance Period and applicable to a Select Item(s) or Service(s), CMS may, at its sole discretion, calculate the Regional Benchmark for the applicable Select Item or Service for one or more Performance Periods by:

i. Identifying all claims for the Select Item or Service that were submitted by Medicare-enrolled providers or suppliers within the WISeR Participant's designated MAC Jurisdiction with a date of service that is:
    a. No earlier than the effective date of the applicable legislation or Medicare policy change;
    b. No earlier than 9 months before the start of the applicable Performance Period; and
    c. No later than the final Day of the applicable Performance Period; and
ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the calendar year that includes the Performance Period being reconciled; and
iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.

4. When calculating the average claim-level payment as set forth in Section 8.3.B.2.iii and Section 8.3.B.3.iii, CMS may exclude payments for certain items or services billed on the same claim as the applicable Select Item or Service. CMS will maintain a list of such exclusions in the WISeR Participant Guide.

C. WISeR Discount. CMS calculates the WISeR Discount separately by state for each of the Select Items and Services as the percentage of claims with a medical necessity denial among all claims submitted by WISeR Providers and WISeR Suppliers within the state for that Select Item or Service with a date of service in 12 months preceding the start of the Model Performance Period. CMS may modify the WISeR Discount, including the dates of service for claims included in the calculation of the WISeR Discount, and to the extent practicable will provide 30 Days' advance written notice before the effective date of such modifications.

D. WISeR Payment. The WISeR Participant may earn a WISeR Payment for each Payable Non-Affirmation and for each Pre-Payment Review resulting in a denied claim for a Select Item or Service.

1. CMS calculates the WISeR Payment for each Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state;
    ii. Multiplying by the WISeR payment rate of 25 percent; and
    iii. Applying the quality adjustment determined by the WISeR Participant's AQS.

2. CMS calculates the WISeR Payment for each Pre-Payment Review resulting in a denied claim for a Select Item or Service by:
    i. Calculating the amount billed on the claim, less any approved payments for services other than the Select Item or Service that were billed on the same claim and less any denied payments billed on the same claim for one or more excluded service(s) noted in the WISeR Participant Guide;
    ii. Reducing the amount set forth in Section 8.3.D.2.i by the WISeR Discount applicable to the Select Item or Service and state;
    iii. Multiplying by the WISeR payment rate of 25 percent; and
    iv. Applying the quality adjustment determined by the WISeR Participant's AQS.

E. WISeR Recoupment. CMS will recoup a WISeR Recoupment from the WISeR Participant if CMS pays the WISeR Participant a WISeR Payment and Medicare subsequently pays the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
    1. The amount of the WISeR Recoupment will equal the amount of the previous WISeR Payment that CMS paid to the WISeR Participant for the applicable Payable Non-Affirmation or Pre-Payment Review.
    2. CMS will identify any WISeR Recoupments on a quarterly basis.
    3. To the extent possible, CMS will net any WISeR Recoupments against the total of WISeR Payments for a future Performance Period as set forth in Section 8.5.
    4. If CMS cannot collect WISeR Recoupments for claims appeals adjudicated after the Reconciliation of the final Performance Period under the Agreement or any other CMS program or initiative, CMS shall issue a demand letter to the WISeR Participant and the WISeR Participant shall pay CMS the amount owed within 30 Days of the date of demand letter.
    5. If CMS does not timely receive payment in full, the remaining amount owed will be considered a delinquent debt subject to the provisions of Section 8.8.D.

Section 8.4 Advance WISeR Payment

A. At the sole discretion of CMS, CMS may pay the WISeR Participant an Advance WISeR Payment prior to completing Reconciliation for a given Performance Period.

B. Eligibility Criteria.
    1. At the sole discretion of CMS, CMS may provide an Advance WISeR Payment to the WISeR Participant for an applicable Performance Period.

2. The WISeR Participant may be eligible to receive an Advance WISeR Payment during an applicable Performance Year if:
    i. CMS has notified the WISeR Participant of the availability of an Advance WISeR Payment for a specified Performance Period;
    ii. CMS has detailed specific data elements that the WISeR Participant must report to CMS in a form and manner and by the date(s) specified by CMS ("**Preliminary Data**");
    iii. The WISeR Participant timely reports the required data elements to CMS; and
    iv. CMS has approved the WISeR Participant's reported data elements and eligibility for an Advance WISeR Payment for the specified Performance Period.
3. If CMS determines that the WISeR Participant has not timely or accurately reported all required data elements, then CMS may deem the WISeR Participant ineligible for an Advance WISeR Payment for the applicable Performance Period.
4. If CMS has approved the WISeR Participant's eligibility for an Advance WISeR Payment for the applicable Performance Period, then CMS calculates the Advance WISeR Payment as set forth in Section 8.4.D.
5. In applicable Performance Periods, CMS will calculate the Advance WISeR Payment no earlier than the first Day after the end of the Performance Period.

C. Adjustments to Future WISeR Payment(s). If CMS determines that the WISeR Participant is eligible to receive an Advance WISeR Payment, CMS will net the amount of the Advance WISeR Payment against future WISeR Payments, including as applicable:
    1. Any WISeR Payments that CMS calculates for the applicable Performance Period during Reconciliation; and
    2. Any WISeR Payments that CMS calculates for subsequent Performance Periods.

D. Calculation of an Advance WISeR Payment. CMS calculates an Advance WISeR Payment using Preliminary Data for the Performance Period submitted by the WISeR Participant as set forth in Section 8.4.B. CMS calculates the Advance WISeR Payment for the applicable Performance Period as follows:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will provisionally determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will provisionally identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will estimate the WISeR Payment for each provisionally identified Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state; and
    ii. Multiplying by the WISeR payment rate of 25 percent.
5. CMS will estimate the WISeR Payment for each provisionally identified Pre-Payment Review qualifying for a WISeR Payment by:
    i. Calculating the amount billed on the claim, less any payments for services other than the Select Item or Service that were billed on the same claim;
    ii. Reducing this amount by the WISeR Discount applicable to the Select Item or Service and state; and
    iii. Multiplying by the WISeR payment rate of 25 percent.
6. CMS will total the estimated WISeR Payments as set forth in Section 8.4.E.4 and Section 8.4.E.5 and multiply this total by 50 percent to obtain the Advance WISeR Payment.

Section 8.5 Reconciliation Process

A. CMS will perform Reconciliation for a Performance Period by completing the following calculations:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will calculate the AQS for the WISeR Participant as set forth in Section 7.4 and in the WISeR Data Reporting Guide.
5. CMS will calculate the WISeR Payment as set forth in Section 8.3.D.
6. CMS will identify any pending WISeR Recoupments as set forth in Section 8.3.E. and will net these WISeR Recoupments against the total of WISeR Payments for the Performance Period.

B. CMS will perform Reconciliation for a Performance Period no earlier than the Day after the last Day on which a Resubmission for a Prior Authorization may be submitted, except as otherwise provided in Section 8.5.C.
    1. After calculating the WISeR Payment amount for the Reconciliation for a Performance Period, CMS will compare this amount against any WISeR Payment that was calculated in the initial Reconciliation for the same Performance Period and already paid or recouped by CMS, to determine the net amount of any WISeR Payment still owed for that Performance Period.
    2. If CMS issues a Reconciliation Report detailing the results of the Reconciliation, as described in Section 8.6, simultaneously with the Reconciliation Report detailing the results of the initial Reconciliation for a subsequent Performance Period, CMS may net any WISeR Payment amount specified in the Reconciliation Report for the initial Reconciliation against the net WISeR Payment amount that CMS calculates for the Reconciliation in accordance with Section 8.5.B.1.
C. If the Agreement or Agreement Performance Period is terminated pursuant to Article XIII, CMS shall conduct an initial Reconciliation and a final financial settlement, in accordance with Section 8.9, for the WISeR Participant's final Performance Period, which shall include all Prior Authorizations and Pre-Payment Reviews conducted by the WISeR Participant through the effective date of termination or expiration of this Agreement.

Section 8.6 Reconciliation Report

A. After performing Reconciliation for a given Performance Period as set forth in Section 8.5, CMS shall issue a Reconciliation Report to the WISeR Participant.
B. The Reconciliation Report will set forth the calculation of the WISeR Participant's Regional Benchmarks, AQS, Payable Non-Affirmations, and any applicable WISeR Payment for that Performance Period. In accordance with Section 8.5, the Reconciliation Report for any subsequent Reconciliation for a given Performance Period will also set forth any necessary adjustments to the WISeR Payment amount, if applicable, calculated in the initial Reconciliation for that Performance Period.
C. CMS shall make reasonable efforts to issue the initial Reconciliation Report for each Performance Period within 6 months after the last Day of that Performance Period.
D. Unless CMS receives a timely calculation error notice in accordance with Section 8.7, the Reconciliation Report shall be deemed final 30 Days from the date of issuance by CMS.

Section 8.7 Reconciliation Report Calculation Error

A. The WISeR Participant may contest a Reconciliation Report in accordance with this Section 8.7.
B. The WISeR Participant shall have 30 Days from the date the Reconciliation Report is issued to provide written notice to CMS of an error in the calculation of the WISeR Payment specified in that Reconciliation Report. The calculation error notice must contain a detailed, written explanation of the basis for the calculation error, including any supporting documentation.
C. If CMS receives a timely calculation error notice, CMS shall issue a written determination within 30 Days to either confirm or revise the calculation error, although CMS may extend the deadline for its determination upon written notice to the WISeR Participant.
    1. If CMS issues a written determination that the amount was calculated in error, CMS shall issue a revised Reconciliation Report, which is final on the date of issuance. The WISeR Participant may dispute the revised Reconciliation Report in accordance with Article XIV if the dispute is not precluded from review.
    2. If CMS issues a written determination that the amount is correct, the Reconciliation Report is final on the date the determination is issued.
    3. The WISeR Participant may dispute the determination issued by CMS in accordance with Article XIV if the dispute is not precluded from review.

D. If the WISeR Participant does not submit a timely calculation error notice to CMS in accordance with this Section 8.7, the WISeR Participant is precluded from later contesting the WISeR Payment amounts specified in that Reconciliation Report.
E. If as a result of any later inspection, evaluation, investigation, or audit, it is determined that any WISeR Payment amounts have been calculated in error, CMS may adjust such amounts, issue a revised Reconciliation Report, and make or demand payment of any additional amounts owed in accordance with this Section 8.7.

Section 8.8 Payment of Amounts Owed

A. CMS will pay the WISeR Participant any WISeR Payment amount owed to the WISeR Participant that is specified in Reconciliation Report within 30 Days after the date the Reconciliation Report is deemed final, as set forth in this Section 8.8.
B. CMS shall issue to the WISeR Participant a demand letter for any WISeR Payment owed pursuant to a Reconciliation Report that has been deemed final. The demand letter will be sent to the WISeR Participant at the address specified on the most recent Electronic Funds Transfer Authorization Agreement submitted by the WISeR Participant in accordance with Section 3.1.E.
C. The WISeR Participant shall pay any WISeR Payment amount owed to CMS within 30 Days of the date of a demand letter.
D. Delinquent Debt
    i. If the WISeR Participant fails to pay amounts due to CMS in full by the date specified in any demand letter, CMS shall assess simple interest on the unpaid balance at the rate applicable to other Medicare debts under 42 C.F.R. § 405.378. Interest shall be calculated in 30-Day periods and shall be assessed for each 30-Day period that payment is not made in full. Any payments received by CMS first shall be applied toward accrued interest and then to any outstanding principal balance due.
    ii. If CMS does not receive payment in full by the date the payment is due, CMS shall invoke all legal means to collect the debt and will use any applicable debt collection tools, including referral of the debt to the United States Department of Treasury, pursuant to 31 U.S.C. § 3711(g).

Section 8.9 Financial Settlement Report

A. Upon the expiration or termination of the Agreement Performance Period, CMS will issue to the WISeR Participant a financial settlement report that sets forth the amount of any WISeR Recoupments that the WISeR Participant must repay to CMS

or the amount of any WISeR Payment that CMS must make to the WISeR Participant, in accordance with this Agreement ("**Financial Settlement Report**").

B. If the Financial Settlement Report indicates that CMS owes the WISeR Participant additional payment, CMS shall make such payment within 30 Days after the Financial Settlement Report is deemed final.

C. If the Financial Settlement Report indicates that the WISeR Participant owes CMS a WISeR Recoupment, CMS will issue the WISeR Participant a demand letter for such monies owed to CMS. The WISeR Participant shall pay CMS any WISeR Recoupment within 30 Days of the date of a demand letter. If CMS does not timely receive payment in full, the remaining monies owed shall be considered a delinquent debt in accordance with Section 8.8.D.

Section 8.10 Extreme and Uncontrollable Circumstances

A. CMS may, in its sole discretion, provide Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers if the WISeR Providers and WISeR Suppliers:

   1. Are located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act; and
   2. Are located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

B. CMS has the sole discretion to determine the time period during which Prior Authorization flexibilities are provided to the WISeR Participant's WISeR Providers and WISeR Suppliers.

C. In the event that CMS provides Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers, CMS will provide written notice to the WISeR Participant of any impact such flexibilities have on the terms of this Agreement.

D. The WISeR Participant shall identify, develop, and coordinate prevention, response, and recovery procedures to ensure the availability of critical resources, and facilitate the continuity of essential business functions in an emergency situation, including natural disasters, manmade incidents, catastrophic emergencies, and public health emergencies ("**Continuity of Operations (COOP) Plan**").

E. The WISeR Participant shall maintain a COOP Plan that addresses protection of the physical infrastructure and business continuity (with or without system availability) of mission essential functions, to include without limitation the Prior Authorization Process, and communicating to WISeR Providers and WISeR Suppliers.

F. The WISeR Participant's COOP Plan shall include an information technology (IT) contingency and disaster recovery plan that addresses identified IT risks and vulnerabilities including, without limitation, cybersecurity issues.

Article IX. Business Associate Agreement, Data Sharing and Reports

Section 9.1 Business Associate Agreement

A. The WISeR Participant agrees to execute a valid Business Associate Agreement ("**BAA**") with CMS no later than 5 Days after the Effective Date of this Agreement.
B. If the WISeR Participant fails to execute a valid BAA pursuant to Section 9.1.A by the date specified by CMS, CMS will terminate the Agreement or the Agreement Performance Period or both in accordance with Section 13.3.
C. The WISeR Participant's BAA with CMS shall be active and valid for the duration of the Agreement Term.
D. The WISeR Participant shall comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") Privacy, Security, and Breach Notification Rules (45 C.F.R. Part 160 & Part 164, subparts A through E) ("**HIPAA Rules**").
E. The parties agree that the terms and conditions of the executed BAA between the WISeR Participant and CMS are hereby incorporated by reference into this Agreement as if fully set forth herein.

Section 9.2 Data Sharing and Reports – General

A. The WISeR Participant shall implement information technology (IT) systems security controls in order to maintain the confidentiality, integrity, and availability of the Medicare systems operations in the event of computer incidents or physical disasters.
B. Subject to the limitations discussed in this Agreement, and in accordance with applicable law, including HIPAA and the regulations in 42 C.F.R. Part 2, in advance of the Start Date of this Agreement, during the Agreement Performance Period, and any other time deemed necessary by CMS, CMS will offer the WISeR Participant an opportunity to request certain Beneficiary-identifiable data and reports in accordance with the terms and conditions set forth in this Agreement and in the BAA.
C. The Beneficiary-identifiable data available for request are described in Section 9.3 of this Agreement and in the BAA between CMS and the WISeR Participant.
D. Consistent with 42 C.F.R. § 403.1110(b), the WISeR Participant shall report data metrics for monitoring and evaluation purposes related to the WISeR Participant's Prior Authorization Process that include without limitation:

1. The total number of Prior Authorizations received during the data reporting period with a detailed description of:
    i. The number of Prior Authorization Provisional Affirmations during the data reporting period; and
    ii. The number of Prior Authorization Non-Affirmations during the data reportion period; and
2. The time (e.g., Days, weeks, hours, etc.) taken for the WISeR Participant's Prior Authorization Process to reach a determination;
    i. The total number of Resubmissions for each Prior Authorization received during the data reporting window or for a previous data reporting window;
    ii. The number of reversals of the Initial Prior Authorization Determination.

Section 9.3 Provision of Certain Beneficiary-Identifiable Claims Data

A. At CMS' sole discretion based on CMS' available resources, the limitations in this Agreement, the limitations in the BAA, and applicable law, CMS and the WISeR Participant may share certain Beneficiary-identifiable data for Beneficiaries in the WISeR Jurisdiction subject to the Prior Authorization Process.
B. The Beneficiary-identifiable data includes the data and reports described in this Section 9.3.B.
    1. Detailed Beneficiary Claims Data. These data will include individual Beneficiary-identifiable Medicare FFS claims data for Select Items and Services provided to Beneficiaries within the WISeR Jurisdiction. This includes without limitation data on Medicare FFS expenditures and utilization, and Prior Authorization Process metrics (e.g., timing, Prior Authorization request determinations, Resubmissions of Prior Authorizations, etc.).
    2. Quality Performance Scoring Data. These data will include Beneficiary-identifiable data and quality performance data specific to the Prior Authorization Process.
C. The parties mutually agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by CMS.
D. The parties further agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by the WISeR Participant as it relates to the Prior Authorization Process.

E. The WISeR Participant represents, and in furnishing the data files specified in Section 9.3.B of this Agreement and the BAA CMS relies upon such representation, that such data files will be used solely for the purpose of carrying out the provisions of this Agreement to improve the efficiency and accuracy of Prior Authorizations, quality improvement activities, reducing health care costs for the Medicare FFS program without causing harm to Beneficiaries, identifying or reducing fraud, waste, and abuse in Medicare FFS, and such other purposes described int his Agreement. The WISeR Participant agrees not to disclosure, use, or reuse the data excepts as specified in this Agreement, the BAA, or except as CMS shall authorize in writing or as otherwise required by law. The WISeR Participant further agrees not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement and the BAA.

F. Information derived from the CMS data specified in Section 9.3.B of this Agreement and in the BAA may be shared and used within the legal confines of the WISeR Participant and its WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers and WISeR Suppliers in a manner consistent with the provisions of this Agreement and the BAA to improve the Prior Authorization Process and Beneficiary care.

G. The WISeR Participant may reuse original or derivative data without prior written authorization from CMS for quality improvement activities relating to improving health or reducing health care costs through the Prior Authorization Process, but shall not disseminate (unless required by law) any individually identifiable original or derived information from the data specified in Section 9.3.B of this Agreement to anyone who is not a HIPAA Covered Entity, a HIPAA Business Associate, a WISeR Clinician or WISeR Clinical Reviewer performing activities related to this Model, or a WISeR Provider or WISeR Supplier in treatment relationship with the subject WISeR Beneficiary. When using or disclosing PHI or personally identifiable information ("**PII**"), obtained from data specified in Section 9.3.B, the WISeR Participant must make "reasonable efforts to limit" the information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure, or request.

H. The WISeR Participant shall establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget ("**OMB**") in OMB Circular No. A-130, Appendix I – Responsibilities for Protecting and Managing Federal Information Resources (https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A130/a130revised.pdf) as well as Federal Information Processing Standard 200 entitled

"Minimum Security Requirement for Federal Information and Information Systems" (http:// (http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf); and, NIST Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" (http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf). The WISeR Participant acknowledges that the use of unsecured telecommunications, including the Internet, to transmit directly or indirectly identifiable information from the files specified in Section 9.2.B or any such derivative data files is strictly prohibited.

I. The WISeR Participant shall grant access to the data and/or the facility(ies) in which the data is maintained to the authorized representatives of CMS or Office of Inspector General of the Department of Health and Human Services ("**OIG**") for the purpose of inspecting to confirm compliance with the terms of this Agreement and the BAA.

J. The WISeR Participant agrees that any use of CMS data in the creation of any document concerning the purpose specified in this section must adhere to CMS' current cell size suppression policy. The policy stipulates that no cell (e.g., patients, services) representing 10 or fewer Beneficiaries may be displayed. Also, no percentages or other mathematical formulas may be used if they result in the display of a cell representing 10 or fewer Beneficiaries. A cell that represents or uses percentages or other mathematical formulas to represent zero Beneficiaries must be displayed.

Article X. Participation in Evaluation, Shared Learning Activities, and Site Visits

Section 10.1 Evaluation Requirement

A. General. The WISeR Participant shall participate and cooperate in any independent evaluation activities conducted by or on behalf of CMS aimed at assessing the impact of the Model on the goals of improving quality of care and reducing fraud, waste, and abuse expenditures for the Medicare program. The WISeR Participant shall require its WISeR Clinicians and WISeR Clinical Reviewers to participate and cooperate in any such independent evaluation activities conducted by or on behalf of CMS. Termination or expiration of this Agreement shall not affect the right of CMS to evaluate WISeR.

B. Primary Data. In its evaluation activities, CMS or its designee(s) may collect qualitative and quantitative data. These data may include, but are not limited to the following sources:

1. Site visits with the WISeR Participant;
2. Surveys or interviews with WISeR Providers and WISeR Suppliers;
3. Surveys or interviews with Beneficiaries and their caregivers;
4. Focus groups of WISeR Providers and WISeR Suppliers;
5. Focus groups of Beneficiaries and their caregivers;
6. Interviews with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
7. Focus groups with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
8. Direct observation of WISeR Provider and/or WISeR Supplier interactions with the WISeR Participant and its staff, and other activities related to the WISeR Participant's participation in the Model;
9. Review of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates; and
10. Surveys.

C. Secondary Data. In its evaluation activities, CMS may use data or information submitted by the WISeR Participant as well as claims submitted to CMS for Select Items and Services furnished to Beneficiaries. These data may include, but are not limited to:
    1. Claims data;
    2. Survey data from Patient Experience surveys;
    3. Medical records;
    4. Clinical data;
    5. Monitoring data (e.g., audit results, etc.); and
    6. Quality and clinical data submitted to CMS.
D. Reporting Requirements. CMS may add or modify evaluation-related reporting requirements during the Agreement Term. CMS will notify the WISeR Participant of any additions or modifications as soon as practicable or at least 30 Days prior to the Day on which such change would take effect.

Section 10.2 Shared Learning Activities

A. The WISeR Participant shall participate in CMS-sponsored learning activities designed to drive improvement and foster innovations in using technology-assisted decision-making through sharing best practices or new knowledge that emerges from participation in the Model.
B. The WISeR Participant shall actively engage in a variety of learning events, learning communities, and sharing promising tools and ideas, as well as their lessons learned.

Section 10.3 Site Visits

A. The WISeR Participant shall cooperate and require its staff to cooperate in any site visits conducted by or on behalf of CMS.
B. CMS or its designee(s) shall, to the extent practicable, schedule any site visits to the WISeR Participant no fewer than 15 Days in advance. To the extent practicable, CMS will attempt to accommodate the WISeR Participant's request for particular dates in scheduling site visits. However, the WISeR Participant may not request a date that is more than 60 Days after the date of the initial site visit notice from CMS.
C. The WISeR Participant shall ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during the site visit.
D. Notwithstanding the foregoing, CMS or its designee(s) may perform unannounced site visits at any of the WISeR Participant's office locations at any time to investigate concerns or other program integrity issues.
E. Nothing in this Agreement shall be construed to limit or otherwise prevent CMS from performing site visits permitted by applicable law or regulations.

Section 10.4 Rights in Data and Intellectual Property

A. CMS may use any data obtained pursuant to the Model to evaluate the Model and to disseminate quantitative results and successful care management techniques to other providers and suppliers and to the public. Data to be disseminated may include results of WISeR Provider and WISeR Supplier surveys, results of patient experience of care and quality of life surveys as well as measures based upon claims, medical records, and other data sources. The WISeR Participant will be permitted to comment on evaluation reports when the WISeR Participant has been specifically cited to ensure factual accuracy but may not edit conclusions or control the dissemination of reports.
B. The parties agree that by participating in the Model, the WISeR Participant grants to CMS and its designees a limited, royalty-free, worldwide, non-sublicensable, non-exclusive license on a warranty-free basis during the term of this Agreement (and for any agreed to extension thereof) in, to and under all intellectual property and information technology owned or licensable (without the consent of, or payment to, any third party) by the WISeR Participant or any of its affiliates, solely for CMS or any of its designees or affiliates to receive and use such information technology.
C. Notwithstanding any other provision in the Agreement, the parties agree that any intellectual property or information technology developed as a result of the collaborative activity under the terms of this Agreement and the requirements associated with this Model will be dealt with by appropriate written agreements

D. Notwithstanding any other provision in the Agreement, all proprietary trade secret information and technology of the WISeR Participant that existed prior to the Effective Date of this Agreement is and shall remain the sole property of the WISeR Participant, and, except as required by federal law, shall not be released by CMS without express written consent. The regulation at 48 C.F.R. § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into the Agreement. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property right or other rights to the WISeR Participant's proprietary information or technology.

E. If the WISeR Participant maintains any information that should not be publicly disclosed because the WISeR Participant considers such information to be proprietary and confidential, the WISeR Participant acknowledges that it may submit to CMS a form, using either the template attached as Appendix C, or a form substantially the same as Appendix C, identifying specific examples of information the WISeR Participant considers to be proprietary and confidential. The WISeR Participant must notify CMS, in a form and manner to be specified by CMS, of any updates to this form. If the WISeR Participant does not submit such a form, the WISeR Participant will be deemed to have confirmed that it has no information it considers proprietary and confidential.

Section 10.5 WISeR Participant Public Release of Information

A. The WISeR Participant shall obtain prior approval from CMS during the Agreement Term and for 6 months thereafter for the publication or release of any press release, external report or statistical/analytical material that materially and substantially references the WISeR Participant's participation in the Model. External reports and statistical/analytical material may include but are not limited to papers, articles, professional publications, speeches, and testimony.

B. All external reports and statistical/analytical material that are subject to this Section 10.5 must include the following statement on the first page: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

Article XI. Compliance and Oversight

Section 11.1 WISeR Participant Compliance Plan

A. The WISeR Participant shall have a compliance plan that includes at least the following elements:

1. A designated compliance official or individual who is not legal counsel to the WISeR Participant and reports directly to the WISeR Participant's governing body;
2. Mechanisms for identifying and addressing compliance problems related to the WISeR Participant's operations and performance;
3. A method for employees or contractors of the WISeR Participant performing functions or services related to this Model to anonymously report suspected problems related to the WISeR Participant's compliance official;
4. Compliance training for the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers; and
5. A requirement for the WISeR Participant to report probable violations of law to an appropriate law enforcement agency.

B. The WISeR Participant shall ensure that its compliance plan is in compliance with all applicable laws and regulations. The WISeR Participant shall periodically update its compliance plan to reflect changes in those laws and regulations.

Section 11.2 CMS Monitoring and Oversight Activities

A. CMS shall conduct monitoring activities to assess compliance by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers with the terms of this Agreement. Such monitoring activities may include, but are not limited to:
   1. Claims analyses to identify fraudulent behavior or program integrity risks such as efforts to manipulate Prior Authorization Process accuracy and efficiency;
   2. Claims and appeals data to identify fraudulent behavior or program integrity risks, including data between the WISeR Participant and any MAC;
   3. Review of documents from the WISeR Participant, WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers, and WISeR Suppliers, including surveys and questionnaires;
   4. Review and audits of the WISeR Participant's Enhanced Technology, including without limitation, reliance on artificial intelligence, machine learning capabilities, and its impact on the timing and accuracy of Prior Authorization determinations, denial rates, affirmation rates, resubmission rates, and other data related to such Enhanced Technology;
   5. Review and audits of the WISeR Participant's Pre-Payment Review processes performed by its WISeR Clinicians and WISeR Clinical Reviewers, and the impact on the timing and accuracy of Pre-Payment Review determinations, denial rates, affirmation rates, resubmission rates, and other data related to such reviews;
   6. Interviews with Beneficiaries and their caregivers;

7. Audits of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant;
8. Audits of data related to Pre-Payment Review, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant; and
9. Site visits to the WISeR Participant.

B. In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including, without limitation, all Medicare claims submitted for items and/or services furnished to Beneficiaries.

C. In conducting monitoring and oversight activities, CMS or its designee(s) may use any relevant data or information including, without limitation, all Prior Authorization requests, Pre-Payment Review activities, determinations, and resubmissions submitted for items and/or services furnished to Beneficiaries.

D. Nothing in this Agreement limits or otherwise prevents CMS from monitoring the WISeR Participant for compliance as permitted by applicable law or regulations.

E. CMS may conduct monitoring activities pursuant to this Article XI for up to two calendar years after the effective date of termination or expiration of this Agreement.

Section 11.3 Compliance with Monitoring and Oversight Activities

A. The WISeR Participant shall cooperate with, and require its WISeR Clinicians and WISeR Clinical Reviewers to cooperate with, all CMS monitoring and oversight requests and activities.

B. The WISeR Participant shall ensure it has sufficient access to all records, data, and information necessary to comply with the monitoring activities described in this Agreement. As necessary, the WISeR Participant shall request this information from any WISeR Clinician, or any WISeR Clinical Reviewer, or individual performing functions or providing services related to WISeR.

Section 11.4 Compliance with Laws

A. Agreement to Comply

1. The WISeR Participant shall comply with, and shall require all WISeR Clinicians and WISeR Clinical Reviewers to comply with, the applicable terms of the Agreement and all applicable statutes, regulations, and guidance, including without limitation: (a) federal criminal laws; (b) the Social Security Act (Public Law 74-271); (c) Title XVIII of the Act; (d) the False Claims Act (31 U.S.C. § 3729 et seq.); (e) the antikickback statute (42 U.S.C. § 1320a-7b(b)); (f) the civil monetary penalties law (42 U.S.C. § 1320a-7a); (g) the federal

physician self-referral law (42 U.S.C. § 1395nn); and (h) any applicable State laws.

2. This Agreement does not waive any obligation of the WISeR Participant to comply with the terms of any other CMS contract, agreement, model, or demonstration.

B. Reservation of Rights

1. Nothing contained in this Agreement or in the application process for WISeR constitutes a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS Office of the Inspector General, or CMS of any right to institute any proceeding or action for violations of any statutes, rules, or regulations administered by the government, or to prevent or limit the rights of the government to obtain relief under any other federal statutes or regulations, or on account of any violation of the Agreement or any other provision of law. This Agreement does not bind any government agency except CMS and the Agreement binds CMS only to the extent provided in this Agreement.
2. The failure by CMS to require performance of any provision of this Agreement does not affect CMS' right to require performance at any time thereafter, nor does a waiver of any breach or default of the Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

C. Office of Inspector General of the Department of Health and Human Services (OIG) Authority. None of the provisions of this Agreement limit or restrict the OIG's authority to audit, evaluate, investigate, or inspect the WISeR Participant or its WISeR Clinicians or its WISeR Clinical Reviewers.

D. Other Government Authority. None of the provisions of this Agreement limit or restrict any other government authority that is permitted by law to audit, evaluate, investigate, or inspect the WISeR Participant.

Section 11.5 Applicable Statutes, Regulations, Manuals, and Documents

In addition to all referenced statutes, regulations, manuals, and documents, the following statutes, regulations, manuals, and documents apply to this Agreement and are hereby incorporated by reference.

A. Financial management and internal controls (e.g., the Federal Managers' Financial Integrity Act of 1982 (FMFIA), the Chief Financial Officers' Act of 1990, etc.);
B. Federal Information Security Management Act of 2014 (FISMA);
C. Privacy and information technology requirements (Privacy Act of 1974, Information Technology Management Reform Act of 1996);

D. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191);
E. Rehabilitation Act of 1973 (including section 508, Accessibility Standards);
F. Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248);
G. Administrative Simplification Compliance Act of 2002 (Public Law 107-105);
H. Benefit Improvement and Protection Act of 2000 (Public Law 106-554);
I. Executive Order 13410, to the extent practicable, Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs;

Medicare manuals (e.g., internet only manuals – IOMs) to administer CMS programs. In the event of any conflict, this Agreement shall have precedence over the IOMs located at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index;

Article XII. Audits and Record Retention

Section 12.1 Right to Audit and Inspect

The WISeR Participant agrees that the government (including CMS, HHS, and the Comptroller General or their designees) has the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the WISeR Participant that pertain to the following:

A. The WISeR Participant's compliance with the terms of this Agreement, including provisions that require the WISeR Participant to impose duties or requirements on its WISeR Clinicians and its WISeR Clinical Reviewers;
B. Whether the WISeR Clinicians and WISeR Clinical Reviewers complied with the duties and requirements imposed on them by the WISeR Participant pursuant to the terms of this Agreement;
C. The quality of services performed under this Agreement;
D. Any activity by the WISeR Participant that may pose a potential risk of harm to Beneficiaries or a vulnerability to the integrity of the Model test;
E. The WISeR Participant's right to WISeR Payments;
F. The ability of the WISeR Participant to repay amounts owed to CMS under this Agreement;
G. The WISeR Participant's financial arrangements.

Section 12.2 Maintenance of Records

The WISeR Participant shall maintain and shall give the government (including CMS, HHS, and the Comptroller General or their designees) access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs,

quality performance measures, and financial arrangements) sufficient to enable the audit, evaluation, inspection, or investigation of the Model, including the subjects identified in Section 11.2. The WISeR Participant shall maintain such books, contracts, records, documents, and other evidence for a period of six years from the expiration or termination of this Agreement or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:

A. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the WISeR Participant at least 30 Days before expiration of the six-year period described above; or
B. There has been a termination, dispute, or allegation of fraud or similar fault against the WISeR Participant in which case the records shall be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

Article XIII. Remedial Action and Termination

Section 13.1 Grounds for Remedial Action

A. CMS may take remedial action against the WISeR Participant if CMS determines that the WISeR Participant:
    1. Has failed to comply with any applicable term of the Agreement or any Medicare program requirement, rule, or regulation;
    2. Has failed to comply with the American with Disabilities Act of 1990, 42 U.S.C. § 12101 *et seq*. (1990);
    3. Has failed to comply with the WISeR Participant's Corrective Action Plan (CAP), the monitoring or auditing plan, or both, developed by CMS for the WISeR Participant, or other remedial action imposed by CMS, if applicable;
    4. Has taken any action that threatens the health or safety of a Beneficiary, including a WISeR Beneficiary;
    5. Has failed to rectify deficiencies following any remedial action;
    6. Has undergone a Change in Control that renders it ineligible for participation in the Model or presents a program integrity risk;
    7. Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model or any requirement of the Medicare program;
    8. Has failed to pay amounts owed to CMS by the date specified in a demand letter;
    9. Has failed to pay a WISeR Recoupment;

10. Has a conflict of interest; or
11. Poses significant program integrity risks, including but not limited to:
    i. Is subject to sanctions or other actions of a federal, state, or local government agency;
    ii. Is subject to investigation or action by HHS (including, but not limited to OIG and CMS) or the Department of Justice due to an allegation of fraud or similar misconduct, including but not limited to being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

Section 13.2 Types of Remedial Action

A. If grounds for remedial action exist, CMS may take one or more of the following actions:
    1. Notify the WISeR Participant of the violation;
    2. Require the WISeR Participant to provide additional information to CMS or its designees;
    3. Conduct site visits, interview WISeR Providers and/or WISeR Suppliers, interview Beneficiaries, or take other actions to gather information;
    4. Place the WISeR Participant on a monitoring and/or auditing plan developed by CMS;
    5. Require the WISeR Participant to not use a WISeR Clinician or WISeR Clinical Reviewer for Medical Review, immediately or within a timeframe specified by CMS;
    6. Withhold, deny, or recoup WISeR Payments;
    7. Withhold, deny, or recoup any Advance WISeR Payments;
    8. Suspend or terminate the WISeR Participant's ability to perform its Prior Authorization Process on new requests;
    9. Require a CAP from the WISeR Participant that is acceptable to CMS. If CMS requires a CAP from the WISeR Participant, the following requirements apply:
        i. The WISeR Participant shall submit a CAP to CMS for approval by a deadline established by CMS:
        ii. CMS must approve the WISeR Participant's CAP;
        iii. The CAP must address what actions the WISeR Participant will take within a specified time period to ensure that all deficiencies will be corrected and that the WISeR Participant will be in compliance with the terms of this Agreement; and

iv. If the WISeR Participant does not comply with the terms of the CAP within the specified period of time, CMS may take additional remedial actions or terminate the Agreement or Agreement Performance Period in accordance with Section 13.3.

B. CMS may impose additional remedial actions, including but not limited to terminating the Agreement or Agreement Performance Period pursuant to Section 13.3, if CMS determines that the WISeR Participant's efforts to address noncompliance or other grounds for remedial action were insufficient.

Section 13.3 Termination by CMS

CMS may immediately or with advance notice terminate the Agreement or Agreement Performance Period if:

A. CMS determines that it no longer has the funds to support the Model;
B. CMS modifies or terminates the Model pursuant to section 1115A(b)(3)(B) of the Act;
C. CMS offers the WISeR Participant an amendment to this Agreement pursuant to Section 1.4, and the WISeR Participant does not sign such amendment by the date specified by CMS;
D. CMS determines that any grounds for remedial action exist;
E. CMS determines that the WISeR Participant has failed to submit, obtain approval for, implement, or fully comply with the terms of a CAP;
F. CMS determines that the WISeR Participant has failed to demonstrate improved performance following any remedial action imposed by CMS;
G. The WISeR Participant has a conflict of interest that cannot be resolved;
H. The WISeR Participant has not executed a valid BAA; or
I. The WISeR Participant assigns or purports to assign any of the rights or obligations under the Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

Section 13.4 Termination of the Agreement Performance Period by WISeR Participant

The WISeR Participant may terminate the Agreement Performance Period upon advance written notice to CMS. Such notice must specify the effective date of the termination, which must be at least 90 Days after the date of the notice.

Section 13.5 Financial Settlement Upon Termination

If CMS terminates the Agreement or the Agreement Performance Period is terminated by either party, CMS shall conduct settlement for the entire Performance Year in which the Agreement is terminated in accordance with Article VIII of the Agreement.

Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination

If the Agreement or Agreement Performance Period is terminated under Section 13.3 or Section 13.4, the WISeR Participant shall provide written notice of the termination to all WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction. The WISeR Participant shall deliver such written notice no later than 45 Days before the effective date of termination unless a different date is specified by CMS. The WISeR Participant shall include in such notices any content specified by CMS.

Article XIV. Limitation on Review and Dispute Resolution

Section 14.1 Limitations on Review

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

A. The selection of organizations, sites, or participants to test models selected for testing or expansion under section 1115A of the Act, including the decision by CMS to terminate the Agreement or Agreement Performance Period;
B. The elements, parameters, scope, and duration of such models for testing or dissemination;
C. Determinations regarding budget neutrality under section 1115A(b)(3);
D. The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B);
E. Determinations about expansion of the duration and scope of a model under section 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection (c);
F. The selection of quality performance standards by CMS;
G. The methodology applied to calculate Regional Benchmarks, WISeR Discount, AQS, and WISeR Payments;
H. The methodology used to calculate the WISeR Participant's WISeR Payment; and
I. The methodology used to calculate the WISeR Recoupment.

Section 14.2 Dispute Resolution

A. Right to Reconsideration. The WISeR Participant may request reconsideration of a determination made by CMS pursuant to the Agreement only if such reconsideration is not precluded by section 1115A(d)(2) of the Act or the Agreement.
    1. Such a request for reconsideration by the WISeR Participant must satisfy the following criteria:

i. The request must be submitted to a designee of CMS ("**Reconsideration Official**") who –
    a. Is authorized to receive such requests;
    b. Did not participate in the determination that is the subject of the reconsideration request; and
    c. May be, but does not have to be, an Inferior Officer.
ii. The request must include a copy of the initial determination issued by CMS and contain a detailed, written explanation of the basis for the dispute, including supporting documentation;
iii. The request must be made within 30 Days of the date of the initial determination for which reconsideration is being requested and
iv. The request must be delivered via email to CMS at InnovationModelsReconsideration@cms.hhs.gov or at such other address specified by CMS.

2. Requests that do not meet the requirements of Section 14.2.A.1 will be denied.
3. Within 15 Days of receiving a request for reconsideration, the parties will be sent a written acknowledgement of receipt of the reconsideration request. Such an acknowledgement will set forth:
    i. The review procedures; and
    ii. A briefing schedule that permits each party to submit written briefs, including any evidence or documentation in support of the party's position for consideration by the Reconsideration Official.

B. Standards for Reconsideration
1. The parties shall proceed diligently with the performance of this Agreement during the course of any dispute arising under the Agreement.
2. The reconsideration will consist of a review of documentation that is submitted timely and in accordance with the standards specified by the Reconsideration Official.
3. The burden of proof is on the WISeR Participant to demonstrate to the Reconsideration Official with clear and convincing evidence that the determination is inconsistent with the terms of the Agreement.

C. Reconsideration Determination
1. The reconsideration determination will be based only upon:
    i. Position papers and supporting documentation that are timely submitted to the Reconsideration Official and meet the standards for submission under Section 14.2.B.2; and

ii. Documents and data that were timely submitted to CMS in the required format before the agency made the determination that is the subject of the reconsideration request.

2. The Reconsideration Official will issue to CMS and the WISeR Participant a written notification of the reconsideration determination ("**Reconsideration Determination**"). Absent unusual circumstances, the Reconsideration Determination will be issued within 60 Days of receipt of timely filed position papers and supporting documentation.
3. The Reconsideration Determination is final and binding 30 Days after its issuance, unless the WISeR Participant or CMS timely requests review of the Reconsideration Determination in accordance with Sections 14.2.D.1 and 2.

D. CMS Administrator Review. The WISeR Participant or CMS may request CMS Administrator review of the Reconsideration Determination.

1. The request must be made via email to InnovationModelsReconsideration@cms.hhs.gov or such other address as specified by CMS within 30 Days after the date of the Reconsideration Determination.
2. The request must include a copy of the Reconsideration Determination and a detailed, written explanation of why the WISeR Participant or CMS disagrees with the Reconsideration Determination.
3. Within 30 business days after receiving a request for review, the CMS Administrator (or a delegate acting on behalf of the CMS Administrator) will determine whether the request for review is granted or denied. The CMS Administrator will promptly send the parties written acknowledgement of receipt of the request for review. Such an acknowledgement will set forth:
    i. Whether the request for review is granted or denied; and
    ii. If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.
4. If the request for review is denied, the Reconsideration Determination is final and binding as of the date the request for review is denied.
5. If the request for review is granted:
    i. The record for review will consist of timely submitted briefs and the evidence contained in the record of the proceedings before the Reconsideration Official. The CMS Administrator will not consider documentation submitted for review other than documents and date described in Section 14.2.B.2;

ii. The CMS Administrator will review the record and issue to CMS and to the WISeR Participant a written determination; and
iii. The written determination of the CMS Administrator is final and binding.

E. Effect of Dispute Resolution. The dispute resolution process under this Agreement shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

Article XV. Miscellaneous

Section 15.1 Agency Notifications and Submission of Reports

A. For a notice or other communication required under this Agreement to be valid, it must be in writing.
B. Unless otherwise specified in this Agreement or stated in writing after the Effective Date, all notifications and reports required under this Agreement must be submitted to the parties at the addresses set forth below:

CMS:
WISeR Model
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop: WB-06-05
Baltimore, MD 21244
Email: WISeR@cms.hhs.gov

WISeR Participant:
Innovaccer Inc.
101 Mission StreetnSuite 1950
San Francisco
CA
94105

Section 15.2 Notice of Bankruptcy

A. If the WISeR Participant has filed a bankruptcy petition, whether voluntary or involuntary, the WISeR Participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the WISeR Participant under the terms of each model tested under section 1115A of the Act in which the WISeR Participant is participating or has participated and all administrative or judicial review proceedings related to any payments under such models have been fully and finally resolved.

B. The notice of bankruptcy must be sent by certified mail no later than 5 Days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the WISeR Participant is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the WISeR Participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the WISeR Participant and CMS have been fully and finally resolved with respect to that model.

C. The notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3-01-24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices.

Section 15.3 Severability

In the event that any one or more of the provisions of this Agreement is, for any reason, held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had never been included in the Agreement, unless the deletion of such provision or provisions would result in such a material change to the Agreement so as to cause continued participation under the terms of this Agreement to be unreasonable.

Section 15.4 Entire Agreement; Amendment

This Agreement, including all appendices, constitutes the entire agreement between the parties. The parties may amend this Agreement or any appendix hereto at any time by mutual written consent; provided, however, that CMS may amend this Agreement or any appendix hereto in writing without the consent of the WISeR Participant as specified in this Agreement or any appendix hereto, or for good cause or as necessary to comply with applicable federal

or state law, regulatory requirements, accreditation standards, or licensing guidelines or rules. To the extent practicable, CMS shall provide the WISeR Participant with 30 Days' advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

Section 15.5 Survival

Expiration or termination of this Agreement by CMS shall not affect the rights and obligations of the parties accrued prior to the effective date of the expiration or termination of this Agreement, except as provided in this Agreement. The rights and duties under the following sections of this Agreement shall survive the expiration or termination of this Agreement and apply thereafter:

Article VIII. Payment;
Article IX. Data Sharing and Reports;
Section 10.1 Evaluation Requirements;
Section 10.4 Rights in Data and Intellectual Property;
Section 10.5 WISeR Participant Public Release of Information;
Section 11.3 Compliance with Monitoring and Oversight Activities;
Article XII. Audits and Record Retention;
Section 13.5 Financial Settlement Upon Termination;
Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination;
Section 14.1 Limitations on Review;
Section 15.2 Notice of Bankruptcy;
Section 15.5 Survival; and
Section 15.7 Prohibition on Assignment.

Section 15.6 Precedence

If any provision of this Agreement conflicts with a provision of any document incorporated herein by reference, the provision of this Agreement shall prevail.

Section 15.7 Prohibition on Assignment

Except with the prior written consent of CMS, the WISeR Participant shall not transfer, including by merger (whether the WISeR Participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under this Agreement; (2) any right that it has to satisfy a condition under this Agreement; (3) any remedy that it has under this Agreement; or (4) any obligation imposed on it under this Agreement. The WISeR Participant shall provide CMS 90 Days' advance written notice of any such proposed transfer. This obligation remains in effect until final payment by or to the WISeR Participant has been made under this Agreement. CMS may condition its consent to transfer on full payment of any amounts owed by the WISeR Participant under this Agreement or owed to CMS by the

proposed assignee. Any purported transfer in violation of this Section is voidable at the discretion of CMS.

Section 15.8 Certification

The WISeR Participant executive signing this Agreement certifies to the best of his or her knowledge, information, and belief that the WISeR Participant satisfies the requirements of Section 3.1.A, that all WISeR Clinicians and WISeR Clinical Reviewers satisfy the requirements of Section 3.4, and that he or she is authorized by the WISeR Participant to execute this Agreement and to legally bind the WISeR Participant to its terms and conditions.

Section 15.9 Execution in Counterpart

This Agreement and any amendments hereto may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof. This Agreement and any amendments hereto may be signed by autopen or electronic signature (e.g., DocuSign or similar electronic signature technology) and may be transmitted by electronic means. Copies of this Agreement and any amendments hereto that are so executed and delivered have the same force and effect as if executed with handwritten signatures and physically delivered.

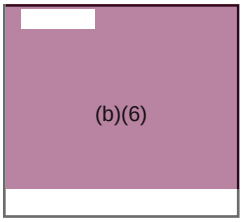
[SIGNATURE PAGE FOLLOWS]

Each party is signing this Agreement on the date stated opposite that party's signature. If a party signs but fails to date a signature, the date that the other party receives the signing party's signature will be deemed to be the date that the signing party signed the Agreement.

WISeR Participant: Innovaccer Inc.

WISeR ID: WISeR-00043

Date: 2025-10-10 15:43:54

By: 

(b)(6)

Name of Authorized Signatory

(b)(6)

Title

CMS:

Date: 2025-10-15 10:07:15

By: _____

Arrah Tabe-Bedward

Name of Authorized Signatory

CMS Executive

Appendices

Appendix A: Select Items and Services

Appendix B: Quality Measures

Appendix C: WISeR Participant Proprietary and Confidential Information

Appendix A: Select Items and Services

CMS uses Covered Services that correspond to the LCDs and NCDs identified in the Table 1 below ("**Select Items and Services**") to determine whether the WISeR Provider's and/or WISeR Supplier's Medicare claim is subject to the Prior Authorization Process for Performance Year 1. The WISeR Participant performs its Prior Authorization Process for each Select Item or Service identified in a Prior Authorization request within its WISeR Jurisdiction.

CMS may unilaterally revise the Select Items and Services identified in Table 1 prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any revisions to the Select Items and Services for a Performance Period prior to the start of the Performance Period in which such change will take effect.

Table 1

Select Items and Services	Associated NCD/LCDs
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)	NCD 160.7 NCD 230.18 NCD 160.19 NCD 160.24 NCD 160.18
Induced Lesions of Nerve Tracts	NCD 160.1
Epidural Steroid Injections for Pain Management	L39015, L39242, L36920
Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L34106, L38201, L35130
Cervical Fusion Excluding codes already included in OPD	L39741, L39762, L39793
Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee	NCD 150.9

Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea	L38307, L38312, L38385
Incontinence Control Devices	NCD 230.10
Diagnosis and Treatment of Impotence	NCD 230.4
Percutaneous Image-Guided Lumbar Decompression for Spinal Stenosis	NCD 150.13
Skin and Tissue Substitutes • Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds • Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities	L35041 L36690

Appendix B: Quality Measures

Consistent with Article VII and the WISeR Data Reporting Guide, CMS shall use the following WISeR Performance Measure Set for purposes of calculating the AQS of the WISeR Participant for Performance Year 1. CMS will also use the following WISeR Performance Measure Set for purposes of monitoring and evaluating the overall performance of the WISeR Participant during the Model.

CMS may update the quality measures identified in the WISeR Performance Measure Set prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any updates for a Performance Period prior to the start of the Performance Period in which such change will take effect.

WISeR Performance Measure Set

Domain	First Applicable Performance Period	Data Source	Measurement Frequency
Timeliness of Determinations	PP1	WISeR Participant-Reported	Quarterly
Accuracy of Determinations	PP1	CMS Audit of WISeR Participant-Reported Data	Quarterly

Appendix C: WISeR Participant Proprietary and Confidential Information

The following are specific examples, without limitation, of what the WISeR Participant considers proprietary and confidential information currently maintained by the WISeR Participant that should not be publicly disclosed:

1) Innovaccer has developed technology that it will use to meet the requirements of this project including software, algos etc.. These are confidential and propriety property of Innovaccer.

2)

3)

4)

In accordance with Section 10.4 of the Agreement, this information shall not be released by CMS without the express written consent of the WISeR Participant except as required by federal law.

Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Patient Care Models Group
7500 Security Blvd
Baltimore, MD 21244

Wasteful and Inappropriate Service Reduction (WISeR) Model

Participation Agreement

Segment 1: January 1, 2026-December 31, 2028

August 29, 2025

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PARTICIPATION AGREEMENT

This Participation Agreement (the "**Agreement**") is between the CENTERS FOR MEDICARE & MEDICAID SERVICES ("**CMS**") and

Virtix Health LLC , ("**WISeR Participant**").

CMS is the agency within the U.S. Department of Health and Human Services ("**HHS**") that is charged with administering the Medicare and Medicaid programs.

The WISeR Participant is a legal entity identified by a single TIN and has Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process and Pre-Payment Review for Select Items and Services on Medicare fee-for-service ("**FFS**") Claims.

CMS is implementing the Wasteful and Inappropriate Service Reduction Model ("**WISeR**" or "**Model**") under section 1115A of the Social Security Act ("**Act**"), which authorizes CMS through its Center for Medicare and Medicaid Innovation ("**Innovation Center**") to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program expenditures while preserving or enhancing the quality of care furnished to Beneficiaries.

The Model seeks to reduce or maintain Medicare FFS expenditures while improving the quality of care and health outcomes for Medicare FFS beneficiaries through the WISeR Participant's Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process for Select Items and Services that do not satisfy existing Medicare Coverage Criteria and may be fraudulent, wasteful, or of low-value to Medicare FFS beneficiaries.

The WISeR Participant applied to participate in WISeR, and CMS has approved the WISeR Participant for participation in the Model for the MAC Jurisdiction of JF Noridian and the state of Washington. The designated state is the WISeR Participant's WISeR Jurisdiction.

The parties therefore agree as follows:

Article I. Agreement Term

Section 1.1 Effective Date

This Agreement will become effective when it is signed by the last party to sign it (as indicated by the date associated with that party's signature) ("**Effective Date**").

Section 1.2 Agreement Term

The term of this Agreement ("**Agreement Term**") begins on the Effective Date and expires two years after the last Day of the Agreement Performance Period, as defined in Section 1.3, unless the Agreement is sooner terminated by CMS in accordance with Section 13.3, in which case the Agreement Term ends on the effective date of such termination.

Section 1.3 Agreement Performance Period

A. The performance period of this Agreement ("**Agreement Performance Period**") begins on the Effective Date and ends at 11:59 PM ET on December 31, 2028, unless the Agreement Period or the Agreement is sooner terminated in accordance with Section 1.4.B or Article XIII, in which case the Agreement Performance Period ends on the date specified in the termination notice.

B. CMS may offer the WISeR Participant the option to participate in a second segment of this Model which would begin on January 1, 2029, and end at 11:59 PM ET on December 31, 2031. The WISeR Participant must execute a new agreement with CMS to participate in the Model during the second segment. Any such agreement will authorize CMS to take remedial action against the WISeR Participant for non-compliance with the terms of this Agreement, regardless of when the non-compliance is discovered by CMS.

Section 1.4 Amended and Restated Agreements

A. No later than 30 Days prior to the start of a calendar year during the Agreement Performance Period, CMS may offer the WISeR Participant the opportunity to sign an amendment to this Agreement, which may be in the form of an amended and restated version of this Agreement.

B. If the WISeR Participant fails to sign an amendment offered by CMS pursuant to Section 1.4.A by a date specified by CMS, CMS may terminate the Agreement Performance Period on December 31 of the year in which the amendment was offered.

Article II. Definitions

Advance WISeR Payment means the payment that meets the requirements in Section 8.4.

Aggregate Quality Score (AQS) means the score that is calculated from the WISeR Participant's quality data and used to determine the quality multiplier applied during the calculation of the WISeR Payment.

ARS stands for **CMS Acceptable Risk Safeguard** and means the standard to CMS and its contractors, including the WISeR Participant, as to the minimum level of required security and privacy controls. *See* https://security.cms.gov/policy-guidance/cms-acceptable-risk-safeguards-ars (last accessed August 2025).

ATO stands for **CMS Authority to Operate** and means the information systems operated by or on behalf of the U.S. federal government that meet FISMA standards.

BAA stands for **Business Associate Agreement** and means the legally binding contract required under HIPAA between CMS and the WISeR Participant that handles Protected Health Information.

Beneficiary means an individual who is entitled to Medicare FFS benefits under Part A or enrolled under Part B.

Change in Control means: (1) the acquisition by any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the WISeR Participant representing more than 50 percent of the WISeR Participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the WISeR Participant by any other individual or entity; (3) the sale, lease exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the WISeR Participant; or (4) the approval and completion of a plan of liquidation of the WISeR Participant, or an agreement for the sale or liquidation of the WISeR Participant.

Covered Services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Day(s) means calendar day(s) unless otherwise specified.

Electronic Submission of Medical Documentation (esMD) means a system used by CMS to enable providers, suppliers, and other entities to reduce or eliminate the need to mail or fax paper documents and instead electronically submit or request supporting medical documentation related to CMS claims and Prior Authorization.

Enhanced Technology means the WISeR Participant's technology that is intended to improve the accuracy and efficiency of the Prior Authorization Process and Pre-Payment Review.

Exemption Status means the status that a WISeR Provider or WISeR Supplier may earn to be exempt from requesting Prior Authorization for the Select Items and Services in accordance with Section 6.2 of this Agreement and the WISeR Participant Guide.

FedRAMP stands for **Federal Risk and Authorization Management Program** and means the government-wide program that standardizes security assessments for cloud services (44 U.S.C. § 3607).

Financial Settlement Report means the report that is defined in Section 8.9.

FISMA stands for **Federal Information Security Management Act of 2002, as amended by the Federal Information Security Modernization Act of 2014** and means the framework of guidelines and security standards to protect government information and operations as set forth in 44 U.S.C. § 3541, *et seq.* and 44 U.S.C. § 3551, *et seq*..

Initial Prior Authorization Determination means the communication to the WISeR Provider or WISeR Supplier detailing the Prior Authorization Affirmation or Prior Authorization Non-Affirmation for an initial Prior Authorization submission.

IS2P2 stands for **CMS Information Systems Security & Privacy Policy** and means the policy that defines how CMS protects and controls access to its information and systems as required under FISMA of 2014 (44 U.S.C. Chapter 35).

Locality means a CMS-defined geographic area within a MAC Jurisdiction (e.g., a state, or other geographic boundary) that CMS uses to determine Medicare payment rates for Covered Services.

LCDs stands for **Local Coverage Determinations** and has the meaning set forth in Section 1869(f)(2)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(2)(B)).

MAC stands for Medicare Administrative Contractor and means a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B medical claims or Durable Medical Equipment (DME) claims for Medicare fee-for-service beneficiaries, as further defined in Section 1874A(a)(3) of the Social Security Act (42 U.S.C. § 1395kk-1(a)(3) and 42 C.F.R. Subpart E).

MAC Jurisdiction means the defined geographic territory for the Medicare Part A and Part B Jurisdictions L, 15, H, and F selected for the WISeR Model and as depicted on the "A/B MAC

Jurisdictions" map at https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/who-are-macs (last accessed August 2025) (*see also* Section 911(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173).

Medical Review means the collection and clinical review of medical records and related information to ensure that Medicare payment is made only for services that meet all Medicare Coverage Criteria.

Medically Necessary means reasonable and necessary as determined in accordance with Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)).

Medicare Coverage Criteria means the existing Medicare coverage criteria as set forth in statute, regulation, NCD, or LCD.

Model Participant means a technology company that has signed an agreement with CMS to participate in WISeR and is not the WISeR Participant.

Model Performance Period means the period of time, regardless of the Agreement Performance Period, that begins on January 1, 2026 and ends on December 31, 2031, unless sooner terminated in accordance with Section 12.3.

Navigation Services means services and information including Medicare Coverage Criteria, Prior Authorization performance data, and such other services as detailed in the WISeR Participant Guide that are provided by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers, as applicable, to all WISeR Providers and WISeR Suppliers to increase clinically appropriate care.

NCDs stands for **National Coverage Determinations** and has the meaning set forth in Section 1869(f)(1)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(1)(B).

NPI stands for **National Provider Identifier**.

Payable Non-Affirmation means an Initial Prior Authorization Determination of Prior Authorization Non-Affirmation that qualifies for a WISeR Payment because there was no Resubmission within 120 Days that received a determination of Prior Authorization Affirmation and, at the time of Reconciliation, there was no associated claim paid by Medicare due to the successful appeal of a claim denial.

Performance Period means the three-month period in which the WISeR Participant issues Initial Prior Authorization Determinations for Prior Authorization requests and issues

determinations for Pre-Payment Reviews, including without limitation all associated Resubmissions submitted within 120 days of the Initial Prior Authorization Determination.

Performance Year or **PY** means the 12-month period beginning on January 1 of each year during the Model Performance Period.

Pre-Payment Review means the review by the WISeR Participant to verify consistency with Medicare Coverage Criteria for a claim for one or more Select Items and Services furnished in the MAC Jurisdiction that is submitted to Medicare without requesting Prior Authorization, consistent with 42 C.F.R. § 405.903.

Prior Authorization is a request by the WISeR Provider or WISeR Supplier for provisional affirmation of Medicare Coverage Criteria for one of the Select Items and Services prior to furnishing such items and services to the WISeR Beneficiary and before the claim is submitted for processing.

Prior Authorization Process means the process detailed in Article VI of the Agreement.

Prior Authorization Provisional Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Prior Authorization Non-Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is not accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Program Integrity Screening means a review of an individual's or entity's program integrity history and current status, which may include a review of the individual's or entity's eligibility, history of exclusion or other sanctions imposed with respect to participation in Medicare, Medicaid, or CHIP; history of failure to pay Medicare debts in a timely manner; current or prior law enforcement investigations or administrative actions regardless of whether such investigations or actions relate to participation in Medicare, Medicaid, or CHIP; affiliations with individuals or entities that have a history of program integrity issues; and other information pertaining to the trustworthiness of the individual or entity.

Reconciliation means the process by which CMS calculates the WISeR Payment amount owed to the WISeR Participant for a specific Performance Period as set forth in Article VIII.

Reconciliation Report means the report issued by CMS that details the Reconciliation calculations for the WISeR Participant and the amount of any WISeR Payment for one or more specified Performance Periods.

Regional Benchmark means a payment amount calculated by CMS for each of the Select Items and Services for a given Locality and Performance Period that CMS uses to calculate the WISeR Payment amount for a Payable Non-Affirmation as set forth in Section 8.3.

Resubmission means a Prior Authorization submitted to the WISeR Participant within 120 Days of an Initial Prior Authorization Determination for a Prior Authorization previously submitted by the same WISeR Provider or WISeR Supplier for the same WISeR Beneficiary and same Select Item or Service.

Resubmission Determination means the communication to the WISeR Provider and/or WISeR Supplier detailing the Prior Authorization Provisional Affirmation or Prior Authorization Non-Affirmation for a Resubmission.

Select Items and Services means the Covered Services detailed in Appendix A that are subject to the Prior Authorization Process. When used in its singular form this term is referred to as "**Select Item or Service**".

Start Date means January 1, 2026.

TIN stands for taxpayer identification number.

VDC stands for CMS Virtual Data Center and means the comprehensive information technology infrastructure designed to centralize and modernize CMS' digital operations.

WISeR Beneficiary means a Beneficiary that meets the requirements set forth in Section 4.1.

WISeR Clinician means an individual that satisfies the requirements of Section 3.6.

WISeR Clinical Reviewer means an individual that satisfies the requirements of Section 3.6.

WISeR Data Reporting Guide means the guidance paper that CMS publishes and provides to the WISeR Participant that sets forth the WISeR Participant's reporting obligations during the Model. CMS may modify the WISeR Data Reporting Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Data Reporting Guide at least 30 Days prior to the effective date of such revisions.

WISeR Discount means the discount specified in Section 8.3.C that CMS applies when calculating the WISeR Payment.

WISeR Jurisdiction means the defined geographic states of New Jersey (Jurisdiction L/Novitas Solutions, Inc.), Ohio (Jurisdiction 15/CGS Administrators, LLC), Oklahoma and Texas (JH/Novitas), and Arizona and Washington (JF/Noridian) selected for the WISeR Model

for which the WISeR Participant conducts Prior Authorization Process on claims for Select Items and Services from institutional providers, physicians, clinicians and suppliers.

WISeR Participant means the technology company that meets the requirements set forth in Article III and has signed this Agreement with CMS to participate in the Model.

WISeR Participant Guide means a guidance paper that CMS publishes and provides to the WISeR Participant that sets forth additional details to support the WISeR Participant's activities and obligations during the Model. CMS may modify the WISeR Participant Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Participant Guide at least 30 Days prior to the effective date of such revisions.

WISeR Payment means the Model specific payment made by CMS for a Payable Non-Affirmation or a Pre-Payment Review that qualifies for payment as set forth in Article VIII.

WISeR Performance Measure Set means the measures detailed in Appendix B, and as may be revised in the WISeR Data Reporting Guide, that CMS uses in calculating the AQS.

WISeR Provider means a provider, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction that furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

WISeR Recoupment means the amount owed to CMS if CMS pays a WISeR Payment to the WISeR Participant and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

WISeR Supplier means a supplier, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction and who furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

Article III. General Requirements

Section 3.1 WISeR Participant Requirements

A. During the Agreement Term, the WISeR Participant shall:
    1. Be a legal entity formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates for the purpose of carrying out the activities required by this Agreement;
    2. Have Enhanced Technology and be identified by a single TIN, to provide specified health insurance benefit administrative services, including

Medicare Prior Authorization and Pre-Payment Review services to interpret and apply Medicare Coverage Criteria and clinical coverage criteria derived from NCDs and LCDs, in support of the Medicare FFS program;

3. Use its Enhanced Technology for implementing and streamlining the Prior Authorization Process and Pre-Payment Review for Select Items and Services in its assigned WISeR Jurisdiction;
4. Have a valid Business Associate Agreement ("**BAA**") with CMS;
5. Support CMS in its efforts to make accurate and timely payments to WISeR Providers or WISeR Suppliers for Select Items and Services furnished to WISeR Beneficiaries;
6. Support CMS in its efforts to ensure care provided to Beneficiaries is Medically Necessary and adheres to Medicare Coverage Criteria, thus protecting Beneficiaries and the Medicare Trust Fund; and
7. Not have a conflict of interest as detailed in Section 3.3 of this Agreement.

The WISeR Participant states that it satisfies the requirements of this Section 3.1.A as of the Effective Date.

B. The WISeR Participant shall satisfy the requirements of this Section 3.1.B no later than 45 Days before the Start Date and throughout the remainder of the Agreement Term:
    1. Have access to Federal Risk and Authorization Management Program ("**FedRAMP**") certified workflows;
    2. Comply with all applicable Federal data protection and security requirements including Federal Information Security Management Act ("**FISMA**") requirements, CMS Information Systems Security & Privacy Policy ("**IS2P2**"), CMS Acceptable Risk Safeguard ("**ARS**");
    3. Follow CMS Authority to Operate ("**ATO**") guidelines for connections established between the Medicare Administrative Contractor ("**MAC**") and WISeR Participant; and
    4. Enter into a valid Joint Operating Agreement ("**JOA**") with the applicable MAC.
C. Changes to the WISeR Participant
    1. Change of WISeR Participant Name. The WISeR Participant shall provide written notice to CMS at least 60 Days before any change in the WISeR Participant's legal name becomes effective. The WISeR Participant shall forward to CMS a copy of the document effectuating the name change, authenticated by the appropriate state official (if applicable), and the parties shall execute an agreement reflecting the change of the WISeR Participant's name. This obligation shall remain in effect until the latter of the effective date

of termination of this Agreement or when the final payment by or to the WISeR Participant has been made under this Agreement.

2. Change in WISeR Participant TIN. The WISeR Participant shall provide at least 90 Days advanced written notice before the effective date of any change in the WISeR Participant's TIN. Such notice must be submitted in the form and manner specified by CMS. In response to a change in the WISeR Participant's TIN, CMS may terminate the Agreement or Agreement Performance Period, or take any other actions consistent with the terms of this Agreement. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
3. Change in Control.
    i. The WISeR Participant shall provide written notice to CMS at least 90 Days before the effective date of any Change in Control. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
    ii. Upon learning of a Change in Control, CMS may conduct a Program Integrity Screening and take other appropriate action to ensure compliance with the terms of the Model by the new controlling entity and may require the new controlling entity to execute a novation agreement with CMS or require the new controlling entity to execute a new Participation Agreement with CMS. CMS may also terminate the Participation Agreement between the former controlling entity and CMS.
    iii. If the WISeR Participant undergoes a Change in Control, CMS may take one or more of the following actions: terminate this Agreement; terminate the Agreement Performance Period; or immediately conduct financial settlement in accordance with Section 8.9.
4. Change in Primary Point of Contact. The WISeR Participant shall provide written notice to CMS of any changes to the contact information for the WISeR Participant's primary point of contact no later than 15 Days after the change.

D. Information for Electronic Funds Transfer

1. The WISeR Participant shall submit to CMS a completed Electronic Funds Transfer Authorization Agreement in the form and manner and by the date(s) specified by CMS.

2. The WISeR Participant shall promptly update its Electronic Funds Transfer Authorization Agreement if there are account or bank changes, or any change to the WISeR Participant set forth in Section 3.1.C.
3. If the WISeR Participant fails to submit or accurately complete the Electronic Funds Transfer Authorization Agreement, CMS may withhold any WISeR Payment owed to the WISeR Participant until the WISeR Participant has submitted and CMS has processed an Electronic Funds Transfer Authorization Agreement with the correct information. In addition, the failure to submit or accurately complete an Electronic Funds Transfer Authorization Agreement could delay the WISeR Participant's receipt and timely payment of a demand for payment under this Agreement, and thereby cause the WISeR Participant to be liable for interest on the amount owed to CMS.

E. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, the WISeR Participant fails to meet any requirements set forth in Section 3.1. The WISeR Participant shall provide such written notice to CMS at least 30 Days before failing to satisfy any requirements in Section 3.1.A, or within 5 Days of becoming aware that the WISeR Participant has failed to satisfy any requirements in Section 3.1(B)-(D).

Section 3.2 WISeR Participant Governance

A. General.
   1. The WISeR Participant shall maintain an identifiable governing body with sole and exclusive authority to execute the functions of the WISeR Participant and make final decisions on behalf of the WISeR Participant. The WISeR Participant shall have a governing body that satisfies the following criteria:
      i. The governing body has responsibility for oversight and strategic direction of the WISeR Participant and is responsible for holding the WISeR Participant management accountable for the WISeR Participant's activities;
      ii. The governing body has a transparent governing process;
      iii. When acting as a member of the governing body of the WISeR Participant, each governing body member has a fiduciary duty to the WISeR Participant and to CMS for actions relating to the terms of this Agreement, the Model and the terms set forth in the Business Associate Agreement, including the duty of loyalty, and shall act consistent with that fiduciary duty; and

iv. The governing body shall receive regular reports from the designated compliance official of the WISeR Participant who satisfies the requirements of Section 11.1.

2. The WISeR Participant shall provide each member of the governing body with a copy of the Agreement and any amendments hereto.
3. If CMS determines that the composition of the WISeR Participant's governing body, executive leadership, or parent organization(s) (as applicable) compromises the WISeR Participant's ability to participate in the Model or to comply with the terms of the Agreement, CMS may take one or more of the remedial actions specified in Section 13.2.
4. The WISeR Participant shall ensure that its governing body implements a process for documenting governing body composition, meetings and decisions, and shall retain such documentation in accordance with Section 12.2.

B. Composition and Control of the Governing Body.

1. The WISeR Participant's governing body shall not include any individual with pending or open investigations, or a history of convictions or sanctions, including without limitation:
    i. Investigations or actions related to participation in Medicare, Medicaid, or Children's Health Insurance Program;
    ii. A history of failure to pay Medicare debts in a timely manner;
    iii. Affiliations with individuals or entities that have a history of program integrity issues;
    iv. Conduct that a reasonable person would deem to be unfit conduct; or
    v. A history of legal or monetary sanctions.
2. The WISeR Participant shall routinely monitor each individual on its governing body to ensure compliance with the provisions of this Section 3.2.
3. The WISeR Participant shall immediately remove from its governing body any individual that becomes subject to a conviction or sanction.
4. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, it removes an individual from its governing body. The WISeR Participant shall provide such written notice to CMS within 5 Days of such removal.
5. The governing body members may serve in similar or complementary roles or positions, subject to Section 3.3.

Section 3.3 Conflict of Interest

A. The WISeR Participant shall have a conflict of interest policy that applies to members of the governing body and satisfies the following criteria:
    1. Requires each member of the governing body to disclose relevant financial interests and other interests that could prevent impartiality;
    2. Requires each member of the governing body to update its disclosure statement whenever the member's personal or financial circumstances change in such a way that a new conflict of interest might occur;
    3. Provides a procedure to determine whether a conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses remedial actions for members of the governing body that fail to comply with the policy.

B. Notwithstanding the obligations set forth in Section 3.3.A, the WISeR Participant shall have a conflict of interest policy that applies to its business operations and satisfies the following criteria:
    1. Requires that the WISeR Participant refrain from engaging in activities that would lead to the preferential or non-preferential treatment of any WISeR Provider, WISeR Supplier, WISeR Clinician, WISeR Clinical Reviewer, individual clinician, medical group, medical practice, Beneficiary, or any other individual or entity with an interest in the Prior Authorization Process or Pre-Payment Review;
    2. Requires that the WISeR Participant prohibit WISeR Clinicians and WISeR Clinical Reviewers from participating in the Prior Authorization Process and Pre-Payment Review associated with a provider or supplier under the same TIN as the reviewing WISeR Clinician or WISeR Clinical Reviewer;
    3. Provides a procedure to determine whether such conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses plans of action to correct instances that fail to comply with the policy.

C. The WISeR Participant shall ensure that its conflict of interest policy sets forth a process to address situations where an individual employed by or contracted by the WISeR Participant and has a financial interest, personal activity, or relationship that could impair that individual's ability to act impartially and in the best interest of CMS when performing under the terms of this Agreement, the Business Associate Agreement, or the Model.

D. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Prior Authorization request not participate in the review of that request or any associated Resubmissions related to that Prior Authorization request.
E. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Pre-Payment Review not participate in the review of that claim or any associated Resubmissions related to that Pre-Payment Review.
F. The WISeR Participant shall de-identify Prior Authorization requests, Resubmissions, and Pre-Payment Review claims prior to permitting its WISeR Clinicians and WISeR Clinical Reviewers to conduct a Medical Review or peer-to-peer review.
G. The WISeR Participant shall designate a committee or group responsible for evaluating disclosed potential conflicts of interest and determine whether they pose a risk to the fairness of the Prior Authorization review or the Pre-Payment Review.
    1. The WISeR Participant shall provide immediate written notice of disclosed potential conflicts of interest to CMS. Such written notice shall be made within 5 Days of becoming aware of the potential conflicts of interest.
    2. The WISeR Participant shall include CMS in the determination process associated with the disclosed potential conflicts of interest.

Section 3.4 Required Prior Authorization Activities

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.
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.
C. The WISeR Participant shall review Prior Authorizations in its WISeR Jurisdiction submitted by all WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).
D. Consistent with Section 3.4.C, the WISeR Participant shall perform its Prior Authorization Process on Prior Authorizations received.
E. Consistent with the terms of this Agreement and the requirements set forth in the WISeR Participant Guide, the WISeR Participant shall issue Prior Authorization determinations to the requesting WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction with a copy to the applicable WISeR Beneficiary.

Section 3.5 WISeR Providers and WISeR Suppliers

A. WISeR Providers and WISeR Suppliers may submit Prior Authorization requests directly to the WISeR Participant and receive a determination for Select Items and Services.

B. If the WISeR Provider or WISeR Supplier submits a Prior Authorization request to its MAC for a Select Item or Service, then:

   1. CMS, through the applicable MAC, will re-route the Prior Authorization request to the WISeR Participant;
   2. The WISeR Participant must perform its Prior Authorization Process on the re-routed Prior Authorization from the MAC for the Select Item or Service and issue a determination directly to the WISeR Provider or WISeR Supplier with copy to the MAC and the WISeR Beneficiary identified on the Prior Authorization request; and
   3. Perform any additional requirements as described in the WISeR Participant Guide.

C. CMS, through the applicable MAC, will notify the WISeR Participant if a WISeR Provider or WISeR Supplier submits a claim to Medicare for one or more Select Items and Services furnished to a WISeR Beneficiary in the WISeR Jurisdiction without requesting Prior Authorization.

D. The WISeR Participant must conduct Pre-Payment Review in accordance with Section 6.5 of this Agreement for each Select Item or Service that does not have a Prior Authorization request from the WISeR Provider or WISeR Supplier.

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.

F. CMS will provide written notice, which may be in the form of the WISeR Participant Guide, to the WISeR Participant regarding additional determination letter requirements.

G. The WISeR Participant shall provide to its WISeR Providers and WISeR Suppliers prior authorization criteria and relevant evidence-based clinical practice guidelines for Select Items and Services in a form and manner and by the date(s) determined by CMS. Such compliance assistance information shall include examples of documentation that would support approval of a Prior Authorization request for each Select Item or Service, as well as examples of common mistakes, omissions, and evidence that would result in a denial of Prior Authorization.

Section 3.6 WISeR Clinicians and WISeR Clinical Reviewers

A. General.

1. The WISeR Participant may choose to:
    i. Directly employ clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinicians**"); or
    ii. Subcontract with a separate entity that provides appropriate clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinical Reviewers**"); or
    iii. Do both (i) and (ii).
2. The WISeR Participant must provide to its subcontractor, if applicable, necessary and appropriate WISeR Participant Guide provisions to ensure that each WISeR Clinical Reviewer meets the Medical Review requirements to ensure proper coverage determinations that adheres to Medicare Coverage Criteria and CMS coverage policy.
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.

B. <u>WISeR Clinicians</u>.
1. The WISeR Participant shall ensure that each WISeR Clinician:
    i. Be a board-certified clinician, including a:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;

iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;

vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and

vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinician performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant shall ensure that each WISeR Clinician performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers in a form and manner determined by CMS, as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that the WISeR Clinician has an active, valid and unrestricted license.

C. Record of WISeR Clinicians. The WISeR Participant shall maintain, in accordance with Article XII, a record of all its WISeR Clinicians.
   1. The WISeR Participant shall retain current and historical records of all its WISeR Clinicians in accordance with Section 12.2 of this Agreement.
   2. CMS may request and the WISeR Participant must provide to CMS a certified copy of all WISeR Clinicians at any given time during the Agreement Term.

D. Monitoring and Compliance of WISeR Clinicians.
   1. CMS will monitor the program integrity history of the WISeR Participant's WISeR Clinicians. CMS may require the WISeR Participant to exclude an individual WISeR Clinician or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
   2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinician be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure that each WISeR Clinician conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks, and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that each WISeR Clinician uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items and Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Items and Services;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

E. WISeR Clinical Reviewers.

1. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer:
    i. Be a board-certified clinician, including:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;
    iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;
vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and
vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinical Reviewer performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall require its subcontractor to ensure that the WISeR Clinical Reviewer has an active, valid and unrestricted license.

F. Record of WISeR Clinical Reviewers. The WISeR Participant must require its subcontractor to maintain, in accordance with Article XII of this Agreement, a record of all WISeR Clinical Reviewers performing activities related to this Model.
1. The WISeR Participant shall require the subcontractor to retain current and historical records of all WISeR Clinical Reviewers consistent with Section 12.2 of this Agreement.
2. The WISeR Participant shall require its subcontractor to provide the WISeR Participant with a certified copy of all WISeR Clinical Reviewers at any given time during the Agreement Term. The WISeR Participant shall provide such information to CMS in a form and manner and by the date(s) specified by CMS.

G. Monitoring and Compliance of WISeR Clinical Reviewers.
1. CMS will monitor the program integrity history of the WISeR Participant's use of WISeR Clinical Reviewers. CMS may require the WISeR Participant to exclude an individual WISeR Clinical Reviewer or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinical Reviewer be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items or Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Item or Service;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

Section 3.7 Customer Service

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.
B. The WISeR Participant shall provide an overall environment where WISeR Providers and WISeR Suppliers understand the Prior Authorization Process and Pre-Payment Review process for Select Items and Services.
C. The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.
D. The WISeR Participant shall maintain effective WISeR Provider and WISeR Supplier education that helps ensure complete Prior Authorization submissions for Select Items and Services and reduces the need for re-submissions, requests for appeal, and overturn of coverage determinations on appeal.
E. The WISeR Participant shall educate WISeR Providers and WISeR Suppliers on how to submit Prior Authorization requests and provide its WISeR Providers and WISeR Suppliers with information related to the Medicare Coverage Criteria associated with

the Select Items and Services. Such educational activities shall be conducted in a form and manner determined or approved by CMS, and as may be detailed in the WISeR Participant Guide.

F. The WISeR Participant must educate WISeR Providers and WISeR Suppliers within its assigned WISeR Jurisdiction about the Prior Authorization Process consistent with the provisions of this Agreement and the WISeR Participant Guide.

Section 3.8 Operational Requirements

A. The WISeR Participant shall promote corporate integrity and establish internal controls and an effective compliance program to achieve Agreement goals and objectives.

B. The WISeR Participant shall work collaboratively with CMS, WISeR Providers, WISeR Suppliers, Medicare Administrative Contractors, and other CMS contractors to foster integration of Medicare operations.

C. The WISeR Participant shall develop and continually refine business processes to foster excellence and quality in the administration of the Medicare program.

D. The WISeR Participant shall foster efficiencies in the administration of the Medicare FFS program to promote best value for the government.

E. The WISeR Participant shall use innovative and creative solutions to improve program operations.

Section 3.9 Overlap with Other CMS Programs and Initiatives

A. The parties agree that the WISeR Model is not a shared savings model and there is no Beneficiary alignment in this Model.

B. The WISeR Participant may simultaneously participate in the WISeR Model and any other Innovation Center model.

C. CMS reserves the right to unilaterally update this overlaps policy upon written notice to the WISeR Participant.

Article IV. Beneficiary Eligibility, Engagement, Verification, and Protections

Section 4.1 Beneficiary Eligibility

A. To be considered a WISeR Beneficiary, a Beneficiary must meet the following criteria:

1. Be identified on a Prior Authorization request or a claim subject to Pre-Payment Review for a Select Item or Service from a WISeR Provider or WISeR Supplier in the WISeR Participant's WISeR Jurisdiction;

2. Is eligible for Medicare Part A and enrolled in Medicare Part B at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review;
3. Is a legal adult aged 18 years or older;
4. Is not enrolled in Medicare Advantage at the time of the Prior Authorization request or the date of service on the claim subject to Pre-Payment Review;
5. Has Medicare as the primary payer at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review; and
6. Is not covered under the United Mine Worker Health and Retirement Funds.

Section 4.2 Beneficiary Engagement and Beneficiary Verification

A. The WISeR Participant does not have Beneficiaries aligned or assigned to it for this Model.
B. CMS may require the WISeR Participant to educate Beneficiaries, including WISeR Beneficiaries, within its WISeR Jurisdiction on the Prior Authorization Process for Select Items and Services.
C. The WISeR Participant must ensure that each Prior Authorization request submitted by a WISeR Provider, WISeR Supplier, or a MAC is for a Select Item or Service that will be furnished to a WISeR Beneficiary within the WISeR Jurisdiction.

Section 4.3 Beneficiary Protections and Non-Affirmed Decisions

A. The WISeR Participant shall provide written Prior Authorization Process decisions to the WISeR Provider and/or WISeR Supplier with a copy to the applicable WISeR Beneficiary and appropriate MAC.
B. The WISeR Participant's Prior Authorization Non-Affirmation decision for the Select Item or Service that is determined to not be Medically Necessary must require the WISeR Provider or WISeR Supplier to notify the WISeR Beneficiary and issue an Advance Beneficiary Notice of Non-coverage (ABN) prior to performing such item(s) or service(s) if it is expected that payment would be denied.
C. For purposes of the WISeR Provider and WISeR Supplier notifications required under Sections 4.3.A and 4.3.B, the WISeR Participant shall use a template letter provided by CMS, in which CMS will designate letter content that the WISeR Participant shall not change, as well as places in which the WISeR Participant may insert its own original content.
D. Beneficiaries continue to have all applicable administrative appeal rights under Original Medicare.

Section 4.4 Prohibition on Beneficiary Inducements

Except as otherwise permitted by applicable law, the WISeR Participant shall not provide gifts or other remuneration to Beneficiaries to induce them to receive or to continue to receive items or services from one or more of the following: WISeR Providers, WISeR Suppliers, WISeR Clinicians, or WISeR Clinical Reviewers.

Section 4.5 HIPAA Requirements

A. The WISeR Participant acknowledges that it is either a covered entity or business associate, as those terms are defined in 45 C.F.R. § 160.103, of CMS that is a covered entity.
B. The WISeR Participant shall have all appropriate administrative, technical, and physical safeguards in place before the Start Date to protect the privacy and security of protected health information ("**PHI**") in accordance with 45 C.F.R. § 164.530(c).
C. The WISeR Participant shall maintain the privacy and security of all Model-related information that identifies individual Beneficiaries in accordance with the Health Insurance Portability and Accountability Act ("**HIPAA**") Privacy and Security Rules and all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of PHI by covered entities and their business associates, as well as all other applicable federal and state laws and regulations.

Article V. Functional Requirements

Section 5.1 Functional and Infrastructure Requirements

A. The WISeR Participant shall develop, execute, and maintain a risk management plan that includes:
    1. WISeR Jurisdiction-wide risks, including without limitation risks related to cybersecurity issues;
    2. Periodic assessment, conducted monthly at a minimum, of new risks; and
    3. Mitigation and contingency planning.
B. The WISeR Participant shall provide and use infrastructure to fulfill the requirements of this Agreement.
C. The WISeR Participant shall provide the infrastructure required to integrate and interact with the assigned CMS Virtual Data Center ("**VDC**") and to accomplish services not provided by the VDC to fulfill the requirements of this Agreement.
    1. The WISeR Participant shall work with all Base Function entities, including the VDC, to interface and/or facilitate the receipt or transmission of files, programs or other such products.

2. **Base Functions** are functions provided either by the shared system or the VDC and include interfaces that are part of the base system processing such as the Common Working File (CWF), Comprehensive Error Rate Testing (CERT), Correct Coding Initiative (CCI), BDRD, PECOS, PIMR, Pricer, PULSE, etc.
3. **Non-base/Non-core applications or interfaces** refers to any applications or interfaces that are not part of the base system processing or are not provided or maintained as part of the Medicare Shared Systems (FISS or MCS).
    i. Non-base/non-core applications or interfaces may involve an outside vendor, a Medicare Data Center, or any entity with which the WISeR Participant communicates or shares information through a software application (not including commercial word processing or spreadsheet programs) in processing Medicare claims.
    ii. Examples of non-base/non-core processes include but are not limited to the following:
        a. Print mail;
        b. American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N Transaction Translation Services (via Commercial Off the Shelf (COTS) products);
        c. Workload Management reports;
        d. Scanning Administration;
        e. ICR/OCR Imaging;
        f. Fraud, Waste, or Abuse reporting;
        g. Data Analysis (Easytrieve, SAS extracts, etc.); and
        h. Data files the WISeR Participant routinely receives.

D. The WISeR Participant shall provide translation software that is HIPAA-compliant and strictly adheres to the ASC X12N Technical Report Type 3 (TR3s) for inbound transactions (e.g., ASC X12N claim, ASC X12N 276 claim status request) and outbound transactions (e.g., ASC X12N 835 remittance advice, ASC X123N 277 claim status response, ASC X12N TA1 interchange acknowledgement, ASC X12N 999 implementation acknowledgment, ASC X12N 277 claim acknowledgment).

E. In the event of termination by CMS or the WISeR Participant pursuant to Article XIII, the WISeR Participant shall be required to perform certain closeout activities detailed by CMS in a form and manner and by the date(s) specified by CMS.

Section 5.2 Telecommunications

A. Unless directed to use another connection by CMS, the WISeR Participant shall use only the CMS-supplied telecommunications network to transmit Medicare data to ensure the privacy and security of this protected information for:
    1. Medicare communications between the WISeR Participant and Medicare Administrative Contractor(s), if any;
    2. Communications between the WISeR Participant and subcontractors, if any; and
    3. Communications between the WISeR Participant and CMS.
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.
C. As applicable, the WISeR Participant shall interact with CMS' current enterprise identity access management systems, or any future enterprise identity access management system as directed by CMS, to ensure that the electronic data interchange (EDI) submitter/receiver is an authorized EDI submitter for each transaction.
D. As applicable, the WISeR Participant shall be responsible for the verification/validation of the WISeR Providers and WISeR Suppliers that will be exchanging EDI with the WISeR Participant.

Section 5.3 CMS Audits and Reviews of Software

A. The WISeR Participant shall allow CMS the use of provided software and software documentation, tools, and equipment to conduct audit reviews, tests, and assessments of the WISeR Participant at its facility, its data center and/or in its data cloud.
B. Consistent with Section 5.3.A, the WISeR Participant shall allow CMS use and access to, without limitation, the WISeR Participant's Enhanced Technology, artificial intelligence, machine learning technology, and other similar technologies.

Article VI. Prior Authorization Process

Section 6.1 General

A. The WISeR Participant shall use its Enhanced Technology to review and assess Prior Authorization requests within its assigned WISeR Jurisdiction ("**Prior Authorization Process**").

B. The WISeR Participant must review and assess each Prior Authorization request to ensure that the request meets the following criteria:
    1. Include all documentation necessary to show that the Select Items and Services meet applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The Prior Authorization request is submitted before the Select Items and Services are provided to the WISeR Beneficiary and before the claim is submitted.
C. The WISeR Participant reviews and assesses each expedited Prior Authorization request to ensure that the expedited request meets the following criteria:
    1. Includes all documentation necessary to show that the Select Item or Service meets applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The expedited Prior Authorization request is submitted before the Select Item or Service is provided to the WISeR Beneficiary and before the claim is submitted.
    3. Includes documentation showing that the processing of the Prior Authorization must be expedited due to the WISeR Beneficiary's life, health, or ability to regain maximum function being in serious jeopardy.
D. The WISeR Participant shall evaluate and refine its Prior Authorization Process to ensure accuracy in its Prior Authorization determinations and to prevent harm to Beneficiaries, including WISeR Beneficiaries.
E. The WISeR Participant shall engage in activities such as Navigation Services to reduce clinically inappropriate care and promote clinically appropriate care with its WISeR Providers and WISeR Suppliers in a form and manner and by the date(s) specified by CMS.
F. The WISeR Participant shall report Prior Authorization Process related activities and metrics to CMS through monthly, yearly, and ad hoc reports in a form and manner and by the date(s) specified by CMS.

Section 6.2 Prior Authorization Process and Exemption Status

A. General. 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).
B. Upon receipt of a Prior Authorization, the WISeR Participant shall review the request for compliance with applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act.

1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to the Select Items and Services detailed in Table 1 of Appendix A of this Agreement.
2. The WISeR Participant shall verify that the Prior Authorization is for a Select Item or Service as detailed in Table 1 of Appendix A.
3. The WISeR Participant must further verify that the Prior Authorization request is from a WISeR Provider or WISeR Supplier within the WISeR Jurisdiction.
4. The WISeR Participant shall verify that the requested Select Item or Service would be furnished to an individual that is a WISeR Beneficiary.

C. The WISeR Participant, its WISeR Clinician(s) and its WISeR Clinical Reviewers shall conduct Medical Review of the Prior Authorization, any Resubmissions, render determinations, and communicate decisions to the WISeR Providers, WISeR Suppliers, and WISeR Beneficiaries in accordance with the terms of this Agreement and the applicable requirements detailed in the WISeR Participant Guide.

D. Resubmission. The WISeR Participant shall accept Resubmissions from a WISeR Provider or WISeR Supplier for a Select Item or Service.
1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to each Resubmission; or
2. At the request of the WISeR Provider or WISeR Supplier through its Resubmission, the WISeR Participant shall require its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, to perform peer-to-peer review of the Resubmission. Such peer-to-peer review activities and requirements are detailed in the WISeR Participant Guide and the WISeR Participant acknowledges and agrees that its WISeR Clinicians and WISeR Clinical Reviewers will comply with such requirements.

E. Exemption Status. The WISeR Participant shall provide Exemption Status to a WISeR Provider or WISeR Supplier that has:
1. Submitted the minimum number of Prior Authorization requests for Select Items and Services furnished to WISeR Beneficiaries within the WISeR Jurisdiction as detailed in the WISeR Participant Guide;
2. Has met the CMS threshold percentage of Prior Authorization Provisional Affirmations as detailed in the WISeR Participant Guide; and
3. Met any additional criteria set forth by CMS in the WISeR Participant Guide.

F. Exemption Status List. The WISeR Participant shall retain current and historical lists of WISeR Providers and WISeR Suppliers that have earned Exemption Status.
1. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it has earned Exemption Status and has been added to the Exemption Status list.

i. The WISeR Participant shall specify in its notice to the WISeR Provider or WISeR Supplier the effective date of its Exemption Status, the process for retaining Exemption Status, and provide such other details as described in the WISeR Participant Guide.

2. The WISeR Participant shall provide current and historical Exemption Status lists to CMS in a form and manner and by the date(s) specified by CMS in accordance with the terms of this Agreement and applicable requirements set forth in the WISeR Participant Guide.
3. The WISeR Participant may remove a WISeR Provider or WISeR Supplier from the Exemption Status list if it fails to meet the requirements for Exemption Status as described in the WISeR Participant Guide.
4. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it is removed from the Exemption Status list and such notice shall specify the effective date of removal, the process for re-earning Exemption Status, and provide such other details as described in the WISeR Participant Guide.

Section 6.3 Prior Authorization Determinations

A. Determination Letters.

1. CMS may develop and provide to the WISeR Participant and Model Participants template determination letters.
2. Upon request of the WISeR Participant to CMS, and at the discretion of CMS, the WISeR Participant may create its own template determination letter(s), and such template(s) must be submitted to CMS for review and written approval prior to use and include at a minimum the following information and any other information as specified in the WISeR Participant Guide:
    i. A Unique Tracking Number (UTN);
    ii. For Prior Authorization Non-Affirmation decisions:
        a. A detailed explanation for the decision;
        b. The availability of unlimited resubmissions by the WISeR Provider or WISeR Supplier;
        c. Instructions for how the WISeR Provider or WISeR Supplier may request peer-to-peer review; and
        d. The opportunity to forego the resubmission process, provide one or more of the Select Items and Services, submit the claim for payment and:
            1. The claim will be denied; and
            2. All Medicare appeal rights will be available.
    iii. For re-routed Prior Authorization decisions:

a. Contact information for the WISeR Participant;
b. Instructions to the requesting WISeR Provider and/or WISeR Supplier on how it may choose to submit future Prior Authorization requests for Select Items and Services directly to the WISeR Participant; and
c. Any additional information that CMS may require through written notification to the WISeR Participant.

3. If CMS determines that the template(s) submitted by the WISeR Participant contains misinformation or is otherwise inconsistent with the terms of this Agreement or the WISeR Participant Guide, CMS may reject the template(s) or require the WISeR Participant to amend the template(s) and resubmit such amended template(s) to CMS for review and approval prior to use.

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.

C. Resubmission of Prior Authorization.
1. The WISeR Participant shall issue a Resubmission Determination to the WISeR Provider or WISeR Supplier within 3 Days of the WISeR Participant's receipt of the Prior Authorization resubmission.
2. The WISeR Participant shall ensure the Resubmission Determination is delivered to the WISeR Provider or WISeR Supplier in the same manner it was submitted via postmark, fax, or electronic delivery.

D. Expedited Circumstances. The WISeR Participant may only consider an expedited review of a Prior Authorization request upon receipt of request for expedited review by the WISeR Provider or WISeR Supplier.
1. If the WISeR Participant, in consultation with its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, determines that delays in receipt of a Prior Authorization decision could jeopardize the life, health, or ability to regain maximum function of the WISeR Beneficiary, then the WISeR Participant will process the Prior Authorization under an expedited timeframe, upon request.
i. The WISeR Participant will communicate a determination within 2 business days of receipt of the expedited request.

ii. WISeR Providers and WISeR Suppliers, and their MAC(s) when applicable, are encouraged to use fax, Electronic Submission of Medical Documentation (esMD), or any other CMS approved electronic portal to avoid delays with mailing.

E. Prior Authorization Provisional Affirmation. The WISeR Participant will issue a Prior Authorization Provisional Affirmation of coverage to a WISeR Provider or WISeR Supplier, with a copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and any applicable criteria in the WISeR Participant Guide are met to support the rendering of such item or service to a WISeR Beneficiary.

1. The WISeR Participant's Prior Authorization Provisional Affirmation decision is valid for 120 days from the date the determination was made.

F. Prior Authorization Non-Affirmation.

1. Consistent with Section 3.6.B.2 and Section 3.6.E.2, the WISeR Participant must require its WISeR Clinician(s) and WISeR Clinical Reviewer(s), as applicable, to perform a Medical Review of each Prior Authorization request that may not meet Medicare Coverage Criteria.
    i. The Medical Review of a Prior Authorization request by a WISeR Clinician or WISeR Clinical Reviewer, as applicable, must be performed before the WISeR Participant issues a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier.
2. The WISeR Participant will issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier, with copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and applicable criteria in the WISeR Participant Guide are not met and do not support the rendering of such item or service to a WISeR Beneficiary.
3. The WISeR Participant may issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier for a Select Item or Service via the same method it was requested if the Prior Authorization request contains technical errors or is otherwise insufficient to meet the requirements for Prior Authorization Provisional Affirmation.

G. Appeals. The WISeR Participant acknowledges and agrees that nothing in this Agreement nor in the WISeR Participant Guide shall be construed to limit or otherwise prevent a WISeR Provider, WISeR Supplier, WISeR Beneficiary or Beneficiary from

engaging in the Medicare appeals process permitted by applicable law, regulations, or Medicare program requirements.

Section 6.4 Prior Authorization Non-Affirmation and Resubmissions

A. The WISeR Participant shall provide written notice consistent with Section 6.3.A of this Agreement to the WISeR Provider or WISeR Supplier that the WISeR Provider or WISeR Supplier may resubmit a Prior Authorization upon receipt of a Prior Authorization Non-Affirmation.
B. The WISeR Participant shall provide written notice, consistent with Section 6.3.A, to the WISeR Provider or WISeR Supplier that it may resubmit a Prior Authorization for expedited review consistent with the requirements in Section 6.3.D of this Agreement.
C. The WISeR Participant shall consider all Resubmissions for Prior Authorization received within 120 Days of the Initial Prior Authorization Determination.
D. The WISeR Participant shall review a Resubmission for Prior Authorization received after 120 Days of the Initial Prior Authorization Determination as an Initial Prior Authorization request.

Section 6.5 Pre-Payment Review

A. The WISeR Participant acknowledges that Prior Authorization is not a condition of payment to the WISeR Provider or WISeR Supplier.
B. The WISeR Participant agrees that the WISeR Provider or WISeR Supplier may elect not to submit a Prior Authorization before furnishing one or more of the Select Items and Services to a WISeR Beneficiary.
C. If the WISeR Provider or WISeR Supplier elects not to submit a Prior Authorization for one or more Select Items and Services it furnishes to a WISeR Beneficiary, then the WISeR Participant shall coordinate with the appropriate MAC to subject the claim to Pre-Payment Review consistent with the terms of this Agreement, Sections 6.5.C.1 and 6.5.C.2, and the requirements detailed in the WISeR Participant Guide.
    1. CMS, through its appropriate MAC, will flag claims submitted by the WISeR Provider or WISeR Supplier for Select Items and Services without a Prior Authorization request.
    2. CMS, through its appropriate MAC, will re-route flagged claims to the WISeR Participant for Pre-Payment Review.
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.

Article VII. Quality Performance

Section 7.1 Quality Score

CMS shall use the quality score in determining the WISeR Participant's Aggregate Quality Score ("**AQS**") according to the methodology described in this Article VII and the WISeR Data Reporting Guide.

Section 7.2 Quality Measures

A. General
   1. The WISeR Participant shall complete reporting for all quality measures and for all Prior Authorizations received, Prior Authorization Provisional Affirmations, Prior Authorization Non-Affirmations, and Resubmissions in accordance with the WISeR Data Reporting Guide.
   2. CMS will publish, at least annually, a WISeR Data Reporting Guide, detailing the WISeR quality reporting requirements.
   3. CMS may modify the WISeR Performance Measure Set, or the number of measures that the WISeR Participant must report, or both. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Performance Measure Set at least 30 Days prior to the effective date of the change.
      i. If CMS removes a quality measure from the WISeR Performance Measure Set in advance of a Performance Period, CMS will not use the removed quality measure to evaluate the WISeR Participant, and the WISeR Participant will not be accountable for performance on such quality measures during the relevant Performance Period.

B. WISeR Performance Measure Set
   1. The WISeR Participant shall report all measures to CMS that are listed in the WISeR Performance Measure Set as described in Appendix B to this Agreement and the WISeR Data Reporting Guide. CMS shall use these measures for the purposes of calculating the WISeR Participant's AQS, the monitoring and evaluation of the overall efficiency and accuracy in WISeR, and to evaluate the WISeR Participant's performance during the Model.
   2. CMS will determine what version of specifications will be used for each measure included in the WISeR Performance Measure Set for the applicable Performance Period. CMS will notify the WISeR Participant of the version of specifications that will be used for each measure included in the WISeR Performance Measure Set as early as possible after such information becomes available.

3. The WISeR Participant must report all required measures from the WISeR Performance Measure Set in order to be eligible to earn the WISeR Payment for a Performance Period in accordance with Section 8.3.

C. Quality Measure Reporting
   1. The WISeR Participant must submit all quality measures that are listed in the WISeR Performance Measure Set to CMS during the defined reporting period for quality measures as communicated in the WISeR Data Reporting Guide.
   2. CMS reserves the right to require submission via any other format, including the Fast Healthcare Interoperability Resources ("**FHIR®**") standard, at any time during the Agreement Term without the consent of the WISeR Participant. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the reporting format of measures at least 90 Days prior to the measurement period.
   3. The WISeR Participant shall comply with the requirements described in this Article VII and Appendix B of this Agreement, and the requirements detailed in the WISeR Data Reporting Guide.

Section 7.3 Collection of Data and Purpose

A. Pursuant to 42 C.F.R. § 403.1110(b), the WISeR Participant must collect and report data described in Section 7.2 to CMS for CMS' Model monitoring and evaluation purposes.
B. The WISeR Participant, at CMS' request, will administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
C. CMS reserves the right to administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
D. CMS may require the WISeR Participant to implement surveys of WISeR Providers, WISeR Suppliers, and/or WISeR Beneficiaries in the WISeR Participant's designated WISeR Jurisdiction and report any survey measures included in the WISeR Data Reporting Guide to CMS.

Section 7.4 Quality Performance Scoring

A. CMS will calculate the WISeR Participant's AQS for each Performance Period at the time of Reconciliation.
B. CMS will calculate the AQS based on quality measures specified in the WISeR Data Reporting Guide.

C. CMS will calculate the AQS by totaling the quality points for all quality measures included in the AQS calculation for a given Performance Period and dividing by the maximum quality points available for these included quality measures.
D. CMS may modify the methodology for Quality Performance Scoring and shall notify the WISeR Participant in writing at least 30 Days before the start of the Performance Period in which such change would take effect. Modifications to the Quality Performance Scoring methodology may include, but are not limited to:
    1. Modifications to the set of quality measures included in the AQS;
    2. Modifications to the point values and point distributions for one or more quality measures included in the AQS;
    3. Modifications to the benchmark for one or more quality measures included in the AQS; and
    4. Modifications to the metrics for one or more quality measures included in the AQS.
E. CMS will convert the AQS to a quality multiplier that will be applied to each WISeR payment for the applicable Performance Period, as detailed in the WISeR Data Reporting Guide.

Article VIII. Financial Management and Payment

Section 8.1 General

A. CMS shall make, adjust, settle, and seek repayment of WISeR Payments in accordance with this Article VIII and Article XIII.
B. CMS may unilaterally amend Article VIII and to the extent practicable will issue advance written notice to the WISeR Participant 30 Days before the start of the Performance Period in which the amendment would take effect.

Section 8.2 Financial Management Requirements

A. The WISeR Participant shall promote the fiscal integrity of the Medicare FFS program and be an accountable steward of public funds.
B. The WISeR Participant shall adhere to the CMS Medicare integrity program.

Section 8.3 WISeR Payments

A. General.
    1. CMS pays the WISeR Payment to the WISeR Participant, as set forth in this Article VIII, subject to initial Reconciliation, financial settlement, and recoupment.

2. The WISeR Participant may receive a WISeR Payment for each Pre-Payment Review that results in a denied claim for a Select Item or Service and for each Payable Non-Affirmation.
3. CMS shall not pay the WISeR Participant a WISeR Payment if the WISeR Participant conducts a Prior Authorization or a Pre-Payment Review and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
4. The WISeR Participant owes a WISeR Recoupment and shall remit all WISeR Recoupments to CMS if Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to a WISeR Beneficiary due to the successful appeal of a claim denial.
5. CMS calculates the WISeR Payment as set forth in Section 8.3.D.

B. Calculation of Regional Benchmark.

1. For each Performance Period and each Locality within the WISeR Participant's designated WISeR Jurisdiction, CMS determines a Locality-specific Regional Benchmark for each of the Select Items and Services identified in Table 1 of Appendix A of this Agreement.
2. Except as specified in Section 8.3.B.3, CMS calculates the Regional Benchmark by:
    i. Identifying all claims that were submitted within the state that include the applicable Locality, were submitted by a WISeR Provider or a WISeR Supplier, include the applicable Select Item or Service, and have a date of service in the 12 months preceding the start of the applicable Performance Period;
    ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the Locality and applicable to the calendar year that includes the Performance Period being reconciled; and
    iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.
3. In the event change in law or Medicare policy changes effective during the Agreement Performance Period and applicable to a Select Item(s) or Service(s), CMS may, at its sole discretion, calculate the Regional Benchmark for the applicable Select Item or Service for one or more Performance Periods by:

i. Identifying all claims for the Select Item or Service that were submitted by Medicare-enrolled providers or suppliers within the WISeR Participant's designated MAC Jurisdiction with a date of service that is:
    a. No earlier than the effective date of the applicable legislation or Medicare policy change;
    b. No earlier than 9 months before the start of the applicable Performance Period; and
    c. No later than the final Day of the applicable Performance Period; and
ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the calendar year that includes the Performance Period being reconciled; and
iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.

4. When calculating the average claim-level payment as set forth in Section 8.3.B.2.iii and Section 8.3.B.3.iii, CMS may exclude payments for certain items or services billed on the same claim as the applicable Select Item or Service. CMS will maintain a list of such exclusions in the WISeR Participant Guide.

C. WISeR Discount. CMS calculates the WISeR Discount separately by state for each of the Select Items and Services as the percentage of claims with a medical necessity denial among all claims submitted by WISeR Providers and WISeR Suppliers within the state for that Select Item or Service with a date of service in 12 months preceding the start of the Model Performance Period. CMS may modify the WISeR Discount, including the dates of service for claims included in the calculation of the WISeR Discount, and to the extent practicable will provide 30 Days' advance written notice before the effective date of such modifications.

D. WISeR Payment. The WISeR Participant may earn a WISeR Payment for each Payable Non-Affirmation and for each Pre-Payment Review resulting in a denied claim for a Select Item or Service.

1. CMS calculates the WISeR Payment for each Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state;
    ii. Multiplying by the WISeR payment rate of 25 percent; and
    iii. Applying the quality adjustment determined by the WISeR Participant's AQS.

2. CMS calculates the WISeR Payment for each Pre-Payment Review resulting in a denied claim for a Select Item or Service by:
    i. Calculating the amount billed on the claim, less any approved payments for services other than the Select Item or Service that were billed on the same claim and less any denied payments billed on the same claim for one or more excluded service(s) noted in the WISeR Participant Guide;
    ii. Reducing the amount set forth in Section 8.3.D.2.i by the WISeR Discount applicable to the Select Item or Service and state;
    iii. Multiplying by the WISeR payment rate of 25 percent; and
    iv. Applying the quality adjustment determined by the WISeR Participant's AQS.

E. WISeR Recoupment. CMS will recoup a WISeR Recoupment from the WISeR Participant if CMS pays the WISeR Participant a WISeR Payment and Medicare subsequently pays the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
    1. The amount of the WISeR Recoupment will equal the amount of the previous WISeR Payment that CMS paid to the WISeR Participant for the applicable Payable Non-Affirmation or Pre-Payment Review.
    2. CMS will identify any WISeR Recoupments on a quarterly basis.
    3. To the extent possible, CMS will net any WISeR Recoupments against the total of WISeR Payments for a future Performance Period as set forth in Section 8.5.
    4. If CMS cannot collect WISeR Recoupments for claims appeals adjudicated after the Reconciliation of the final Performance Period under the Agreement or any other CMS program or initiative, CMS shall issue a demand letter to the WISeR Participant and the WISeR Participant shall pay CMS the amount owed within 30 Days of the date of demand letter.
    5. If CMS does not timely receive payment in full, the remaining amount owed will be considered a delinquent debt subject to the provisions of Section 8.8.D.

Section 8.4 Advance WISeR Payment

A. At the sole discretion of CMS, CMS may pay the WISeR Participant an Advance WISeR Payment prior to completing Reconciliation for a given Performance Period.

B. Eligibility Criteria.
    1. At the sole discretion of CMS, CMS may provide an Advance WISeR Payment to the WISeR Participant for an applicable Performance Period.

2. The WISeR Participant may be eligible to receive an Advance WISeR Payment during an applicable Performance Year if:
    i. CMS has notified the WISeR Participant of the availability of an Advance WISeR Payment for a specified Performance Period;
    ii. CMS has detailed specific data elements that the WISeR Participant must report to CMS in a form and manner and by the date(s) specified by CMS ("**Preliminary Data**");
    iii. The WISeR Participant timely reports the required data elements to CMS; and
    iv. CMS has approved the WISeR Participant's reported data elements and eligibility for an Advance WISeR Payment for the specified Performance Period.
3. If CMS determines that the WISeR Participant has not timely or accurately reported all required data elements, then CMS may deem the WISeR Participant ineligible for an Advance WISeR Payment for the applicable Performance Period.
4. If CMS has approved the WISeR Participant's eligibility for an Advance WISeR Payment for the applicable Performance Period, then CMS calculates the Advance WISeR Payment as set forth in Section 8.4.D.
5. In applicable Performance Periods, CMS will calculate the Advance WISeR Payment no earlier than the first Day after the end of the Performance Period.

C. Adjustments to Future WISeR Payment(s). If CMS determines that the WISeR Participant is eligible to receive an Advance WISeR Payment, CMS will net the amount of the Advance WISeR Payment against future WISeR Payments, including as applicable:
    1. Any WISeR Payments that CMS calculates for the applicable Performance Period during Reconciliation; and
    2. Any WISeR Payments that CMS calculates for subsequent Performance Periods.

D. Calculation of an Advance WISeR Payment. CMS calculates an Advance WISeR Payment using Preliminary Data for the Performance Period submitted by the WISeR Participant as set forth in Section 8.4.B. CMS calculates the Advance WISeR Payment for the applicable Performance Period as follows:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will provisionally determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will provisionally identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will estimate the WISeR Payment for each provisionally identified Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state; and
    ii. Multiplying by the WISeR payment rate of 25 percent.
5. CMS will estimate the WISeR Payment for each provisionally identified Pre-Payment Review qualifying for a WISeR Payment by:
    i. Calculating the amount billed on the claim, less any payments for services other than the Select Item or Service that were billed on the same claim;
    ii. Reducing this amount by the WISeR Discount applicable to the Select Item or Service and state; and
    iii. Multiplying by the WISeR payment rate of 25 percent.
6. CMS will total the estimated WISeR Payments as set forth in Section 8.4.E.4 and Section 8.4.E.5 and multiply this total by 50 percent to obtain the Advance WISeR Payment.

Section 8.5 Reconciliation Process

A. CMS will perform Reconciliation for a Performance Period by completing the following calculations:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will calculate the AQS for the WISeR Participant as set forth in Section 7.4 and in the WISeR Data Reporting Guide.
5. CMS will calculate the WISeR Payment as set forth in Section 8.3.D.
6. CMS will identify any pending WISeR Recoupments as set forth in Section 8.3.E. and will net these WISeR Recoupments against the total of WISeR Payments for the Performance Period.

B. CMS will perform Reconciliation for a Performance Period no earlier than the Day after the last Day on which a Resubmission for a Prior Authorization may be submitted, except as otherwise provided in Section 8.5.C.
    1. After calculating the WISeR Payment amount for the Reconciliation for a Performance Period, CMS will compare this amount against any WISeR Payment that was calculated in the initial Reconciliation for the same Performance Period and already paid or recouped by CMS, to determine the net amount of any WISeR Payment still owed for that Performance Period.
    2. If CMS issues a Reconciliation Report detailing the results of the Reconciliation, as described in Section 8.6, simultaneously with the Reconciliation Report detailing the results of the initial Reconciliation for a subsequent Performance Period, CMS may net any WISeR Payment amount specified in the Reconciliation Report for the initial Reconciliation against the net WISeR Payment amount that CMS calculates for the Reconciliation in accordance with Section 8.5.B.1.
C. If the Agreement or Agreement Performance Period is terminated pursuant to Article XIII, CMS shall conduct an initial Reconciliation and a final financial settlement, in accordance with Section 8.9, for the WISeR Participant's final Performance Period, which shall include all Prior Authorizations and Pre-Payment Reviews conducted by the WISeR Participant through the effective date of termination or expiration of this Agreement.

Section 8.6 Reconciliation Report

A. After performing Reconciliation for a given Performance Period as set forth in Section 8.5, CMS shall issue a Reconciliation Report to the WISeR Participant.
B. The Reconciliation Report will set forth the calculation of the WISeR Participant's Regional Benchmarks, AQS, Payable Non-Affirmations, and any applicable WISeR Payment for that Performance Period. In accordance with Section 8.5, the Reconciliation Report for any subsequent Reconciliation for a given Performance Period will also set forth any necessary adjustments to the WISeR Payment amount, if applicable, calculated in the initial Reconciliation for that Performance Period.
C. CMS shall make reasonable efforts to issue the initial Reconciliation Report for each Performance Period within 6 months after the last Day of that Performance Period.
D. Unless CMS receives a timely calculation error notice in accordance with Section 8.7, the Reconciliation Report shall be deemed final 30 Days from the date of issuance by CMS.

Section 8.7 Reconciliation Report Calculation Error

A. The WISeR Participant may contest a Reconciliation Report in accordance with this Section 8.7.
B. The WISeR Participant shall have 30 Days from the date the Reconciliation Report is issued to provide written notice to CMS of an error in the calculation of the WISeR Payment specified in that Reconciliation Report. The calculation error notice must contain a detailed, written explanation of the basis for the calculation error, including any supporting documentation.
C. If CMS receives a timely calculation error notice, CMS shall issue a written determination within 30 Days to either confirm or revise the calculation error, although CMS may extend the deadline for its determination upon written notice to the WISeR Participant.
    1. If CMS issues a written determination that the amount was calculated in error, CMS shall issue a revised Reconciliation Report, which is final on the date of issuance. The WISeR Participant may dispute the revised Reconciliation Report in accordance with Article XIV if the dispute is not precluded from review.
    2. If CMS issues a written determination that the amount is correct, the Reconciliation Report is final on the date the determination is issued.
    3. The WISeR Participant may dispute the determination issued by CMS in accordance with Article XIV if the dispute is not precluded from review.

D. If the WISeR Participant does not submit a timely calculation error notice to CMS in accordance with this Section 8.7, the WISeR Participant is precluded from later contesting the WISeR Payment amounts specified in that Reconciliation Report.
E. If as a result of any later inspection, evaluation, investigation, or audit, it is determined that any WISeR Payment amounts have been calculated in error, CMS may adjust such amounts, issue a revised Reconciliation Report, and make or demand payment of any additional amounts owed in accordance with this Section 8.7.

Section 8.8 Payment of Amounts Owed

A. CMS will pay the WISeR Participant any WISeR Payment amount owed to the WISeR Participant that is specified in Reconciliation Report within 30 Days after the date the Reconciliation Report is deemed final, as set forth in this Section 8.8.
B. CMS shall issue to the WISeR Participant a demand letter for any WISeR Payment owed pursuant to a Reconciliation Report that has been deemed final. The demand letter will be sent to the WISeR Participant at the address specified on the most recent Electronic Funds Transfer Authorization Agreement submitted by the WISeR Participant in accordance with Section 3.1.E.
C. The WISeR Participant shall pay any WISeR Payment amount owed to CMS within 30 Days of the date of a demand letter.
D. Delinquent Debt
    i. If the WISeR Participant fails to pay amounts due to CMS in full by the date specified in any demand letter, CMS shall assess simple interest on the unpaid balance at the rate applicable to other Medicare debts under 42 C.F.R. § 405.378. Interest shall be calculated in 30-Day periods and shall be assessed for each 30-Day period that payment is not made in full. Any payments received by CMS first shall be applied toward accrued interest and then to any outstanding principal balance due.
    ii. If CMS does not receive payment in full by the date the payment is due, CMS shall invoke all legal means to collect the debt and will use any applicable debt collection tools, including referral of the debt to the United States Department of Treasury, pursuant to 31 U.S.C. § 3711(g).

Section 8.9 Financial Settlement Report

A. Upon the expiration or termination of the Agreement Performance Period, CMS will issue to the WISeR Participant a financial settlement report that sets forth the amount of any WISeR Recoupments that the WISeR Participant must repay to CMS

or the amount of any WISeR Payment that CMS must make to the WISeR Participant, in accordance with this Agreement ("**Financial Settlement Report**").

B. If the Financial Settlement Report indicates that CMS owes the WISeR Participant additional payment, CMS shall make such payment within 30 Days after the Financial Settlement Report is deemed final.

C. If the Financial Settlement Report indicates that the WISeR Participant owes CMS a WISeR Recoupment, CMS will issue the WISeR Participant a demand letter for such monies owed to CMS. The WISeR Participant shall pay CMS any WISeR Recoupment within 30 Days of the date of a demand letter. If CMS does not timely receive payment in full, the remaining monies owed shall be considered a delinquent debt in accordance with Section 8.8.D.

Section 8.10 Extreme and Uncontrollable Circumstances

A. CMS may, in its sole discretion, provide Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers if the WISeR Providers and WISeR Suppliers:

   1. Are located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act; and
   2. Are located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

B. CMS has the sole discretion to determine the time period during which Prior Authorization flexibilities are provided to the WISeR Participant's WISeR Providers and WISeR Suppliers.

C. In the event that CMS provides Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers, CMS will provide written notice to the WISeR Participant of any impact such flexibilities have on the terms of this Agreement.

D. The WISeR Participant shall identify, develop, and coordinate prevention, response, and recovery procedures to ensure the availability of critical resources, and facilitate the continuity of essential business functions in an emergency situation, including natural disasters, manmade incidents, catastrophic emergencies, and public health emergencies ("**Continuity of Operations (COOP) Plan**").

E. The WISeR Participant shall maintain a COOP Plan that addresses protection of the physical infrastructure and business continuity (with or without system availability) of mission essential functions, to include without limitation the Prior Authorization Process, and communicating to WISeR Providers and WISeR Suppliers.

F. The WISeR Participant's COOP Plan shall include an information technology (IT) contingency and disaster recovery plan that addresses identified IT risks and vulnerabilities including, without limitation, cybersecurity issues.

Article IX. Business Associate Agreement, Data Sharing and Reports

Section 9.1 Business Associate Agreement

A. The WISeR Participant agrees to execute a valid Business Associate Agreement ("**BAA**") with CMS no later than 5 Days after the Effective Date of this Agreement.
B. If the WISeR Participant fails to execute a valid BAA pursuant to Section 9.1.A by the date specified by CMS, CMS will terminate the Agreement or the Agreement Performance Period or both in accordance with Section 13.3.
C. The WISeR Participant's BAA with CMS shall be active and valid for the duration of the Agreement Term.
D. The WISeR Participant shall comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") Privacy, Security, and Breach Notification Rules (45 C.F.R. Part 160 & Part 164, subparts A through E) ("**HIPAA Rules**").
E. The parties agree that the terms and conditions of the executed BAA between the WISeR Participant and CMS are hereby incorporated by reference into this Agreement as if fully set forth herein.

Section 9.2 Data Sharing and Reports – General

A. The WISeR Participant shall implement information technology (IT) systems security controls in order to maintain the confidentiality, integrity, and availability of the Medicare systems operations in the event of computer incidents or physical disasters.
B. Subject to the limitations discussed in this Agreement, and in accordance with applicable law, including HIPAA and the regulations in 42 C.F.R. Part 2, in advance of the Start Date of this Agreement, during the Agreement Performance Period, and any other time deemed necessary by CMS, CMS will offer the WISeR Participant an opportunity to request certain Beneficiary-identifiable data and reports in accordance with the terms and conditions set forth in this Agreement and in the BAA.
C. The Beneficiary-identifiable data available for request are described in Section 9.3 of this Agreement and in the BAA between CMS and the WISeR Participant.
D. Consistent with 42 C.F.R. § 403.1110(b), the WISeR Participant shall report data metrics for monitoring and evaluation purposes related to the WISeR Participant's Prior Authorization Process that include without limitation:

1. The total number of Prior Authorizations received during the data reporting period with a detailed description of:
    i. The number of Prior Authorization Provisional Affirmations during the data reporting period; and
    ii. The number of Prior Authorization Non-Affirmations during the data reportion period; and
2. The time (e.g., Days, weeks, hours, etc.) taken for the WISeR Participant's Prior Authorization Process to reach a determination;
    i. The total number of Resubmissions for each Prior Authorization received during the data reporting window or for a previous data reporting window;
    ii. The number of reversals of the Initial Prior Authorization Determination.

Section 9.3 Provision of Certain Beneficiary-Identifiable Claims Data

A. At CMS' sole discretion based on CMS' available resources, the limitations in this Agreement, the limitations in the BAA, and applicable law, CMS and the WISeR Participant may share certain Beneficiary-identifiable data for Beneficiaries in the WISeR Jurisdiction subject to the Prior Authorization Process.
B. The Beneficiary-identifiable data includes the data and reports described in this Section 9.3.B.
    1. Detailed Beneficiary Claims Data. These data will include individual Beneficiary-identifiable Medicare FFS claims data for Select Items and Services provided to Beneficiaries within the WISeR Jurisdiction. This includes without limitation data on Medicare FFS expenditures and utilization, and Prior Authorization Process metrics (e.g., timing, Prior Authorization request determinations, Resubmissions of Prior Authorizations, etc.).
    2. Quality Performance Scoring Data. These data will include Beneficiary-identifiable data and quality performance data specific to the Prior Authorization Process.
C. The parties mutually agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by CMS.
D. The parties further agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by the WISeR Participant as it relates to the Prior Authorization Process.

E. The WISeR Participant represents, and in furnishing the data files specified in Section 9.3.B of this Agreement and the BAA CMS relies upon such representation, that such data files will be used solely for the purpose of carrying out the provisions of this Agreement to improve the efficiency and accuracy of Prior Authorizations, quality improvement activities, reducing health care costs for the Medicare FFS program without causing harm to Beneficiaries, identifying or reducing fraud, waste, and abuse in Medicare FFS, and such other purposes described int his Agreement. The WISeR Participant agrees not to disclosure, use, or reuse the data excepts as specified in this Agreement, the BAA, or except as CMS shall authorize in writing or as otherwise required by law. The WISeR Participant further agrees not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement and the BAA.

F. Information derived from the CMS data specified in Section 9.3.B of this Agreement and in the BAA may be shared and used within the legal confines of the WISeR Participant and its WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers and WISeR Suppliers in a manner consistent with the provisions of this Agreement and the BAA to improve the Prior Authorization Process and Beneficiary care.

G. The WISeR Participant may reuse original or derivative data without prior written authorization from CMS for quality improvement activities relating to improving health or reducing health care costs through the Prior Authorization Process, but shall not disseminate (unless required by law) any individually identifiable original or derived information from the data specified in Section 9.3.B of this Agreement to anyone who is not a HIPAA Covered Entity, a HIPAA Business Associate, a WISeR Clinician or WISeR Clinical Reviewer performing activities related to this Model, or a WISeR Provider or WISeR Supplier in treatment relationship with the subject WISeR Beneficiary. When using or disclosing PHI or personally identifiable information ("**PII**"), obtained from data specified in Section 9.3.B, the WISeR Participant must make "reasonable efforts to limit" the information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure, or request.

H. The WISeR Participant shall establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget ("**OMB**") in OMB Circular No. A-130, Appendix I – Responsibilities for Protecting and Managing Federal Information Resources (https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A130/a130revised.pdf) as well as Federal Information Processing Standard 200 entitled

"Minimum Security Requirement for Federal Information and Information Systems" (http:// (http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf); and, NIST Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" (http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf). The WISeR Participant acknowledges that the use of unsecured telecommunications, including the Internet, to transmit directly or indirectly identifiable information from the files specified in Section 9.2.B or any such derivative data files is strictly prohibited.

I. The WISeR Participant shall grant access to the data and/or the facility(ies) in which the data is maintained to the authorized representatives of CMS or Office of Inspector General of the Department of Health and Human Services ("**OIG**") for the purpose of inspecting to confirm compliance with the terms of this Agreement and the BAA.

J. The WISeR Participant agrees that any use of CMS data in the creation of any document concerning the purpose specified in this section must adhere to CMS' current cell size suppression policy. The policy stipulates that no cell (e.g., patients, services) representing 10 or fewer Beneficiaries may be displayed. Also, no percentages or other mathematical formulas may be used if they result in the display of a cell representing 10 or fewer Beneficiaries. A cell that represents or uses percentages or other mathematical formulas to represent zero Beneficiaries must be displayed.

Article X. Participation in Evaluation, Shared Learning Activities, and Site Visits

Section 10.1 Evaluation Requirement

A. General. The WISeR Participant shall participate and cooperate in any independent evaluation activities conducted by or on behalf of CMS aimed at assessing the impact of the Model on the goals of improving quality of care and reducing fraud, waste, and abuse expenditures for the Medicare program. The WISeR Participant shall require its WISeR Clinicians and WISeR Clinical Reviewers to participate and cooperate in any such independent evaluation activities conducted by or on behalf of CMS. Termination or expiration of this Agreement shall not affect the right of CMS to evaluate WISeR.

B. Primary Data. In its evaluation activities, CMS or its designee(s) may collect qualitative and quantitative data. These data may include, but are not limited to the following sources:

1. Site visits with the WISeR Participant;
2. Surveys or interviews with WISeR Providers and WISeR Suppliers;
3. Surveys or interviews with Beneficiaries and their caregivers;
4. Focus groups of WISeR Providers and WISeR Suppliers;
5. Focus groups of Beneficiaries and their caregivers;
6. Interviews with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
7. Focus groups with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
8. Direct observation of WISeR Provider and/or WISeR Supplier interactions with the WISeR Participant and its staff, and other activities related to the WISeR Participant's participation in the Model;
9. Review of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates; and
10. Surveys.

C. Secondary Data. In its evaluation activities, CMS may use data or information submitted by the WISeR Participant as well as claims submitted to CMS for Select Items and Services furnished to Beneficiaries. These data may include, but are not limited to:
    1. Claims data;
    2. Survey data from Patient Experience surveys;
    3. Medical records;
    4. Clinical data;
    5. Monitoring data (e.g., audit results, etc.); and
    6. Quality and clinical data submitted to CMS.
D. Reporting Requirements. CMS may add or modify evaluation-related reporting requirements during the Agreement Term. CMS will notify the WISeR Participant of any additions or modifications as soon as practicable or at least 30 Days prior to the Day on which such change would take effect.

Section 10.2 Shared Learning Activities

A. The WISeR Participant shall participate in CMS-sponsored learning activities designed to drive improvement and foster innovations in using technology-assisted decision-making through sharing best practices or new knowledge that emerges from participation in the Model.
B. The WISeR Participant shall actively engage in a variety of learning events, learning communities, and sharing promising tools and ideas, as well as their lessons learned.

Section 10.3 Site Visits

A. The WISeR Participant shall cooperate and require its staff to cooperate in any site visits conducted by or on behalf of CMS.
B. CMS or its designee(s) shall, to the extent practicable, schedule any site visits to the WISeR Participant no fewer than 15 Days in advance. To the extent practicable, CMS will attempt to accommodate the WISeR Participant's request for particular dates in scheduling site visits. However, the WISeR Participant may not request a date that is more than 60 Days after the date of the initial site visit notice from CMS.
C. The WISeR Participant shall ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during the site visit.
D. Notwithstanding the foregoing, CMS or its designee(s) may perform unannounced site visits at any of the WISeR Participant's office locations at any time to investigate concerns or other program integrity issues.
E. Nothing in this Agreement shall be construed to limit or otherwise prevent CMS from performing site visits permitted by applicable law or regulations.

Section 10.4 Rights in Data and Intellectual Property

A. CMS may use any data obtained pursuant to the Model to evaluate the Model and to disseminate quantitative results and successful care management techniques to other providers and suppliers and to the public. Data to be disseminated may include results of WISeR Provider and WISeR Supplier surveys, results of patient experience of care and quality of life surveys as well as measures based upon claims, medical records, and other data sources. The WISeR Participant will be permitted to comment on evaluation reports when the WISeR Participant has been specifically cited to ensure factual accuracy but may not edit conclusions or control the dissemination of reports.
B. The parties agree that by participating in the Model, the WISeR Participant grants to CMS and its designees a limited, royalty-free, worldwide, non-sublicensable, non-exclusive license on a warranty-free basis during the term of this Agreement (and for any agreed to extension thereof) in, to and under all intellectual property and information technology owned or licensable (without the consent of, or payment to, any third party) by the WISeR Participant or any of its affiliates, solely for CMS or any of its designees or affiliates to receive and use such information technology.
C. Notwithstanding any other provision in the Agreement, the parties agree that any intellectual property or information technology developed as a result of the collaborative activity under the terms of this Agreement and the requirements associated with this Model will be dealt with by appropriate written agreements

D. Notwithstanding any other provision in the Agreement, all proprietary trade secret information and technology of the WISeR Participant that existed prior to the Effective Date of this Agreement is and shall remain the sole property of the WISeR Participant, and, except as required by federal law, shall not be released by CMS without express written consent. The regulation at 48 C.F.R. § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into the Agreement. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property right or other rights to the WISeR Participant's proprietary information or technology.

E. If the WISeR Participant maintains any information that should not be publicly disclosed because the WISeR Participant considers such information to be proprietary and confidential, the WISeR Participant acknowledges that it may submit to CMS a form, using either the template attached as Appendix C, or a form substantially the same as Appendix C, identifying specific examples of information the WISeR Participant considers to be proprietary and confidential. The WISeR Participant must notify CMS, in a form and manner to be specified by CMS, of any updates to this form. If the WISeR Participant does not submit such a form, the WISeR Participant will be deemed to have confirmed that it has no information it considers proprietary and confidential.

Section 10.5 WISeR Participant Public Release of Information

A. The WISeR Participant shall obtain prior approval from CMS during the Agreement Term and for 6 months thereafter for the publication or release of any press release, external report or statistical/analytical material that materially and substantially references the WISeR Participant's participation in the Model. External reports and statistical/analytical material may include but are not limited to papers, articles, professional publications, speeches, and testimony.

B. All external reports and statistical/analytical material that are subject to this Section 10.5 must include the following statement on the first page: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

Article XI. Compliance and Oversight

Section 11.1 WISeR Participant Compliance Plan

A. The WISeR Participant shall have a compliance plan that includes at least the following elements:

1. A designated compliance official or individual who is not legal counsel to the WISeR Participant and reports directly to the WISeR Participant's governing body;
2. Mechanisms for identifying and addressing compliance problems related to the WISeR Participant's operations and performance;
3. A method for employees or contractors of the WISeR Participant performing functions or services related to this Model to anonymously report suspected problems related to the WISeR Participant's compliance official;
4. Compliance training for the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers; and
5. A requirement for the WISeR Participant to report probable violations of law to an appropriate law enforcement agency.

B. The WISeR Participant shall ensure that its compliance plan is in compliance with all applicable laws and regulations. The WISeR Participant shall periodically update its compliance plan to reflect changes in those laws and regulations.

Section 11.2 CMS Monitoring and Oversight Activities

A. CMS shall conduct monitoring activities to assess compliance by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers with the terms of this Agreement. Such monitoring activities may include, but are not limited to:
   1. Claims analyses to identify fraudulent behavior or program integrity risks such as efforts to manipulate Prior Authorization Process accuracy and efficiency;
   2. Claims and appeals data to identify fraudulent behavior or program integrity risks, including data between the WISeR Participant and any MAC;
   3. Review of documents from the WISeR Participant, WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers, and WISeR Suppliers, including surveys and questionnaires;
   4. Review and audits of the WISeR Participant's Enhanced Technology, including without limitation, reliance on artificial intelligence, machine learning capabilities, and its impact on the timing and accuracy of Prior Authorization determinations, denial rates, affirmation rates, resubmission rates, and other data related to such Enhanced Technology;
   5. Review and audits of the WISeR Participant's Pre-Payment Review processes performed by its WISeR Clinicians and WISeR Clinical Reviewers, and the impact on the timing and accuracy of Pre-Payment Review determinations, denial rates, affirmation rates, resubmission rates, and other data related to such reviews;
   6. Interviews with Beneficiaries and their caregivers;

7. Audits of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant;
8. Audits of data related to Pre-Payment Review, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant; and
9. Site visits to the WISeR Participant.

B. In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including, without limitation, all Medicare claims submitted for items and/or services furnished to Beneficiaries.

C. In conducting monitoring and oversight activities, CMS or its designee(s) may use any relevant data or information including, without limitation, all Prior Authorization requests, Pre-Payment Review activities, determinations, and resubmissions submitted for items and/or services furnished to Beneficiaries.

D. Nothing in this Agreement limits or otherwise prevents CMS from monitoring the WISeR Participant for compliance as permitted by applicable law or regulations.

E. CMS may conduct monitoring activities pursuant to this Article XI for up to two calendar years after the effective date of termination or expiration of this Agreement.

Section 11.3 Compliance with Monitoring and Oversight Activities

A. The WISeR Participant shall cooperate with, and require its WISeR Clinicians and WISeR Clinical Reviewers to cooperate with, all CMS monitoring and oversight requests and activities.

B. The WISeR Participant shall ensure it has sufficient access to all records, data, and information necessary to comply with the monitoring activities described in this Agreement. As necessary, the WISeR Participant shall request this information from any WISeR Clinician, or any WISeR Clinical Reviewer, or individual performing functions or providing services related to WISeR.

Section 11.4 Compliance with Laws

A. Agreement to Comply

1. The WISeR Participant shall comply with, and shall require all WISeR Clinicians and WISeR Clinical Reviewers to comply with, the applicable terms of the Agreement and all applicable statutes, regulations, and guidance, including without limitation: (a) federal criminal laws; (b) the Social Security Act (Public Law 74-271); (c) Title XVIII of the Act; (d) the False Claims Act (31 U.S.C. § 3729 et seq.); (e) the antikickback statute (42 U.S.C. § 1320a-7b(b)); (f) the civil monetary penalties law (42 U.S.C. § 1320a-7a); (g) the federal

physician self-referral law (42 U.S.C. § 1395nn); and (h) any applicable State laws.

2. This Agreement does not waive any obligation of the WISeR Participant to comply with the terms of any other CMS contract, agreement, model, or demonstration.

B. Reservation of Rights

1. Nothing contained in this Agreement or in the application process for WISeR constitutes a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS Office of the Inspector General, or CMS of any right to institute any proceeding or action for violations of any statutes, rules, or regulations administered by the government, or to prevent or limit the rights of the government to obtain relief under any other federal statutes or regulations, or on account of any violation of the Agreement or any other provision of law. This Agreement does not bind any government agency except CMS and the Agreement binds CMS only to the extent provided in this Agreement.
2. The failure by CMS to require performance of any provision of this Agreement does not affect CMS' right to require performance at any time thereafter, nor does a waiver of any breach or default of the Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

C. Office of Inspector General of the Department of Health and Human Services (OIG) Authority. None of the provisions of this Agreement limit or restrict the OIG's authority to audit, evaluate, investigate, or inspect the WISeR Participant or its WISeR Clinicians or its WISeR Clinical Reviewers.

D. Other Government Authority. None of the provisions of this Agreement limit or restrict any other government authority that is permitted by law to audit, evaluate, investigate, or inspect the WISeR Participant.

Section 11.5 Applicable Statutes, Regulations, Manuals, and Documents

In addition to all referenced statutes, regulations, manuals, and documents, the following statutes, regulations, manuals, and documents apply to this Agreement and are hereby incorporated by reference.

A. Financial management and internal controls (e.g., the Federal Managers' Financial Integrity Act of 1982 (FMFIA), the Chief Financial Officers' Act of 1990, etc.);
B. Federal Information Security Management Act of 2014 (FISMA);
C. Privacy and information technology requirements (Privacy Act of 1974, Information Technology Management Reform Act of 1996);

D. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191);
E. Rehabilitation Act of 1973 (including section 508, Accessibility Standards);
F. Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248);
G. Administrative Simplification Compliance Act of 2002 (Public Law 107-105);
H. Benefit Improvement and Protection Act of 2000 (Public Law 106-554);
I. Executive Order 13410, to the extent practicable, Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs;

Medicare manuals (e.g., internet only manuals – IOMs) to administer CMS programs. In the event of any conflict, this Agreement shall have precedence over the IOMs located at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index;

Article XII. Audits and Record Retention

Section 12.1 Right to Audit and Inspect

The WISeR Participant agrees that the government (including CMS, HHS, and the Comptroller General or their designees) has the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the WISeR Participant that pertain to the following:

A. The WISeR Participant's compliance with the terms of this Agreement, including provisions that require the WISeR Participant to impose duties or requirements on its WISeR Clinicians and its WISeR Clinical Reviewers;
B. Whether the WISeR Clinicians and WISeR Clinical Reviewers complied with the duties and requirements imposed on them by the WISeR Participant pursuant to the terms of this Agreement;
C. The quality of services performed under this Agreement;
D. Any activity by the WISeR Participant that may pose a potential risk of harm to Beneficiaries or a vulnerability to the integrity of the Model test;
E. The WISeR Participant's right to WISeR Payments;
F. The ability of the WISeR Participant to repay amounts owed to CMS under this Agreement;
G. The WISeR Participant's financial arrangements.

Section 12.2 Maintenance of Records

The WISeR Participant shall maintain and shall give the government (including CMS, HHS, and the Comptroller General or their designees) access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs,

quality performance measures, and financial arrangements) sufficient to enable the audit, evaluation, inspection, or investigation of the Model, including the subjects identified in Section 11.2. The WISeR Participant shall maintain such books, contracts, records, documents, and other evidence for a period of six years from the expiration or termination of this Agreement or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:

A. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the WISeR Participant at least 30 Days before expiration of the six-year period described above; or
B. There has been a termination, dispute, or allegation of fraud or similar fault against the WISeR Participant in which case the records shall be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

Article XIII. Remedial Action and Termination

Section 13.1 Grounds for Remedial Action

A. CMS may take remedial action against the WISeR Participant if CMS determines that the WISeR Participant:
    1. Has failed to comply with any applicable term of the Agreement or any Medicare program requirement, rule, or regulation;
    2. Has failed to comply with the American with Disabilities Act of 1990, 42 U.S.C. § 12101 *et seq*. (1990);
    3. Has failed to comply with the WISeR Participant's Corrective Action Plan (CAP), the monitoring or auditing plan, or both, developed by CMS for the WISeR Participant, or other remedial action imposed by CMS, if applicable;
    4. Has taken any action that threatens the health or safety of a Beneficiary, including a WISeR Beneficiary;
    5. Has failed to rectify deficiencies following any remedial action;
    6. Has undergone a Change in Control that renders it ineligible for participation in the Model or presents a program integrity risk;
    7. Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model or any requirement of the Medicare program;
    8. Has failed to pay amounts owed to CMS by the date specified in a demand letter;
    9. Has failed to pay a WISeR Recoupment;

10. Has a conflict of interest; or
11. Poses significant program integrity risks, including but not limited to:
    i. Is subject to sanctions or other actions of a federal, state, or local government agency;
    ii. Is subject to investigation or action by HHS (including, but not limited to OIG and CMS) or the Department of Justice due to an allegation of fraud or similar misconduct, including but not limited to being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

Section 13.2 Types of Remedial Action

A. If grounds for remedial action exist, CMS may take one or more of the following actions:
    1. Notify the WISeR Participant of the violation;
    2. Require the WISeR Participant to provide additional information to CMS or its designees;
    3. Conduct site visits, interview WISeR Providers and/or WISeR Suppliers, interview Beneficiaries, or take other actions to gather information;
    4. Place the WISeR Participant on a monitoring and/or auditing plan developed by CMS;
    5. Require the WISeR Participant to not use a WISeR Clinician or WISeR Clinical Reviewer for Medical Review, immediately or within a timeframe specified by CMS;
    6. Withhold, deny, or recoup WISeR Payments;
    7. Withhold, deny, or recoup any Advance WISeR Payments;
    8. Suspend or terminate the WISeR Participant's ability to perform its Prior Authorization Process on new requests;
    9. Require a CAP from the WISeR Participant that is acceptable to CMS. If CMS requires a CAP from the WISeR Participant, the following requirements apply:
        i. The WISeR Participant shall submit a CAP to CMS for approval by a deadline established by CMS:
        ii. CMS must approve the WISeR Participant's CAP;
        iii. The CAP must address what actions the WISeR Participant will take within a specified time period to ensure that all deficiencies will be corrected and that the WISeR Participant will be in compliance with the terms of this Agreement; and

iv. If the WISeR Participant does not comply with the terms of the CAP within the specified period of time, CMS may take additional remedial actions or terminate the Agreement or Agreement Performance Period in accordance with Section 13.3.

B. CMS may impose additional remedial actions, including but not limited to terminating the Agreement or Agreement Performance Period pursuant to Section 13.3, if CMS determines that the WISeR Participant's efforts to address noncompliance or other grounds for remedial action were insufficient.

Section 13.3 Termination by CMS

CMS may immediately or with advance notice terminate the Agreement or Agreement Performance Period if:

A. CMS determines that it no longer has the funds to support the Model;
B. CMS modifies or terminates the Model pursuant to section 1115A(b)(3)(B) of the Act;
C. CMS offers the WISeR Participant an amendment to this Agreement pursuant to Section 1.4, and the WISeR Participant does not sign such amendment by the date specified by CMS;
D. CMS determines that any grounds for remedial action exist;
E. CMS determines that the WISeR Participant has failed to submit, obtain approval for, implement, or fully comply with the terms of a CAP;
F. CMS determines that the WISeR Participant has failed to demonstrate improved performance following any remedial action imposed by CMS;
G. The WISeR Participant has a conflict of interest that cannot be resolved;
H. The WISeR Participant has not executed a valid BAA; or
I. The WISeR Participant assigns or purports to assign any of the rights or obligations under the Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

Section 13.4 Termination of the Agreement Performance Period by WISeR Participant

The WISeR Participant may terminate the Agreement Performance Period upon advance written notice to CMS. Such notice must specify the effective date of the termination, which must be at least 90 Days after the date of the notice.

Section 13.5 Financial Settlement Upon Termination

If CMS terminates the Agreement or the Agreement Performance Period is terminated by either party, CMS shall conduct settlement for the entire Performance Year in which the Agreement is terminated in accordance with Article VIII of the Agreement.

Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination

If the Agreement or Agreement Performance Period is terminated under Section 13.3 or Section 13.4, the WISeR Participant shall provide written notice of the termination to all WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction. The WISeR Participant shall deliver such written notice no later than 45 Days before the effective date of termination unless a different date is specified by CMS. The WISeR Participant shall include in such notices any content specified by CMS.

Article XIV. Limitation on Review and Dispute Resolution

Section 14.1 Limitations on Review

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

A. The selection of organizations, sites, or participants to test models selected for testing or expansion under section 1115A of the Act, including the decision by CMS to terminate the Agreement or Agreement Performance Period;
B. The elements, parameters, scope, and duration of such models for testing or dissemination;
C. Determinations regarding budget neutrality under section 1115A(b)(3);
D. The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B);
E. Determinations about expansion of the duration and scope of a model under section 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection (c);
F. The selection of quality performance standards by CMS;
G. The methodology applied to calculate Regional Benchmarks, WISeR Discount, AQS, and WISeR Payments;
H. The methodology used to calculate the WISeR Participant's WISeR Payment; and
I. The methodology used to calculate the WISeR Recoupment.

Section 14.2 Dispute Resolution

A. Right to Reconsideration. The WISeR Participant may request reconsideration of a determination made by CMS pursuant to the Agreement only if such reconsideration is not precluded by section 1115A(d)(2) of the Act or the Agreement.
    1. Such a request for reconsideration by the WISeR Participant must satisfy the following criteria:

i. The request must be submitted to a designee of CMS ("**Reconsideration Official**") who –
    a. Is authorized to receive such requests;
    b. Did not participate in the determination that is the subject of the reconsideration request; and
    c. May be, but does not have to be, an Inferior Officer.
ii. The request must include a copy of the initial determination issued by CMS and contain a detailed, written explanation of the basis for the dispute, including supporting documentation;
iii. The request must be made within 30 Days of the date of the initial determination for which reconsideration is being requested and
iv. The request must be delivered via email to CMS at InnovationModelsReconsideration@cms.hhs.gov or at such other address specified by CMS.

2. Requests that do not meet the requirements of Section 14.2.A.1 will be denied.
3. Within 15 Days of receiving a request for reconsideration, the parties will be sent a written acknowledgement of receipt of the reconsideration request. Such an acknowledgement will set forth:
    i. The review procedures; and
    ii. A briefing schedule that permits each party to submit written briefs, including any evidence or documentation in support of the party's position for consideration by the Reconsideration Official.

B. Standards for Reconsideration
1. The parties shall proceed diligently with the performance of this Agreement during the course of any dispute arising under the Agreement.
2. The reconsideration will consist of a review of documentation that is submitted timely and in accordance with the standards specified by the Reconsideration Official.
3. The burden of proof is on the WISeR Participant to demonstrate to the Reconsideration Official with clear and convincing evidence that the determination is inconsistent with the terms of the Agreement.

C. Reconsideration Determination
1. The reconsideration determination will be based only upon:
    i. Position papers and supporting documentation that are timely submitted to the Reconsideration Official and meet the standards for submission under Section 14.2.B.2; and

ii. Documents and data that were timely submitted to CMS in the required format before the agency made the determination that is the subject of the reconsideration request.

2. The Reconsideration Official will issue to CMS and the WISeR Participant a written notification of the reconsideration determination ("**Reconsideration Determination**"). Absent unusual circumstances, the Reconsideration Determination will be issued within 60 Days of receipt of timely filed position papers and supporting documentation.
3. The Reconsideration Determination is final and binding 30 Days after its issuance, unless the WISeR Participant or CMS timely requests review of the Reconsideration Determination in accordance with Sections 14.2.D.1 and 2.

D. CMS Administrator Review. The WISeR Participant or CMS may request CMS Administrator review of the Reconsideration Determination.

1. The request must be made via email to InnovationModelsReconsideration@cms.hhs.gov or such other address as specified by CMS within 30 Days after the date of the Reconsideration Determination.
2. The request must include a copy of the Reconsideration Determination and a detailed, written explanation of why the WISeR Participant or CMS disagrees with the Reconsideration Determination.
3. Within 30 business days after receiving a request for review, the CMS Administrator (or a delegate acting on behalf of the CMS Administrator) will determine whether the request for review is granted or denied. The CMS Administrator will promptly send the parties written acknowledgement of receipt of the request for review. Such an acknowledgement will set forth:
    i. Whether the request for review is granted or denied; and
    ii. If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.
4. If the request for review is denied, the Reconsideration Determination is final and binding as of the date the request for review is denied.
5. If the request for review is granted:
    i. The record for review will consist of timely submitted briefs and the evidence contained in the record of the proceedings before the Reconsideration Official. The CMS Administrator will not consider documentation submitted for review other than documents and date described in Section 14.2.B.2;

ii. The CMS Administrator will review the record and issue to CMS and to the WISeR Participant a written determination; and
iii. The written determination of the CMS Administrator is final and binding.

E. Effect of Dispute Resolution. The dispute resolution process under this Agreement shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

Article XV. Miscellaneous

Section 15.1 Agency Notifications and Submission of Reports

A. For a notice or other communication required under this Agreement to be valid, it must be in writing.
B. Unless otherwise specified in this Agreement or stated in writing after the Effective Date, all notifications and reports required under this Agreement must be submitted to the parties at the addresses set forth below:

CMS:
WISeR Model
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop: WB-06-05
Baltimore, MD 21244
Email: WISeR@cms.hhs.gov

WISeR Participant:
Virtix Health LLC
13835 N. Tatum Boulevard Suite 9277
Phoenix
AZ
85032

Section 15.2 Notice of Bankruptcy

A. If the WISeR Participant has filed a bankruptcy petition, whether voluntary or involuntary, the WISeR Participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the WISeR Participant under the terms of each model tested under section 1115A of the Act in which the WISeR Participant is participating or has participated and all administrative or judicial review proceedings related to any payments under such models have been fully and finally resolved.

B. The notice of bankruptcy must be sent by certified mail no later than 5 Days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the WISeR Participant is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the WISeR Participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the WISeR Participant and CMS have been fully and finally resolved with respect to that model.

C. The notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3-01-24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices.

Section 15.3 Severability

In the event that any one or more of the provisions of this Agreement is, for any reason, held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had never been included in the Agreement, unless the deletion of such provision or provisions would result in such a material change to the Agreement so as to cause continued participation under the terms of this Agreement to be unreasonable.

Section 15.4 Entire Agreement; Amendment

This Agreement, including all appendices, constitutes the entire agreement between the parties. The parties may amend this Agreement or any appendix hereto at any time by mutual written consent; provided, however, that CMS may amend this Agreement or any appendix hereto in writing without the consent of the WISeR Participant as specified in this Agreement or any appendix hereto, or for good cause or as necessary to comply with applicable federal

or state law, regulatory requirements, accreditation standards, or licensing guidelines or rules. To the extent practicable, CMS shall provide the WISeR Participant with 30 Days' advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

Section 15.5 Survival

Expiration or termination of this Agreement by CMS shall not affect the rights and obligations of the parties accrued prior to the effective date of the expiration or termination of this Agreement, except as provided in this Agreement. The rights and duties under the following sections of this Agreement shall survive the expiration or termination of this Agreement and apply thereafter:

Article VIII. Payment;
Article IX. Data Sharing and Reports;
Section 10.1 Evaluation Requirements;
Section 10.4 Rights in Data and Intellectual Property;
Section 10.5 WISeR Participant Public Release of Information;
Section 11.3 Compliance with Monitoring and Oversight Activities;
Article XII. Audits and Record Retention;
Section 13.5 Financial Settlement Upon Termination;
Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination;
Section 14.1 Limitations on Review;
Section 15.2 Notice of Bankruptcy;
Section 15.5 Survival; and
Section 15.7 Prohibition on Assignment.

Section 15.6 Precedence

If any provision of this Agreement conflicts with a provision of any document incorporated herein by reference, the provision of this Agreement shall prevail.

Section 15.7 Prohibition on Assignment

Except with the prior written consent of CMS, the WISeR Participant shall not transfer, including by merger (whether the WISeR Participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under this Agreement; (2) any right that it has to satisfy a condition under this Agreement; (3) any remedy that it has under this Agreement; or (4) any obligation imposed on it under this Agreement. The WISeR Participant shall provide CMS 90 Days' advance written notice of any such proposed transfer. This obligation remains in effect until final payment by or to the WISeR Participant has been made under this Agreement. CMS may condition its consent to transfer on full payment of any amounts owed by the WISeR Participant under this Agreement or owed to CMS by the

proposed assignee. Any purported transfer in violation of this Section is voidable at the discretion of CMS.

Section 15.8 Certification

The WISeR Participant executive signing this Agreement certifies to the best of his or her knowledge, information, and belief that the WISeR Participant satisfies the requirements of Section 3.1.A, that all WISeR Clinicians and WISeR Clinical Reviewers satisfy the requirements of Section 3.4, and that he or she is authorized by the WISeR Participant to execute this Agreement and to legally bind the WISeR Participant to its terms and conditions.

Section 15.9 Execution in Counterpart

This Agreement and any amendments hereto may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof. This Agreement and any amendments hereto may be signed by autopen or electronic signature (e.g., DocuSign or similar electronic signature technology) and may be transmitted by electronic means. Copies of this Agreement and any amendments hereto that are so executed and delivered have the same force and effect as if executed with handwritten signatures and physically delivered.

[SIGNATURE PAGE FOLLOWS]

Each party is signing this Agreement on the date stated opposite that party's signature. If a party signs but fails to date a signature, the date that the other party receives the signing party's signature will be deemed to be the date that the signing party signed the Agreement.

WISeR Participant: Virtix Health LLC

WISeR ID: WISeR-00040

(b)(6)

Date: 2025-09-24 17:06:51

By: _____

(b)(6)

Name of Authorized Signatory

(b)(6)

Title

CMS:

Date: 2025-10-01 14:14:13

By: _____

Arrah Tabe-Bedward

Name of Authorized Signatory

CMS Executive

Appendices

Appendix A: Select Items and Services

Appendix B: Quality Measures

Appendix C: WISeR Participant Proprietary and Confidential Information

Appendix A: Select Items and Services

CMS uses Covered Services that correspond to the LCDs and NCDs identified in the Table 1 below ("**Select Items and Services**") to determine whether the WISeR Provider's and/or WISeR Supplier's Medicare claim is subject to the Prior Authorization Process for Performance Year 1. The WISeR Participant performs its Prior Authorization Process for each Select Item or Service identified in a Prior Authorization request within its WISeR Jurisdiction.

CMS may unilaterally revise the Select Items and Services identified in Table 1 prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any revisions to the Select Items and Services for a Performance Period prior to the start of the Performance Period in which such change will take effect.

Table 1

Select Items and Services	Associated NCD/LCDs
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)	NCD 160.7 NCD 230.18 NCD 160.19 NCD 160.24 NCD 160.18
Induced Lesions of Nerve Tracts	NCD 160.1
Epidural Steroid Injections for Pain Management	L39015, L39242, L36920
Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L34106, L38201, L35130
Cervical Fusion Excluding codes already included in OPD	L39741, L39762, L39793
Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee	NCD 150.9

Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea	L38307, L38312, L38385
Incontinence Control Devices	NCD 230.10
Diagnosis and Treatment of Impotence	NCD 230.4
Percutaneous Image-Guided Lumbar Decompression for Spinal Stenosis	NCD 150.13
Skin and Tissue Substitutes • Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds • Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities	L35041 L36690

Appendix B: Quality Measures

Consistent with Article VII and the WISeR Data Reporting Guide, CMS shall use the following WISeR Performance Measure Set for purposes of calculating the AQS of the WISeR Participant for Performance Year 1. CMS will also use the following WISeR Performance Measure Set for purposes of monitoring and evaluating the overall performance of the WISeR Participant during the Model.

CMS may update the quality measures identified in the WISeR Performance Measure Set prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any updates for a Performance Period prior to the start of the Performance Period in which such change will take effect.

WISeR Performance Measure Set

Domain	First Applicable Performance Period	Data Source	Measurement Frequency
Timeliness of Determinations	PP1	WISeR Participant-Reported	Quarterly
Accuracy of Determinations	PP1	CMS Audit of WISeR Participant-Reported Data	Quarterly

Appendix C: WISeR Participant Proprietary and Confidential Information

The following are specific examples, without limitation, of what the WISeR Participant considers proprietary and confidential information currently maintained by the WISeR Participant that should not be publicly disclosed:

1) (b)(4)

2)

3)

4)

In accordance with Section 10.4 of the Agreement, this information shall not be released by CMS without the express written consent of the WISeR Participant except as required by federal law.

Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Patient Care Models Group
7500 Security Blvd
Baltimore, MD 21244

Wasteful and Inappropriate Service Reduction (WISeR) Model

Participation Agreement

Segment 1: January 1, 2026-December 31, 2028

August 29, 2025

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PARTICIPATION AGREEMENT

This Participation Agreement (the "**Agreement**") is between the CENTERS FOR MEDICARE & MEDICAID SERVICES ("**CMS**") and

Zyter Inc. , ("**WISeR Participant**").

CMS is the agency within the U.S. Department of Health and Human Services ("**HHS**") that is charged with administering the Medicare and Medicaid programs.

The WISeR Participant is a legal entity identified by a single TIN and has Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process and Pre-Payment Review for Select Items and Services on Medicare fee-for-service ("**FFS**") Claims.

CMS is implementing the Wasteful and Inappropriate Service Reduction Model ("**WISeR**" or "**Model**") under section 1115A of the Social Security Act ("**Act**"), which authorizes CMS through its Center for Medicare and Medicaid Innovation ("**Innovation Center**") to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program expenditures while preserving or enhancing the quality of care furnished to Beneficiaries.

The Model seeks to reduce or maintain Medicare FFS expenditures while improving the quality of care and health outcomes for Medicare FFS beneficiaries through the WISeR Participant's Enhanced Technology to implement and increase the efficiency and accuracy of the Prior Authorization Process for Select Items and Services that do not satisfy existing Medicare Coverage Criteria and may be fraudulent, wasteful, or of low-value to Medicare FFS beneficiaries.

The WISeR Participant applied to participate in WISeR, and CMS has approved the WISeR Participant for participation in the Model for the MAC Jurisdiction of JF Noridian and the state of Arizona. The designated state is the WISeR Participant's WISeR Jurisdiction.

The parties therefore agree as follows:

Article I. Agreement Term

Section 1.1 Effective Date

This Agreement will become effective when it is signed by the last party to sign it (as indicated by the date associated with that party's signature) ("**Effective Date**").

Section 1.2 Agreement Term

The term of this Agreement ("**Agreement Term**") begins on the Effective Date and expires two years after the last Day of the Agreement Performance Period, as defined in Section 1.3, unless the Agreement is sooner terminated by CMS in accordance with Section 13.3, in which case the Agreement Term ends on the effective date of such termination.

Section 1.3 Agreement Performance Period

A. The performance period of this Agreement ("**Agreement Performance Period**") begins on the Effective Date and ends at 11:59 PM ET on December 31, 2028, unless the Agreement Period or the Agreement is sooner terminated in accordance with Section 1.4.B or Article XIII, in which case the Agreement Performance Period ends on the date specified in the termination notice.

B. CMS may offer the WISeR Participant the option to participate in a second segment of this Model which would begin on January 1, 2029, and end at 11:59 PM ET on December 31, 2031. The WISeR Participant must execute a new agreement with CMS to participate in the Model during the second segment. Any such agreement will authorize CMS to take remedial action against the WISeR Participant for non-compliance with the terms of this Agreement, regardless of when the non-compliance is discovered by CMS.

Section 1.4 Amended and Restated Agreements

A. No later than 30 Days prior to the start of a calendar year during the Agreement Performance Period, CMS may offer the WISeR Participant the opportunity to sign an amendment to this Agreement, which may be in the form of an amended and restated version of this Agreement.

B. If the WISeR Participant fails to sign an amendment offered by CMS pursuant to Section 1.4.A by a date specified by CMS, CMS may terminate the Agreement Performance Period on December 31 of the year in which the amendment was offered.

Article II. Definitions

Advance WISeR Payment means the payment that meets the requirements in Section 8.4.

Aggregate Quality Score (AQS) means the score that is calculated from the WISeR Participant's quality data and used to determine the quality multiplier applied during the calculation of the WISeR Payment.

ARS stands for **CMS Acceptable Risk Safeguard** and means the standard to CMS and its contractors, including the WISeR Participant, as to the minimum level of required security and privacy controls. *See* https://security.cms.gov/policy-guidance/cms-acceptable-risk-safeguards-ars (last accessed August 2025).

ATO stands for **CMS Authority to Operate** and means the information systems operated by or on behalf of the U.S. federal government that meet FISMA standards.

BAA stands for **Business Associate Agreement** and means the legally binding contract required under HIPAA between CMS and the WISeR Participant that handles Protected Health Information.

Beneficiary means an individual who is entitled to Medicare FFS benefits under Part A or enrolled under Part B.

Change in Control means: (1) the acquisition by any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the WISeR Participant representing more than 50 percent of the WISeR Participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the WISeR Participant by any other individual or entity; (3) the sale, lease exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the WISeR Participant; or (4) the approval and completion of a plan of liquidation of the WISeR Participant, or an agreement for the sale or liquidation of the WISeR Participant.

Covered Services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Day(s) means calendar day(s) unless otherwise specified.

Electronic Submission of Medical Documentation (esMD) means a system used by CMS to enable providers, suppliers, and other entities to reduce or eliminate the need to mail or fax paper documents and instead electronically submit or request supporting medical documentation related to CMS claims and Prior Authorization.

Enhanced Technology means the WISeR Participant's technology that is intended to improve the accuracy and efficiency of the Prior Authorization Process and Pre-Payment Review.

Exemption Status means the status that a WISeR Provider or WISeR Supplier may earn to be exempt from requesting Prior Authorization for the Select Items and Services in accordance with Section 6.2 of this Agreement and the WISeR Participant Guide.

FedRAMP stands for **Federal Risk and Authorization Management Program** and means the government-wide program that standardizes security assessments for cloud services (44 U.S.C. § 3607).

Financial Settlement Report means the report that is defined in Section 8.9.

FISMA stands for **Federal Information Security Management Act of 2002, as amended by the Federal Information Security Modernization Act of 2014** and means the framework of guidelines and security standards to protect government information and operations as set forth in 44 U.S.C. § 3541, *et seq.* and 44 U.S.C. § 3551, *et seq*..

Initial Prior Authorization Determination means the communication to the WISeR Provider or WISeR Supplier detailing the Prior Authorization Affirmation or Prior Authorization Non-Affirmation for an initial Prior Authorization submission.

IS2P2 stands for **CMS Information Systems Security & Privacy Policy** and means the policy that defines how CMS protects and controls access to its information and systems as required under FISMA of 2014 (44 U.S.C. Chapter 35).

Locality means a CMS-defined geographic area within a MAC Jurisdiction (e.g., a state, or other geographic boundary) that CMS uses to determine Medicare payment rates for Covered Services.

LCDs stands for **Local Coverage Determinations** and has the meaning set forth in Section 1869(f)(2)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(2)(B)).

MAC stands for Medicare Administrative Contractor and means a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B medical claims or Durable Medical Equipment (DME) claims for Medicare fee-for-service beneficiaries, as further defined in Section 1874A(a)(3) of the Social Security Act (42 U.S.C. § 1395kk-1(a)(3) and 42 C.F.R. Subpart E).

MAC Jurisdiction means the defined geographic territory for the Medicare Part A and Part B Jurisdictions L, 15, H, and F selected for the WISeR Model and as depicted on the "A/B MAC

Jurisdictions" map at https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/who-are-macs (last accessed August 2025) (*see also* Section 911(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173).

Medical Review means the collection and clinical review of medical records and related information to ensure that Medicare payment is made only for services that meet all Medicare Coverage Criteria.

Medically Necessary means reasonable and necessary as determined in accordance with Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)).

Medicare Coverage Criteria means the existing Medicare coverage criteria as set forth in statute, regulation, NCD, or LCD.

Model Participant means a technology company that has signed an agreement with CMS to participate in WISeR and is not the WISeR Participant.

Model Performance Period means the period of time, regardless of the Agreement Performance Period, that begins on January 1, 2026 and ends on December 31, 2031, unless sooner terminated in accordance with Section 12.3.

Navigation Services means services and information including Medicare Coverage Criteria, Prior Authorization performance data, and such other services as detailed in the WISeR Participant Guide that are provided by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers, as applicable, to all WISeR Providers and WISeR Suppliers to increase clinically appropriate care.

NCDs stands for **National Coverage Determinations** and has the meaning set forth in Section 1869(f)(1)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(1)(B).

NPI stands for **National Provider Identifier**.

Payable Non-Affirmation means an Initial Prior Authorization Determination of Prior Authorization Non-Affirmation that qualifies for a WISeR Payment because there was no Resubmission within 120 Days that received a determination of Prior Authorization Affirmation and, at the time of Reconciliation, there was no associated claim paid by Medicare due to the successful appeal of a claim denial.

Performance Period means the three-month period in which the WISeR Participant issues Initial Prior Authorization Determinations for Prior Authorization requests and issues

determinations for Pre-Payment Reviews, including without limitation all associated Resubmissions submitted within 120 days of the Initial Prior Authorization Determination.

Performance Year or **PY** means the 12-month period beginning on January 1 of each year during the Model Performance Period.

Pre-Payment Review means the review by the WISeR Participant to verify consistency with Medicare Coverage Criteria for a claim for one or more Select Items and Services furnished in the MAC Jurisdiction that is submitted to Medicare without requesting Prior Authorization, consistent with 42 C.F.R. § 405.903.

Prior Authorization is a request by the WISeR Provider or WISeR Supplier for provisional affirmation of Medicare Coverage Criteria for one of the Select Items and Services prior to furnishing such items and services to the WISeR Beneficiary and before the claim is submitted for processing.

Prior Authorization Process means the process detailed in Article VI of the Agreement.

Prior Authorization Provisional Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Prior Authorization Non-Affirmation means a WISeR Provider or WISeR Supplier prior authorization request that is not accepted by the WISeR Participant as meeting the Medicare Coverage Criteria for the Select Item or Service.

Program Integrity Screening means a review of an individual's or entity's program integrity history and current status, which may include a review of the individual's or entity's eligibility, history of exclusion or other sanctions imposed with respect to participation in Medicare, Medicaid, or CHIP; history of failure to pay Medicare debts in a timely manner; current or prior law enforcement investigations or administrative actions regardless of whether such investigations or actions relate to participation in Medicare, Medicaid, or CHIP; affiliations with individuals or entities that have a history of program integrity issues; and other information pertaining to the trustworthiness of the individual or entity.

Reconciliation means the process by which CMS calculates the WISeR Payment amount owed to the WISeR Participant for a specific Performance Period as set forth in Article VIII.

Reconciliation Report means the report issued by CMS that details the Reconciliation calculations for the WISeR Participant and the amount of any WISeR Payment for one or more specified Performance Periods.

Regional Benchmark means a payment amount calculated by CMS for each of the Select Items and Services for a given Locality and Performance Period that CMS uses to calculate the WISeR Payment amount for a Payable Non-Affirmation as set forth in Section 8.3.

Resubmission means a Prior Authorization submitted to the WISeR Participant within 120 Days of an Initial Prior Authorization Determination for a Prior Authorization previously submitted by the same WISeR Provider or WISeR Supplier for the same WISeR Beneficiary and same Select Item or Service.

Resubmission Determination means the communication to the WISeR Provider and/or WISeR Supplier detailing the Prior Authorization Provisional Affirmation or Prior Authorization Non-Affirmation for a Resubmission.

Select Items and Services means the Covered Services detailed in Appendix A that are subject to the Prior Authorization Process. When used in its singular form this term is referred to as "**Select Item or Service**".

Start Date means January 1, 2026.

TIN stands for taxpayer identification number.

VDC stands for CMS Virtual Data Center and means the comprehensive information technology infrastructure designed to centralize and modernize CMS' digital operations.

WISeR Beneficiary means a Beneficiary that meets the requirements set forth in Section 4.1.

WISeR Clinician means an individual that satisfies the requirements of Section 3.6.

WISeR Clinical Reviewer means an individual that satisfies the requirements of Section 3.6.

WISeR Data Reporting Guide means the guidance paper that CMS publishes and provides to the WISeR Participant that sets forth the WISeR Participant's reporting obligations during the Model. CMS may modify the WISeR Data Reporting Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Data Reporting Guide at least 30 Days prior to the effective date of such revisions.

WISeR Discount means the discount specified in Section 8.3.C that CMS applies when calculating the WISeR Payment.

WISeR Jurisdiction means the defined geographic states of New Jersey (Jurisdiction L/Novitas Solutions, Inc.), Ohio (Jurisdiction 15/CGS Administrators, LLC), Oklahoma and Texas (JH/Novitas), and Arizona and Washington (JF/Noridian) selected for the WISeR Model

for which the WISeR Participant conducts Prior Authorization Process on claims for Select Items and Services from institutional providers, physicians, clinicians and suppliers.

WISeR Participant means the technology company that meets the requirements set forth in Article III and has signed this Agreement with CMS to participate in the Model.

WISeR Participant Guide means a guidance paper that CMS publishes and provides to the WISeR Participant that sets forth additional details to support the WISeR Participant's activities and obligations during the Model. CMS may modify the WISeR Participant Guide at any time and, to the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Participant Guide at least 30 Days prior to the effective date of such revisions.

WISeR Payment means the Model specific payment made by CMS for a Payable Non-Affirmation or a Pre-Payment Review that qualifies for payment as set forth in Article VIII.

WISeR Performance Measure Set means the measures detailed in Appendix B, and as may be revised in the WISeR Data Reporting Guide, that CMS uses in calculating the AQS.

WISeR Provider means a provider, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction that furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

WISeR Recoupment means the amount owed to CMS if CMS pays a WISeR Payment to the WISeR Participant and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

WISeR Supplier means a supplier, as that term is defined in 42 C.F.R. § 400.202, that is in the WISeR Participant's designated WISeR Jurisdiction and who furnishes items and services to WISeR Beneficiaries, consistent with Section 3.5.

Article III. General Requirements

Section 3.1 WISeR Participant Requirements

A. During the Agreement Term, the WISeR Participant shall:
    1. Be a legal entity formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates for the purpose of carrying out the activities required by this Agreement;
    2. Have Enhanced Technology and be identified by a single TIN, to provide specified health insurance benefit administrative services, including

Medicare Prior Authorization and Pre-Payment Review services to interpret and apply Medicare Coverage Criteria and clinical coverage criteria derived from NCDs and LCDs, in support of the Medicare FFS program;

3. Use its Enhanced Technology for implementing and streamlining the Prior Authorization Process and Pre-Payment Review for Select Items and Services in its assigned WISeR Jurisdiction;
4. Have a valid Business Associate Agreement ("**BAA**") with CMS;
5. Support CMS in its efforts to make accurate and timely payments to WISeR Providers or WISeR Suppliers for Select Items and Services furnished to WISeR Beneficiaries;
6. Support CMS in its efforts to ensure care provided to Beneficiaries is Medically Necessary and adheres to Medicare Coverage Criteria, thus protecting Beneficiaries and the Medicare Trust Fund; and
7. Not have a conflict of interest as detailed in Section 3.3 of this Agreement.

The WISeR Participant states that it satisfies the requirements of this Section 3.1.A as of the Effective Date.

B. The WISeR Participant shall satisfy the requirements of this Section 3.1.B no later than 45 Days before the Start Date and throughout the remainder of the Agreement Term:
    1. Have access to Federal Risk and Authorization Management Program ("**FedRAMP**") certified workflows;
    2. Comply with all applicable Federal data protection and security requirements including Federal Information Security Management Act ("**FISMA**") requirements, CMS Information Systems Security & Privacy Policy ("**IS2P2**"), CMS Acceptable Risk Safeguard ("**ARS**");
    3. Follow CMS Authority to Operate ("**ATO**") guidelines for connections established between the Medicare Administrative Contractor ("**MAC**") and WISeR Participant; and
    4. Enter into a valid Joint Operating Agreement ("**JOA**") with the applicable MAC.
C. Changes to the WISeR Participant
    1. Change of WISeR Participant Name. The WISeR Participant shall provide written notice to CMS at least 60 Days before any change in the WISeR Participant's legal name becomes effective. The WISeR Participant shall forward to CMS a copy of the document effectuating the name change, authenticated by the appropriate state official (if applicable), and the parties shall execute an agreement reflecting the change of the WISeR Participant's name. This obligation shall remain in effect until the latter of the effective date

of termination of this Agreement or when the final payment by or to the WISeR Participant has been made under this Agreement.

2. Change in WISeR Participant TIN. The WISeR Participant shall provide at least 90 Days advanced written notice before the effective date of any change in the WISeR Participant's TIN. Such notice must be submitted in the form and manner specified by CMS. In response to a change in the WISeR Participant's TIN, CMS may terminate the Agreement or Agreement Performance Period, or take any other actions consistent with the terms of this Agreement. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
3. Change in Control.
    i. The WISeR Participant shall provide written notice to CMS at least 90 Days before the effective date of any Change in Control. This obligation remains in effect until the latter of the effective date of termination of this Agreement or when final payment by or to the WISeR Participant has been made under this Agreement.
    ii. Upon learning of a Change in Control, CMS may conduct a Program Integrity Screening and take other appropriate action to ensure compliance with the terms of the Model by the new controlling entity and may require the new controlling entity to execute a novation agreement with CMS or require the new controlling entity to execute a new Participation Agreement with CMS. CMS may also terminate the Participation Agreement between the former controlling entity and CMS.
    iii. If the WISeR Participant undergoes a Change in Control, CMS may take one or more of the following actions: terminate this Agreement; terminate the Agreement Performance Period; or immediately conduct financial settlement in accordance with Section 8.9.
4. Change in Primary Point of Contact. The WISeR Participant shall provide written notice to CMS of any changes to the contact information for the WISeR Participant's primary point of contact no later than 15 Days after the change.

D. Information for Electronic Funds Transfer

1. The WISeR Participant shall submit to CMS a completed Electronic Funds Transfer Authorization Agreement in the form and manner and by the date(s) specified by CMS.

2. The WISeR Participant shall promptly update its Electronic Funds Transfer Authorization Agreement if there are account or bank changes, or any change to the WISeR Participant set forth in Section 3.1.C.
3. If the WISeR Participant fails to submit or accurately complete the Electronic Funds Transfer Authorization Agreement, CMS may withhold any WISeR Payment owed to the WISeR Participant until the WISeR Participant has submitted and CMS has processed an Electronic Funds Transfer Authorization Agreement with the correct information. In addition, the failure to submit or accurately complete an Electronic Funds Transfer Authorization Agreement could delay the WISeR Participant's receipt and timely payment of a demand for payment under this Agreement, and thereby cause the WISeR Participant to be liable for interest on the amount owed to CMS.

E. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, the WISeR Participant fails to meet any requirements set forth in Section 3.1. The WISeR Participant shall provide such written notice to CMS at least 30 Days before failing to satisfy any requirements in Section 3.1.A, or within 5 Days of becoming aware that the WISeR Participant has failed to satisfy any requirements in Section 3.1(B)-(D).

Section 3.2 WISeR Participant Governance

A. General.
   1. The WISeR Participant shall maintain an identifiable governing body with sole and exclusive authority to execute the functions of the WISeR Participant and make final decisions on behalf of the WISeR Participant. The WISeR Participant shall have a governing body that satisfies the following criteria:
      i. The governing body has responsibility for oversight and strategic direction of the WISeR Participant and is responsible for holding the WISeR Participant management accountable for the WISeR Participant's activities;
      ii. The governing body has a transparent governing process;
      iii. When acting as a member of the governing body of the WISeR Participant, each governing body member has a fiduciary duty to the WISeR Participant and to CMS for actions relating to the terms of this Agreement, the Model and the terms set forth in the Business Associate Agreement, including the duty of loyalty, and shall act consistent with that fiduciary duty; and

iv. The governing body shall receive regular reports from the designated compliance official of the WISeR Participant who satisfies the requirements of Section 11.1.

2. The WISeR Participant shall provide each member of the governing body with a copy of the Agreement and any amendments hereto.
3. If CMS determines that the composition of the WISeR Participant's governing body, executive leadership, or parent organization(s) (as applicable) compromises the WISeR Participant's ability to participate in the Model or to comply with the terms of the Agreement, CMS may take one or more of the remedial actions specified in Section 13.2.
4. The WISeR Participant shall ensure that its governing body implements a process for documenting governing body composition, meetings and decisions, and shall retain such documentation in accordance with Section 12.2.

B. Composition and Control of the Governing Body.

1. The WISeR Participant's governing body shall not include any individual with pending or open investigations, or a history of convictions or sanctions, including without limitation:
    i. Investigations or actions related to participation in Medicare, Medicaid, or Children's Health Insurance Program;
    ii. A history of failure to pay Medicare debts in a timely manner;
    iii. Affiliations with individuals or entities that have a history of program integrity issues;
    iv. Conduct that a reasonable person would deem to be unfit conduct; or
    v. A history of legal or monetary sanctions.
2. The WISeR Participant shall routinely monitor each individual on its governing body to ensure compliance with the provisions of this Section 3.2.
3. The WISeR Participant shall immediately remove from its governing body any individual that becomes subject to a conviction or sanction.
4. The WISeR Participant shall provide written notice to CMS if, at any time during the Agreement Term, it removes an individual from its governing body. The WISeR Participant shall provide such written notice to CMS within 5 Days of such removal.
5. The governing body members may serve in similar or complementary roles or positions, subject to Section 3.3.

Section 3.3 Conflict of Interest

A. The WISeR Participant shall have a conflict of interest policy that applies to members of the governing body and satisfies the following criteria:
    1. Requires each member of the governing body to disclose relevant financial interests and other interests that could prevent impartiality;
    2. Requires each member of the governing body to update its disclosure statement whenever the member's personal or financial circumstances change in such a way that a new conflict of interest might occur;
    3. Provides a procedure to determine whether a conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses remedial actions for members of the governing body that fail to comply with the policy.

B. Notwithstanding the obligations set forth in Section 3.3.A, the WISeR Participant shall have a conflict of interest policy that applies to its business operations and satisfies the following criteria:
    1. Requires that the WISeR Participant refrain from engaging in activities that would lead to the preferential or non-preferential treatment of any WISeR Provider, WISeR Supplier, WISeR Clinician, WISeR Clinical Reviewer, individual clinician, medical group, medical practice, Beneficiary, or any other individual or entity with an interest in the Prior Authorization Process or Pre-Payment Review;
    2. Requires that the WISeR Participant prohibit WISeR Clinicians and WISeR Clinical Reviewers from participating in the Prior Authorization Process and Pre-Payment Review associated with a provider or supplier under the same TIN as the reviewing WISeR Clinician or WISeR Clinical Reviewer;
    3. Provides a procedure to determine whether such conflict of interest exists and sets forth a process to address any conflicts that arise; and
    4. Addresses plans of action to correct instances that fail to comply with the policy.

C. The WISeR Participant shall ensure that its conflict of interest policy sets forth a process to address situations where an individual employed by or contracted by the WISeR Participant and has a financial interest, personal activity, or relationship that could impair that individual's ability to act impartially and in the best interest of CMS when performing under the terms of this Agreement, the Business Associate Agreement, or the Model.

D. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Prior Authorization request not participate in the review of that request or any associated Resubmissions related to that Prior Authorization request.
E. The WISeR Participant shall ensure that individuals with a real or apparent conflict of interest in a particular Pre-Payment Review not participate in the review of that claim or any associated Resubmissions related to that Pre-Payment Review.
F. The WISeR Participant shall de-identify Prior Authorization requests, Resubmissions, and Pre-Payment Review claims prior to permitting its WISeR Clinicians and WISeR Clinical Reviewers to conduct a Medical Review or peer-to-peer review.
G. The WISeR Participant shall designate a committee or group responsible for evaluating disclosed potential conflicts of interest and determine whether they pose a risk to the fairness of the Prior Authorization review or the Pre-Payment Review.
    1. The WISeR Participant shall provide immediate written notice of disclosed potential conflicts of interest to CMS. Such written notice shall be made within 5 Days of becoming aware of the potential conflicts of interest.
    2. The WISeR Participant shall include CMS in the determination process associated with the disclosed potential conflicts of interest.

Section 3.4 Required Prior Authorization Activities

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.
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.
C. The WISeR Participant shall review Prior Authorizations in its WISeR Jurisdiction submitted by all WISeR Providers, WISeR Suppliers, and their corresponding MAC(s).
D. Consistent with Section 3.4.C, the WISeR Participant shall perform its Prior Authorization Process on Prior Authorizations received.
E. Consistent with the terms of this Agreement and the requirements set forth in the WISeR Participant Guide, the WISeR Participant shall issue Prior Authorization determinations to the requesting WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction with a copy to the applicable WISeR Beneficiary.

Section 3.5 WISeR Providers and WISeR Suppliers

A. WISeR Providers and WISeR Suppliers may submit Prior Authorization requests directly to the WISeR Participant and receive a determination for Select Items and Services.

B. If the WISeR Provider or WISeR Supplier submits a Prior Authorization request to its MAC for a Select Item or Service, then:

   1. CMS, through the applicable MAC, will re-route the Prior Authorization request to the WISeR Participant;
   2. The WISeR Participant must perform its Prior Authorization Process on the re-routed Prior Authorization from the MAC for the Select Item or Service and issue a determination directly to the WISeR Provider or WISeR Supplier with copy to the MAC and the WISeR Beneficiary identified on the Prior Authorization request; and
   3. Perform any additional requirements as described in the WISeR Participant Guide.

C. CMS, through the applicable MAC, will notify the WISeR Participant if a WISeR Provider or WISeR Supplier submits a claim to Medicare for one or more Select Items and Services furnished to a WISeR Beneficiary in the WISeR Jurisdiction without requesting Prior Authorization.

D. The WISeR Participant must conduct Pre-Payment Review in accordance with Section 6.5 of this Agreement for each Select Item or Service that does not have a Prior Authorization request from the WISeR Provider or WISeR Supplier.

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.

F. CMS will provide written notice, which may be in the form of the WISeR Participant Guide, to the WISeR Participant regarding additional determination letter requirements.

G. The WISeR Participant shall provide to its WISeR Providers and WISeR Suppliers prior authorization criteria and relevant evidence-based clinical practice guidelines for Select Items and Services in a form and manner and by the date(s) determined by CMS. Such compliance assistance information shall include examples of documentation that would support approval of a Prior Authorization request for each Select Item or Service, as well as examples of common mistakes, omissions, and evidence that would result in a denial of Prior Authorization.

Section 3.6 WISeR Clinicians and WISeR Clinical Reviewers

A. General.

1. The WISeR Participant may choose to:
    i. Directly employ clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinicians**"); or
    ii. Subcontract with a separate entity that provides appropriate clinicians to conduct Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review ("**WISeR Clinical Reviewers**"); or
    iii. Do both (i) and (ii).
2. The WISeR Participant must provide to its subcontractor, if applicable, necessary and appropriate WISeR Participant Guide provisions to ensure that each WISeR Clinical Reviewer meets the Medical Review requirements to ensure proper coverage determinations that adheres to Medicare Coverage Criteria and CMS coverage policy.
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.

B. <u>WISeR Clinicians</u>.
1. The WISeR Participant shall ensure that each WISeR Clinician:
    i. Be a board-certified clinician, including a:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;

iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;

vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and

vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinician performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant shall ensure that each WISeR Clinician performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers in a form and manner determined by CMS, as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that the WISeR Clinician has an active, valid and unrestricted license.

C. Record of WISeR Clinicians. The WISeR Participant shall maintain, in accordance with Article XII, a record of all its WISeR Clinicians.
   1. The WISeR Participant shall retain current and historical records of all its WISeR Clinicians in accordance with Section 12.2 of this Agreement.
   2. CMS may request and the WISeR Participant must provide to CMS a certified copy of all WISeR Clinicians at any given time during the Agreement Term.

D. Monitoring and Compliance of WISeR Clinicians.
   1. CMS will monitor the program integrity history of the WISeR Participant's WISeR Clinicians. CMS may require the WISeR Participant to exclude an individual WISeR Clinician or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
   2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinician be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure that each WISeR Clinician conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks, and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure that each WISeR Clinician uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items and Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Items and Services;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

E. WISeR Clinical Reviewers.

1. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer:
    i. Be a board-certified clinician, including:
        a. Doctor of Medicine or a Doctor of Osteopathy identified by an individual NPI in a specialty recognized by the American Board of Medical Specialties; or
        b. Doctor of Podiatric Medicine identified by an individual NPI recognized by the American Board of Podiatric Medicine;
    ii. Is board certified for at least 3 years;
    iii. Be currently licensed to practice medicine in at least one U.S. state, territory, or the District of Columbia;
    iv. Be associated with a primary specialty designation that aligns with the specialty designation of the WISeR Provider or WISeR Supplier furnishing the Select Item or Service to a WISeR Beneficiary for which the claim or Prior Authorization review has been selected for Pre-Payment Review;

v. Performs Medical Review of Prior Authorization requests, Prior Authorization Non-Affirmations, and Pre-Payment Review for a timely and consistent execution of Select Items and Services;
vi. Must not be a medical trainee, including but not limited to interns, residents, and fellows; and
vii. Must not be excluded from participating in Medicare, Medicaid or the Children's Health Insurance Program.

2. The WISeR Participant shall ensure that each WISeR Clinical Reviewer performs Medical Review of Prior Authorization requests that may not meet the Medicare Coverage Criteria before issuing to the WISeR Provider or WISeR Supplier a Prior Authorization Non-Affirmation determination letter.
3. The WISeR Participant must require its subcontractor to ensure that each WISeR Clinical Reviewer performs peer-to-peer reviews, provides Navigation Services, and communicates Medicare Coverage Criteria with WISeR Providers and WISeR Suppliers as detailed in the WISeR Participant Guide.
4. The WISeR Participant shall require its subcontractor to ensure that the WISeR Clinical Reviewer has an active, valid and unrestricted license.

F. Record of WISeR Clinical Reviewers. The WISeR Participant must require its subcontractor to maintain, in accordance with Article XII of this Agreement, a record of all WISeR Clinical Reviewers performing activities related to this Model.
1. The WISeR Participant shall require the subcontractor to retain current and historical records of all WISeR Clinical Reviewers consistent with Section 12.2 of this Agreement.
2. The WISeR Participant shall require its subcontractor to provide the WISeR Participant with a certified copy of all WISeR Clinical Reviewers at any given time during the Agreement Term. The WISeR Participant shall provide such information to CMS in a form and manner and by the date(s) specified by CMS.

G. Monitoring and Compliance of WISeR Clinical Reviewers.
1. CMS will monitor the program integrity history of the WISeR Participant's use of WISeR Clinical Reviewers. CMS may require the WISeR Participant to exclude an individual WISeR Clinical Reviewer or subject the WISeR Participant to additional monitoring pursuant to Section 13.2 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
2. CMS will notify the WISeR Participant if CMS requires that an individual WISeR Clinical Reviewer be excluded by the WISeR Participant.

3. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer conducts Medical Review activities, take party or participant status in Administrative Law Judge (ALJ) appeals hearings, performs appeals-related tasks and meets all requirements set forth by CMS in the WISeR Participant Guide.
4. The WISeR Participant shall ensure through its subcontractor that each WISeR Clinical Reviewer uses its clinical review judgment to conduct Medical Review for adherence to applicable Medicare Coverage Criteria during the Prior Authorization Process, to include without limitation:
    i. Adequate information from the WISeR Beneficiary's medical record to identify the WISeR Beneficiary for whom the Select Items or Services is intended;
    ii. The intended use of the Select Items and Services;
    iii. The medical condition of the WISeR Beneficiary that necessitates the use of the Select Item or Service;
    iv. Application of the criteria and clinical documentation requirements and, if applicable, relevant evidence-based clinical care guidelines for the Select Items and Services; and
    v. Adherence to the additional requirements set forth in the WISeR Participant Guide.

Section 3.7 Customer Service

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.
B. The WISeR Participant shall provide an overall environment where WISeR Providers and WISeR Suppliers understand the Prior Authorization Process and Pre-Payment Review process for Select Items and Services.
C. The WISeR Participant shall respond to WISeR Provider and WISeR Supplier electronic, telephone and written inquiries promptly, clearly and accurately.
D. The WISeR Participant shall maintain effective WISeR Provider and WISeR Supplier education that helps ensure complete Prior Authorization submissions for Select Items and Services and reduces the need for re-submissions, requests for appeal, and overturn of coverage determinations on appeal.
E. The WISeR Participant shall educate WISeR Providers and WISeR Suppliers on how to submit Prior Authorization requests and provide its WISeR Providers and WISeR Suppliers with information related to the Medicare Coverage Criteria associated with

the Select Items and Services. Such educational activities shall be conducted in a form and manner determined or approved by CMS, and as may be detailed in the WISeR Participant Guide.

F. The WISeR Participant must educate WISeR Providers and WISeR Suppliers within its assigned WISeR Jurisdiction about the Prior Authorization Process consistent with the provisions of this Agreement and the WISeR Participant Guide.

Section 3.8 Operational Requirements

A. The WISeR Participant shall promote corporate integrity and establish internal controls and an effective compliance program to achieve Agreement goals and objectives.

B. The WISeR Participant shall work collaboratively with CMS, WISeR Providers, WISeR Suppliers, Medicare Administrative Contractors, and other CMS contractors to foster integration of Medicare operations.

C. The WISeR Participant shall develop and continually refine business processes to foster excellence and quality in the administration of the Medicare program.

D. The WISeR Participant shall foster efficiencies in the administration of the Medicare FFS program to promote best value for the government.

E. The WISeR Participant shall use innovative and creative solutions to improve program operations.

Section 3.9 Overlap with Other CMS Programs and Initiatives

A. The parties agree that the WISeR Model is not a shared savings model and there is no Beneficiary alignment in this Model.

B. The WISeR Participant may simultaneously participate in the WISeR Model and any other Innovation Center model.

C. CMS reserves the right to unilaterally update this overlaps policy upon written notice to the WISeR Participant.

Article IV. Beneficiary Eligibility, Engagement, Verification, and Protections

Section 4.1 Beneficiary Eligibility

A. To be considered a WISeR Beneficiary, a Beneficiary must meet the following criteria:

1. Be identified on a Prior Authorization request or a claim subject to Pre-Payment Review for a Select Item or Service from a WISeR Provider or WISeR Supplier in the WISeR Participant's WISeR Jurisdiction;

2. Is eligible for Medicare Part A and enrolled in Medicare Part B at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review;
3. Is a legal adult aged 18 years or older;
4. Is not enrolled in Medicare Advantage at the time of the Prior Authorization request or the date of service on the claim subject to Pre-Payment Review;
5. Has Medicare as the primary payer at the time of the Prior Authorization request or on the date of service for the claim subject to Pre-Payment Review; and
6. Is not covered under the United Mine Worker Health and Retirement Funds.

Section 4.2 Beneficiary Engagement and Beneficiary Verification

A. The WISeR Participant does not have Beneficiaries aligned or assigned to it for this Model.
B. CMS may require the WISeR Participant to educate Beneficiaries, including WISeR Beneficiaries, within its WISeR Jurisdiction on the Prior Authorization Process for Select Items and Services.
C. The WISeR Participant must ensure that each Prior Authorization request submitted by a WISeR Provider, WISeR Supplier, or a MAC is for a Select Item or Service that will be furnished to a WISeR Beneficiary within the WISeR Jurisdiction.

Section 4.3 Beneficiary Protections and Non-Affirmed Decisions

A. The WISeR Participant shall provide written Prior Authorization Process decisions to the WISeR Provider and/or WISeR Supplier with a copy to the applicable WISeR Beneficiary and appropriate MAC.
B. The WISeR Participant's Prior Authorization Non-Affirmation decision for the Select Item or Service that is determined to not be Medically Necessary must require the WISeR Provider or WISeR Supplier to notify the WISeR Beneficiary and issue an Advance Beneficiary Notice of Non-coverage (ABN) prior to performing such item(s) or service(s) if it is expected that payment would be denied.
C. For purposes of the WISeR Provider and WISeR Supplier notifications required under Sections 4.3.A and 4.3.B, the WISeR Participant shall use a template letter provided by CMS, in which CMS will designate letter content that the WISeR Participant shall not change, as well as places in which the WISeR Participant may insert its own original content.
D. Beneficiaries continue to have all applicable administrative appeal rights under Original Medicare.

Section 4.4 Prohibition on Beneficiary Inducements

Except as otherwise permitted by applicable law, the WISeR Participant shall not provide gifts or other remuneration to Beneficiaries to induce them to receive or to continue to receive items or services from one or more of the following: WISeR Providers, WISeR Suppliers, WISeR Clinicians, or WISeR Clinical Reviewers.

Section 4.5 HIPAA Requirements

A. The WISeR Participant acknowledges that it is either a covered entity or business associate, as those terms are defined in 45 C.F.R. § 160.103, of CMS that is a covered entity.
B. The WISeR Participant shall have all appropriate administrative, technical, and physical safeguards in place before the Start Date to protect the privacy and security of protected health information ("**PHI**") in accordance with 45 C.F.R. § 164.530(c).
C. The WISeR Participant shall maintain the privacy and security of all Model-related information that identifies individual Beneficiaries in accordance with the Health Insurance Portability and Accountability Act ("**HIPAA**") Privacy and Security Rules and all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of PHI by covered entities and their business associates, as well as all other applicable federal and state laws and regulations.

Article V. Functional Requirements

Section 5.1 Functional and Infrastructure Requirements

A. The WISeR Participant shall develop, execute, and maintain a risk management plan that includes:
    1. WISeR Jurisdiction-wide risks, including without limitation risks related to cybersecurity issues;
    2. Periodic assessment, conducted monthly at a minimum, of new risks; and
    3. Mitigation and contingency planning.
B. The WISeR Participant shall provide and use infrastructure to fulfill the requirements of this Agreement.
C. The WISeR Participant shall provide the infrastructure required to integrate and interact with the assigned CMS Virtual Data Center ("**VDC**") and to accomplish services not provided by the VDC to fulfill the requirements of this Agreement.
    1. The WISeR Participant shall work with all Base Function entities, including the VDC, to interface and/or facilitate the receipt or transmission of files, programs or other such products.

2. **Base Functions** are functions provided either by the shared system or the VDC and include interfaces that are part of the base system processing such as the Common Working File (CWF), Comprehensive Error Rate Testing (CERT), Correct Coding Initiative (CCI), BDRD, PECOS, PIMR, Pricer, PULSE, etc.
3. **Non-base/Non-core applications or interfaces** refers to any applications or interfaces that are not part of the base system processing or are not provided or maintained as part of the Medicare Shared Systems (FISS or MCS).
    i. Non-base/non-core applications or interfaces may involve an outside vendor, a Medicare Data Center, or any entity with which the WISeR Participant communicates or shares information through a software application (not including commercial word processing or spreadsheet programs) in processing Medicare claims.
    ii. Examples of non-base/non-core processes include but are not limited to the following:
        a. Print mail;
        b. American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N Transaction Translation Services (via Commercial Off the Shelf (COTS) products);
        c. Workload Management reports;
        d. Scanning Administration;
        e. ICR/OCR Imaging;
        f. Fraud, Waste, or Abuse reporting;
        g. Data Analysis (Easytrieve, SAS extracts, etc.); and
        h. Data files the WISeR Participant routinely receives.

D. The WISeR Participant shall provide translation software that is HIPAA-compliant and strictly adheres to the ASC X12N Technical Report Type 3 (TR3s) for inbound transactions (e.g., ASC X12N claim, ASC X12N 276 claim status request) and outbound transactions (e.g., ASC X12N 835 remittance advice, ASC X123N 277 claim status response, ASC X12N TA1 interchange acknowledgement, ASC X12N 999 implementation acknowledgment, ASC X12N 277 claim acknowledgment).

E. In the event of termination by CMS or the WISeR Participant pursuant to Article XIII, the WISeR Participant shall be required to perform certain closeout activities detailed by CMS in a form and manner and by the date(s) specified by CMS.

Section 5.2 Telecommunications

A. Unless directed to use another connection by CMS, the WISeR Participant shall use only the CMS-supplied telecommunications network to transmit Medicare data to ensure the privacy and security of this protected information for:
    1. Medicare communications between the WISeR Participant and Medicare Administrative Contractor(s), if any;
    2. Communications between the WISeR Participant and subcontractors, if any; and
    3. Communications between the WISeR Participant and CMS.
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.
C. As applicable, the WISeR Participant shall interact with CMS' current enterprise identity access management systems, or any future enterprise identity access management system as directed by CMS, to ensure that the electronic data interchange (EDI) submitter/receiver is an authorized EDI submitter for each transaction.
D. As applicable, the WISeR Participant shall be responsible for the verification/validation of the WISeR Providers and WISeR Suppliers that will be exchanging EDI with the WISeR Participant.

Section 5.3 CMS Audits and Reviews of Software

A. The WISeR Participant shall allow CMS the use of provided software and software documentation, tools, and equipment to conduct audit reviews, tests, and assessments of the WISeR Participant at its facility, its data center and/or in its data cloud.
B. Consistent with Section 5.3.A, the WISeR Participant shall allow CMS use and access to, without limitation, the WISeR Participant's Enhanced Technology, artificial intelligence, machine learning technology, and other similar technologies.

Article VI. Prior Authorization Process

Section 6.1 General

A. The WISeR Participant shall use its Enhanced Technology to review and assess Prior Authorization requests within its assigned WISeR Jurisdiction ("**Prior Authorization Process**").

B. The WISeR Participant must review and assess each Prior Authorization request to ensure that the request meets the following criteria:
    1. Include all documentation necessary to show that the Select Items and Services meet applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The Prior Authorization request is submitted before the Select Items and Services are provided to the WISeR Beneficiary and before the claim is submitted.
C. The WISeR Participant reviews and assesses each expedited Prior Authorization request to ensure that the expedited request meets the following criteria:
    1. Includes all documentation necessary to show that the Select Item or Service meets applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Social Security Act.
    2. The expedited Prior Authorization request is submitted before the Select Item or Service is provided to the WISeR Beneficiary and before the claim is submitted.
    3. Includes documentation showing that the processing of the Prior Authorization must be expedited due to the WISeR Beneficiary's life, health, or ability to regain maximum function being in serious jeopardy.
D. The WISeR Participant shall evaluate and refine its Prior Authorization Process to ensure accuracy in its Prior Authorization determinations and to prevent harm to Beneficiaries, including WISeR Beneficiaries.
E. The WISeR Participant shall engage in activities such as Navigation Services to reduce clinically inappropriate care and promote clinically appropriate care with its WISeR Providers and WISeR Suppliers in a form and manner and by the date(s) specified by CMS.
F. The WISeR Participant shall report Prior Authorization Process related activities and metrics to CMS through monthly, yearly, and ad hoc reports in a form and manner and by the date(s) specified by CMS.

Section 6.2 Prior Authorization Process and Exemption Status

A. General. 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).
B. Upon receipt of a Prior Authorization, the WISeR Participant shall review the request for compliance with applicable Medicare Coverage Criteria including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act.

1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to the Select Items and Services detailed in Table 1 of Appendix A of this Agreement.
2. The WISeR Participant shall verify that the Prior Authorization is for a Select Item or Service as detailed in Table 1 of Appendix A.
3. The WISeR Participant must further verify that the Prior Authorization request is from a WISeR Provider or WISeR Supplier within the WISeR Jurisdiction.
4. The WISeR Participant shall verify that the requested Select Item or Service would be furnished to an individual that is a WISeR Beneficiary.

C. The WISeR Participant, its WISeR Clinician(s) and its WISeR Clinical Reviewers shall conduct Medical Review of the Prior Authorization, any Resubmissions, render determinations, and communicate decisions to the WISeR Providers, WISeR Suppliers, and WISeR Beneficiaries in accordance with the terms of this Agreement and the applicable requirements detailed in the WISeR Participant Guide.

D. Resubmission. The WISeR Participant shall accept Resubmissions from a WISeR Provider or WISeR Supplier for a Select Item or Service.
1. The WISeR Participant shall use its Enhanced Technology to apply its Prior Authorization Process to each Resubmission; or
2. At the request of the WISeR Provider or WISeR Supplier through its Resubmission, the WISeR Participant shall require its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, to perform peer-to-peer review of the Resubmission. Such peer-to-peer review activities and requirements are detailed in the WISeR Participant Guide and the WISeR Participant acknowledges and agrees that its WISeR Clinicians and WISeR Clinical Reviewers will comply with such requirements.

E. Exemption Status. The WISeR Participant shall provide Exemption Status to a WISeR Provider or WISeR Supplier that has:
1. Submitted the minimum number of Prior Authorization requests for Select Items and Services furnished to WISeR Beneficiaries within the WISeR Jurisdiction as detailed in the WISeR Participant Guide;
2. Has met the CMS threshold percentage of Prior Authorization Provisional Affirmations as detailed in the WISeR Participant Guide; and
3. Met any additional criteria set forth by CMS in the WISeR Participant Guide.

F. Exemption Status List. The WISeR Participant shall retain current and historical lists of WISeR Providers and WISeR Suppliers that have earned Exemption Status.
1. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it has earned Exemption Status and has been added to the Exemption Status list.

i. The WISeR Participant shall specify in its notice to the WISeR Provider or WISeR Supplier the effective date of its Exemption Status, the process for retaining Exemption Status, and provide such other details as described in the WISeR Participant Guide.

2. The WISeR Participant shall provide current and historical Exemption Status lists to CMS in a form and manner and by the date(s) specified by CMS in accordance with the terms of this Agreement and applicable requirements set forth in the WISeR Participant Guide.
3. The WISeR Participant may remove a WISeR Provider or WISeR Supplier from the Exemption Status list if it fails to meet the requirements for Exemption Status as described in the WISeR Participant Guide.
4. The WISeR Participant shall notify the WISeR Provider or WISeR Supplier if it is removed from the Exemption Status list and such notice shall specify the effective date of removal, the process for re-earning Exemption Status, and provide such other details as described in the WISeR Participant Guide.

Section 6.3 Prior Authorization Determinations

A. Determination Letters.

1. CMS may develop and provide to the WISeR Participant and Model Participants template determination letters.
2. Upon request of the WISeR Participant to CMS, and at the discretion of CMS, the WISeR Participant may create its own template determination letter(s), and such template(s) must be submitted to CMS for review and written approval prior to use and include at a minimum the following information and any other information as specified in the WISeR Participant Guide:
    i. A Unique Tracking Number (UTN);
    ii. For Prior Authorization Non-Affirmation decisions:
        a. A detailed explanation for the decision;
        b. The availability of unlimited resubmissions by the WISeR Provider or WISeR Supplier;
        c. Instructions for how the WISeR Provider or WISeR Supplier may request peer-to-peer review; and
        d. The opportunity to forego the resubmission process, provide one or more of the Select Items and Services, submit the claim for payment and:
            1. The claim will be denied; and
            2. All Medicare appeal rights will be available.
    iii. For re-routed Prior Authorization decisions:

a. Contact information for the WISeR Participant;
b. Instructions to the requesting WISeR Provider and/or WISeR Supplier on how it may choose to submit future Prior Authorization requests for Select Items and Services directly to the WISeR Participant; and
c. Any additional information that CMS may require through written notification to the WISeR Participant.

3. If CMS determines that the template(s) submitted by the WISeR Participant contains misinformation or is otherwise inconsistent with the terms of this Agreement or the WISeR Participant Guide, CMS may reject the template(s) or require the WISeR Participant to amend the template(s) and resubmit such amended template(s) to CMS for review and approval prior to use.

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.

C. Resubmission of Prior Authorization.
1. The WISeR Participant shall issue a Resubmission Determination to the WISeR Provider or WISeR Supplier within 3 Days of the WISeR Participant's receipt of the Prior Authorization resubmission.
2. The WISeR Participant shall ensure the Resubmission Determination is delivered to the WISeR Provider or WISeR Supplier in the same manner it was submitted via postmark, fax, or electronic delivery.

D. Expedited Circumstances. The WISeR Participant may only consider an expedited review of a Prior Authorization request upon receipt of request for expedited review by the WISeR Provider or WISeR Supplier.
1. If the WISeR Participant, in consultation with its WISeR Clinician or its WISeR Clinical Reviewer, as applicable, determines that delays in receipt of a Prior Authorization decision could jeopardize the life, health, or ability to regain maximum function of the WISeR Beneficiary, then the WISeR Participant will process the Prior Authorization under an expedited timeframe, upon request.
i. The WISeR Participant will communicate a determination within 2 business days of receipt of the expedited request.

ii. WISeR Providers and WISeR Suppliers, and their MAC(s) when applicable, are encouraged to use fax, Electronic Submission of Medical Documentation (esMD), or any other CMS approved electronic portal to avoid delays with mailing.

E. Prior Authorization Provisional Affirmation. The WISeR Participant will issue a Prior Authorization Provisional Affirmation of coverage to a WISeR Provider or WISeR Supplier, with a copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and any applicable criteria in the WISeR Participant Guide are met to support the rendering of such item or service to a WISeR Beneficiary.

1. The WISeR Participant's Prior Authorization Provisional Affirmation decision is valid for 120 days from the date the determination was made.

F. Prior Authorization Non-Affirmation.

1. Consistent with Section 3.6.B.2 and Section 3.6.E.2, the WISeR Participant must require its WISeR Clinician(s) and WISeR Clinical Reviewer(s), as applicable, to perform a Medical Review of each Prior Authorization request that may not meet Medicare Coverage Criteria.
    i. The Medical Review of a Prior Authorization request by a WISeR Clinician or WISeR Clinical Reviewer, as applicable, must be performed before the WISeR Participant issues a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier.
2. The WISeR Participant will issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier, with copy to the WISeR Beneficiary, for the Select Item or Service via the same method it was requested if it is determined that the applicable Medicare Coverage Criteria, including coding and payment rules in chapter IV of Title 42 or in Title XVIII of the Act and applicable criteria in the WISeR Participant Guide are not met and do not support the rendering of such item or service to a WISeR Beneficiary.
3. The WISeR Participant may issue a Prior Authorization Non-Affirmation of coverage to a WISeR Provider or WISeR Supplier for a Select Item or Service via the same method it was requested if the Prior Authorization request contains technical errors or is otherwise insufficient to meet the requirements for Prior Authorization Provisional Affirmation.

G. Appeals. The WISeR Participant acknowledges and agrees that nothing in this Agreement nor in the WISeR Participant Guide shall be construed to limit or otherwise prevent a WISeR Provider, WISeR Supplier, WISeR Beneficiary or Beneficiary from

engaging in the Medicare appeals process permitted by applicable law, regulations, or Medicare program requirements.

Section 6.4 Prior Authorization Non-Affirmation and Resubmissions

A. The WISeR Participant shall provide written notice consistent with Section 6.3.A of this Agreement to the WISeR Provider or WISeR Supplier that the WISeR Provider or WISeR Supplier may resubmit a Prior Authorization upon receipt of a Prior Authorization Non-Affirmation.
B. The WISeR Participant shall provide written notice, consistent with Section 6.3.A, to the WISeR Provider or WISeR Supplier that it may resubmit a Prior Authorization for expedited review consistent with the requirements in Section 6.3.D of this Agreement.
C. The WISeR Participant shall consider all Resubmissions for Prior Authorization received within 120 Days of the Initial Prior Authorization Determination.
D. The WISeR Participant shall review a Resubmission for Prior Authorization received after 120 Days of the Initial Prior Authorization Determination as an Initial Prior Authorization request.

Section 6.5 Pre-Payment Review

A. The WISeR Participant acknowledges that Prior Authorization is not a condition of payment to the WISeR Provider or WISeR Supplier.
B. The WISeR Participant agrees that the WISeR Provider or WISeR Supplier may elect not to submit a Prior Authorization before furnishing one or more of the Select Items and Services to a WISeR Beneficiary.
C. If the WISeR Provider or WISeR Supplier elects not to submit a Prior Authorization for one or more Select Items and Services it furnishes to a WISeR Beneficiary, then the WISeR Participant shall coordinate with the appropriate MAC to subject the claim to Pre-Payment Review consistent with the terms of this Agreement, Sections 6.5.C.1 and 6.5.C.2, and the requirements detailed in the WISeR Participant Guide.
    1. CMS, through its appropriate MAC, will flag claims submitted by the WISeR Provider or WISeR Supplier for Select Items and Services without a Prior Authorization request.
    2. CMS, through its appropriate MAC, will re-route flagged claims to the WISeR Participant for Pre-Payment Review.
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.

Article VII. Quality Performance

Section 7.1 Quality Score

CMS shall use the quality score in determining the WISeR Participant's Aggregate Quality Score ("**AQS**") according to the methodology described in this Article VII and the WISeR Data Reporting Guide.

Section 7.2 Quality Measures

A. General
   1. The WISeR Participant shall complete reporting for all quality measures and for all Prior Authorizations received, Prior Authorization Provisional Affirmations, Prior Authorization Non-Affirmations, and Resubmissions in accordance with the WISeR Data Reporting Guide.
   2. CMS will publish, at least annually, a WISeR Data Reporting Guide, detailing the WISeR quality reporting requirements.
   3. CMS may modify the WISeR Performance Measure Set, or the number of measures that the WISeR Participant must report, or both. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the WISeR Performance Measure Set at least 30 Days prior to the effective date of the change.
      i. If CMS removes a quality measure from the WISeR Performance Measure Set in advance of a Performance Period, CMS will not use the removed quality measure to evaluate the WISeR Participant, and the WISeR Participant will not be accountable for performance on such quality measures during the relevant Performance Period.

B. WISeR Performance Measure Set
   1. The WISeR Participant shall report all measures to CMS that are listed in the WISeR Performance Measure Set as described in Appendix B to this Agreement and the WISeR Data Reporting Guide. CMS shall use these measures for the purposes of calculating the WISeR Participant's AQS, the monitoring and evaluation of the overall efficiency and accuracy in WISeR, and to evaluate the WISeR Participant's performance during the Model.
   2. CMS will determine what version of specifications will be used for each measure included in the WISeR Performance Measure Set for the applicable Performance Period. CMS will notify the WISeR Participant of the version of specifications that will be used for each measure included in the WISeR Performance Measure Set as early as possible after such information becomes available.

3. The WISeR Participant must report all required measures from the WISeR Performance Measure Set in order to be eligible to earn the WISeR Payment for a Performance Period in accordance with Section 8.3.

C. Quality Measure Reporting
   1. The WISeR Participant must submit all quality measures that are listed in the WISeR Performance Measure Set to CMS during the defined reporting period for quality measures as communicated in the WISeR Data Reporting Guide.
   2. CMS reserves the right to require submission via any other format, including the Fast Healthcare Interoperability Resources ("**FHIR®**") standard, at any time during the Agreement Term without the consent of the WISeR Participant. To the extent practicable, CMS will notify the WISeR Participant in writing of any changes to the reporting format of measures at least 90 Days prior to the measurement period.
   3. The WISeR Participant shall comply with the requirements described in this Article VII and Appendix B of this Agreement, and the requirements detailed in the WISeR Data Reporting Guide.

Section 7.3 Collection of Data and Purpose

A. Pursuant to 42 C.F.R. § 403.1110(b), the WISeR Participant must collect and report data described in Section 7.2 to CMS for CMS' Model monitoring and evaluation purposes.
B. The WISeR Participant, at CMS' request, will administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
C. CMS reserves the right to administer and analyze the WISeR Beneficiary experience survey for the relevant quality measure(s) described in the Table in Appendix B.
D. CMS may require the WISeR Participant to implement surveys of WISeR Providers, WISeR Suppliers, and/or WISeR Beneficiaries in the WISeR Participant's designated WISeR Jurisdiction and report any survey measures included in the WISeR Data Reporting Guide to CMS.

Section 7.4 Quality Performance Scoring

A. CMS will calculate the WISeR Participant's AQS for each Performance Period at the time of Reconciliation.
B. CMS will calculate the AQS based on quality measures specified in the WISeR Data Reporting Guide.

C. CMS will calculate the AQS by totaling the quality points for all quality measures included in the AQS calculation for a given Performance Period and dividing by the maximum quality points available for these included quality measures.
D. CMS may modify the methodology for Quality Performance Scoring and shall notify the WISeR Participant in writing at least 30 Days before the start of the Performance Period in which such change would take effect. Modifications to the Quality Performance Scoring methodology may include, but are not limited to:
    1. Modifications to the set of quality measures included in the AQS;
    2. Modifications to the point values and point distributions for one or more quality measures included in the AQS;
    3. Modifications to the benchmark for one or more quality measures included in the AQS; and
    4. Modifications to the metrics for one or more quality measures included in the AQS.
E. CMS will convert the AQS to a quality multiplier that will be applied to each WISeR payment for the applicable Performance Period, as detailed in the WISeR Data Reporting Guide.

Article VIII. Financial Management and Payment

Section 8.1 General

A. CMS shall make, adjust, settle, and seek repayment of WISeR Payments in accordance with this Article VIII and Article XIII.
B. CMS may unilaterally amend Article VIII and to the extent practicable will issue advance written notice to the WISeR Participant 30 Days before the start of the Performance Period in which the amendment would take effect.

Section 8.2 Financial Management Requirements

A. The WISeR Participant shall promote the fiscal integrity of the Medicare FFS program and be an accountable steward of public funds.
B. The WISeR Participant shall adhere to the CMS Medicare integrity program.

Section 8.3 WISeR Payments

A. General.
    1. CMS pays the WISeR Payment to the WISeR Participant, as set forth in this Article VIII, subject to initial Reconciliation, financial settlement, and recoupment.

2. The WISeR Participant may receive a WISeR Payment for each Pre-Payment Review that results in a denied claim for a Select Item or Service and for each Payable Non-Affirmation.
3. CMS shall not pay the WISeR Participant a WISeR Payment if the WISeR Participant conducts a Prior Authorization or a Pre-Payment Review and Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
4. The WISeR Participant owes a WISeR Recoupment and shall remit all WISeR Recoupments to CMS if Medicare subsequently pays a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to a WISeR Beneficiary due to the successful appeal of a claim denial.
5. CMS calculates the WISeR Payment as set forth in Section 8.3.D.

B. Calculation of Regional Benchmark.

1. For each Performance Period and each Locality within the WISeR Participant's designated WISeR Jurisdiction, CMS determines a Locality-specific Regional Benchmark for each of the Select Items and Services identified in Table 1 of Appendix A of this Agreement.
2. Except as specified in Section 8.3.B.3, CMS calculates the Regional Benchmark by:
    i. Identifying all claims that were submitted within the state that include the applicable Locality, were submitted by a WISeR Provider or a WISeR Supplier, include the applicable Select Item or Service, and have a date of service in the 12 months preceding the start of the applicable Performance Period;
    ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the Locality and applicable to the calendar year that includes the Performance Period being reconciled; and
    iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.
3. In the event change in law or Medicare policy changes effective during the Agreement Performance Period and applicable to a Select Item(s) or Service(s), CMS may, at its sole discretion, calculate the Regional Benchmark for the applicable Select Item or Service for one or more Performance Periods by:

i. Identifying all claims for the Select Item or Service that were submitted by Medicare-enrolled providers or suppliers within the WISeR Participant's designated MAC Jurisdiction with a date of service that is:
    a. No earlier than the effective date of the applicable legislation or Medicare policy change;
    b. No earlier than 9 months before the start of the applicable Performance Period; and
    c. No later than the final Day of the applicable Performance Period; and
ii. Adjusting the payment amounts on such claims to account for Medicare payment rates and payment policies applicable to the calendar year that includes the Performance Period being reconciled; and
iii. Calculating the Regional Benchmark as the average claim-level payment for such claims.

4. When calculating the average claim-level payment as set forth in Section 8.3.B.2.iii and Section 8.3.B.3.iii, CMS may exclude payments for certain items or services billed on the same claim as the applicable Select Item or Service. CMS will maintain a list of such exclusions in the WISeR Participant Guide.

C. WISeR Discount. CMS calculates the WISeR Discount separately by state for each of the Select Items and Services as the percentage of claims with a medical necessity denial among all claims submitted by WISeR Providers and WISeR Suppliers within the state for that Select Item or Service with a date of service in 12 months preceding the start of the Model Performance Period. CMS may modify the WISeR Discount, including the dates of service for claims included in the calculation of the WISeR Discount, and to the extent practicable will provide 30 Days' advance written notice before the effective date of such modifications.

D. WISeR Payment. The WISeR Participant may earn a WISeR Payment for each Payable Non-Affirmation and for each Pre-Payment Review resulting in a denied claim for a Select Item or Service.

1. CMS calculates the WISeR Payment for each Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state;
    ii. Multiplying by the WISeR payment rate of 25 percent; and
    iii. Applying the quality adjustment determined by the WISeR Participant's AQS.

2. CMS calculates the WISeR Payment for each Pre-Payment Review resulting in a denied claim for a Select Item or Service by:
    i. Calculating the amount billed on the claim, less any approved payments for services other than the Select Item or Service that were billed on the same claim and less any denied payments billed on the same claim for one or more excluded service(s) noted in the WISeR Participant Guide;
    ii. Reducing the amount set forth in Section 8.3.D.2.i by the WISeR Discount applicable to the Select Item or Service and state;
    iii. Multiplying by the WISeR payment rate of 25 percent; and
    iv. Applying the quality adjustment determined by the WISeR Participant's AQS.

E. WISeR Recoupment. CMS will recoup a WISeR Recoupment from the WISeR Participant if CMS pays the WISeR Participant a WISeR Payment and Medicare subsequently pays the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.
    1. The amount of the WISeR Recoupment will equal the amount of the previous WISeR Payment that CMS paid to the WISeR Participant for the applicable Payable Non-Affirmation or Pre-Payment Review.
    2. CMS will identify any WISeR Recoupments on a quarterly basis.
    3. To the extent possible, CMS will net any WISeR Recoupments against the total of WISeR Payments for a future Performance Period as set forth in Section 8.5.
    4. If CMS cannot collect WISeR Recoupments for claims appeals adjudicated after the Reconciliation of the final Performance Period under the Agreement or any other CMS program or initiative, CMS shall issue a demand letter to the WISeR Participant and the WISeR Participant shall pay CMS the amount owed within 30 Days of the date of demand letter.
    5. If CMS does not timely receive payment in full, the remaining amount owed will be considered a delinquent debt subject to the provisions of Section 8.8.D.

Section 8.4 Advance WISeR Payment

A. At the sole discretion of CMS, CMS may pay the WISeR Participant an Advance WISeR Payment prior to completing Reconciliation for a given Performance Period.

B. Eligibility Criteria.
    1. At the sole discretion of CMS, CMS may provide an Advance WISeR Payment to the WISeR Participant for an applicable Performance Period.

2. The WISeR Participant may be eligible to receive an Advance WISeR Payment during an applicable Performance Year if:
    i. CMS has notified the WISeR Participant of the availability of an Advance WISeR Payment for a specified Performance Period;
    ii. CMS has detailed specific data elements that the WISeR Participant must report to CMS in a form and manner and by the date(s) specified by CMS ("**Preliminary Data**");
    iii. The WISeR Participant timely reports the required data elements to CMS; and
    iv. CMS has approved the WISeR Participant's reported data elements and eligibility for an Advance WISeR Payment for the specified Performance Period.
3. If CMS determines that the WISeR Participant has not timely or accurately reported all required data elements, then CMS may deem the WISeR Participant ineligible for an Advance WISeR Payment for the applicable Performance Period.
4. If CMS has approved the WISeR Participant's eligibility for an Advance WISeR Payment for the applicable Performance Period, then CMS calculates the Advance WISeR Payment as set forth in Section 8.4.D.
5. In applicable Performance Periods, CMS will calculate the Advance WISeR Payment no earlier than the first Day after the end of the Performance Period.

C. Adjustments to Future WISeR Payment(s). If CMS determines that the WISeR Participant is eligible to receive an Advance WISeR Payment, CMS will net the amount of the Advance WISeR Payment against future WISeR Payments, including as applicable:
    1. Any WISeR Payments that CMS calculates for the applicable Performance Period during Reconciliation; and
    2. Any WISeR Payments that CMS calculates for subsequent Performance Periods.

D. Calculation of an Advance WISeR Payment. CMS calculates an Advance WISeR Payment using Preliminary Data for the Performance Period submitted by the WISeR Participant as set forth in Section 8.4.B. CMS calculates the Advance WISeR Payment for the applicable Performance Period as follows:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will provisionally determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will provisionally identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will estimate the WISeR Payment for each provisionally identified Payable Non-Affirmation by:
    i. Reducing the Regional Benchmark for the applicable Select Item or Service, Locality, and Performance Period by the WISeR Discount applicable to the Select Item or Service and state; and
    ii. Multiplying by the WISeR payment rate of 25 percent.
5. CMS will estimate the WISeR Payment for each provisionally identified Pre-Payment Review qualifying for a WISeR Payment by:
    i. Calculating the amount billed on the claim, less any payments for services other than the Select Item or Service that were billed on the same claim;
    ii. Reducing this amount by the WISeR Discount applicable to the Select Item or Service and state; and
    iii. Multiplying by the WISeR payment rate of 25 percent.
6. CMS will total the estimated WISeR Payments as set forth in Section 8.4.E.4 and Section 8.4.E.5 and multiply this total by 50 percent to obtain the Advance WISeR Payment.

Section 8.5 Reconciliation Process

A. CMS will perform Reconciliation for a Performance Period by completing the following calculations:
    1. CMS will calculate the Regional Benchmark for each of the Select Items and Services for each Locality within the WISeR Participant's designated WISeR Jurisdiction, as set forth in Section 8.3.B.
    2. CMS will determine the Payable Non-Affirmations for the WISeR Participant by:

i. Identifying all initial Prior Authorization Non-Affirmations issued by the WISeR Participant during the Performance Period;
ii. Excluding any initial Prior Authorization Non-Affirmation followed by a Resubmission with a Prior Authorization Provisional Affirmation; and
iii. Excluding any initial Prior Authorization Non-Affirmation if Medicare subsequently paid a claim submitted by the applicable WISeR Provider or WISeR Supplier for furnishing the applicable Select Item or Service to the applicable WISeR Beneficiary due to the successful appeal of a claim denial.

3. CMS will identify any Pre-Payment Reviews that qualify for a WISeR Payment as set forth in Section 8.3.D.
4. CMS will calculate the AQS for the WISeR Participant as set forth in Section 7.4 and in the WISeR Data Reporting Guide.
5. CMS will calculate the WISeR Payment as set forth in Section 8.3.D.
6. CMS will identify any pending WISeR Recoupments as set forth in Section 8.3.E. and will net these WISeR Recoupments against the total of WISeR Payments for the Performance Period.

B. CMS will perform Reconciliation for a Performance Period no earlier than the Day after the last Day on which a Resubmission for a Prior Authorization may be submitted, except as otherwise provided in Section 8.5.C.
    1. After calculating the WISeR Payment amount for the Reconciliation for a Performance Period, CMS will compare this amount against any WISeR Payment that was calculated in the initial Reconciliation for the same Performance Period and already paid or recouped by CMS, to determine the net amount of any WISeR Payment still owed for that Performance Period.
    2. If CMS issues a Reconciliation Report detailing the results of the Reconciliation, as described in Section 8.6, simultaneously with the Reconciliation Report detailing the results of the initial Reconciliation for a subsequent Performance Period, CMS may net any WISeR Payment amount specified in the Reconciliation Report for the initial Reconciliation against the net WISeR Payment amount that CMS calculates for the Reconciliation in accordance with Section 8.5.B.1.
C. If the Agreement or Agreement Performance Period is terminated pursuant to Article XIII, CMS shall conduct an initial Reconciliation and a final financial settlement, in accordance with Section 8.9, for the WISeR Participant's final Performance Period, which shall include all Prior Authorizations and Pre-Payment Reviews conducted by the WISeR Participant through the effective date of termination or expiration of this Agreement.

Section 8.6 Reconciliation Report

A. After performing Reconciliation for a given Performance Period as set forth in Section 8.5, CMS shall issue a Reconciliation Report to the WISeR Participant.
B. The Reconciliation Report will set forth the calculation of the WISeR Participant's Regional Benchmarks, AQS, Payable Non-Affirmations, and any applicable WISeR Payment for that Performance Period. In accordance with Section 8.5, the Reconciliation Report for any subsequent Reconciliation for a given Performance Period will also set forth any necessary adjustments to the WISeR Payment amount, if applicable, calculated in the initial Reconciliation for that Performance Period.
C. CMS shall make reasonable efforts to issue the initial Reconciliation Report for each Performance Period within 6 months after the last Day of that Performance Period.
D. Unless CMS receives a timely calculation error notice in accordance with Section 8.7, the Reconciliation Report shall be deemed final 30 Days from the date of issuance by CMS.

Section 8.7 Reconciliation Report Calculation Error

A. The WISeR Participant may contest a Reconciliation Report in accordance with this Section 8.7.
B. The WISeR Participant shall have 30 Days from the date the Reconciliation Report is issued to provide written notice to CMS of an error in the calculation of the WISeR Payment specified in that Reconciliation Report. The calculation error notice must contain a detailed, written explanation of the basis for the calculation error, including any supporting documentation.
C. If CMS receives a timely calculation error notice, CMS shall issue a written determination within 30 Days to either confirm or revise the calculation error, although CMS may extend the deadline for its determination upon written notice to the WISeR Participant.
    1. If CMS issues a written determination that the amount was calculated in error, CMS shall issue a revised Reconciliation Report, which is final on the date of issuance. The WISeR Participant may dispute the revised Reconciliation Report in accordance with Article XIV if the dispute is not precluded from review.
    2. If CMS issues a written determination that the amount is correct, the Reconciliation Report is final on the date the determination is issued.
    3. The WISeR Participant may dispute the determination issued by CMS in accordance with Article XIV if the dispute is not precluded from review.

D. If the WISeR Participant does not submit a timely calculation error notice to CMS in accordance with this Section 8.7, the WISeR Participant is precluded from later contesting the WISeR Payment amounts specified in that Reconciliation Report.
E. If as a result of any later inspection, evaluation, investigation, or audit, it is determined that any WISeR Payment amounts have been calculated in error, CMS may adjust such amounts, issue a revised Reconciliation Report, and make or demand payment of any additional amounts owed in accordance with this Section 8.7.

Section 8.8 Payment of Amounts Owed

A. CMS will pay the WISeR Participant any WISeR Payment amount owed to the WISeR Participant that is specified in Reconciliation Report within 30 Days after the date the Reconciliation Report is deemed final, as set forth in this Section 8.8.
B. CMS shall issue to the WISeR Participant a demand letter for any WISeR Payment owed pursuant to a Reconciliation Report that has been deemed final. The demand letter will be sent to the WISeR Participant at the address specified on the most recent Electronic Funds Transfer Authorization Agreement submitted by the WISeR Participant in accordance with Section 3.1.E.
C. The WISeR Participant shall pay any WISeR Payment amount owed to CMS within 30 Days of the date of a demand letter.
D. Delinquent Debt
    i. If the WISeR Participant fails to pay amounts due to CMS in full by the date specified in any demand letter, CMS shall assess simple interest on the unpaid balance at the rate applicable to other Medicare debts under 42 C.F.R. § 405.378. Interest shall be calculated in 30-Day periods and shall be assessed for each 30-Day period that payment is not made in full. Any payments received by CMS first shall be applied toward accrued interest and then to any outstanding principal balance due.
    ii. If CMS does not receive payment in full by the date the payment is due, CMS shall invoke all legal means to collect the debt and will use any applicable debt collection tools, including referral of the debt to the United States Department of Treasury, pursuant to 31 U.S.C. § 3711(g).

Section 8.9 Financial Settlement Report

A. Upon the expiration or termination of the Agreement Performance Period, CMS will issue to the WISeR Participant a financial settlement report that sets forth the amount of any WISeR Recoupments that the WISeR Participant must repay to CMS

or the amount of any WISeR Payment that CMS must make to the WISeR Participant, in accordance with this Agreement ("**Financial Settlement Report**").

B. If the Financial Settlement Report indicates that CMS owes the WISeR Participant additional payment, CMS shall make such payment within 30 Days after the Financial Settlement Report is deemed final.

C. If the Financial Settlement Report indicates that the WISeR Participant owes CMS a WISeR Recoupment, CMS will issue the WISeR Participant a demand letter for such monies owed to CMS. The WISeR Participant shall pay CMS any WISeR Recoupment within 30 Days of the date of a demand letter. If CMS does not timely receive payment in full, the remaining monies owed shall be considered a delinquent debt in accordance with Section 8.8.D.

Section 8.10 Extreme and Uncontrollable Circumstances

A. CMS may, in its sole discretion, provide Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers if the WISeR Providers and WISeR Suppliers:

   1. Are located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act; and
   2. Are located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

B. CMS has the sole discretion to determine the time period during which Prior Authorization flexibilities are provided to the WISeR Participant's WISeR Providers and WISeR Suppliers.

C. In the event that CMS provides Prior Authorization flexibilities to the WISeR Participant's WISeR Providers and WISeR Suppliers, CMS will provide written notice to the WISeR Participant of any impact such flexibilities have on the terms of this Agreement.

D. The WISeR Participant shall identify, develop, and coordinate prevention, response, and recovery procedures to ensure the availability of critical resources, and facilitate the continuity of essential business functions in an emergency situation, including natural disasters, manmade incidents, catastrophic emergencies, and public health emergencies ("**Continuity of Operations (COOP) Plan**").

E. The WISeR Participant shall maintain a COOP Plan that addresses protection of the physical infrastructure and business continuity (with or without system availability) of mission essential functions, to include without limitation the Prior Authorization Process, and communicating to WISeR Providers and WISeR Suppliers.

F. The WISeR Participant's COOP Plan shall include an information technology (IT) contingency and disaster recovery plan that addresses identified IT risks and vulnerabilities including, without limitation, cybersecurity issues.

Article IX. Business Associate Agreement, Data Sharing and Reports

Section 9.1 Business Associate Agreement

A. The WISeR Participant agrees to execute a valid Business Associate Agreement ("**BAA**") with CMS no later than 5 Days after the Effective Date of this Agreement.
B. If the WISeR Participant fails to execute a valid BAA pursuant to Section 9.1.A by the date specified by CMS, CMS will terminate the Agreement or the Agreement Performance Period or both in accordance with Section 13.3.
C. The WISeR Participant's BAA with CMS shall be active and valid for the duration of the Agreement Term.
D. The WISeR Participant shall comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") Privacy, Security, and Breach Notification Rules (45 C.F.R. Part 160 & Part 164, subparts A through E) ("**HIPAA Rules**").
E. The parties agree that the terms and conditions of the executed BAA between the WISeR Participant and CMS are hereby incorporated by reference into this Agreement as if fully set forth herein.

Section 9.2 Data Sharing and Reports – General

A. The WISeR Participant shall implement information technology (IT) systems security controls in order to maintain the confidentiality, integrity, and availability of the Medicare systems operations in the event of computer incidents or physical disasters.
B. Subject to the limitations discussed in this Agreement, and in accordance with applicable law, including HIPAA and the regulations in 42 C.F.R. Part 2, in advance of the Start Date of this Agreement, during the Agreement Performance Period, and any other time deemed necessary by CMS, CMS will offer the WISeR Participant an opportunity to request certain Beneficiary-identifiable data and reports in accordance with the terms and conditions set forth in this Agreement and in the BAA.
C. The Beneficiary-identifiable data available for request are described in Section 9.3 of this Agreement and in the BAA between CMS and the WISeR Participant.
D. Consistent with 42 C.F.R. § 403.1110(b), the WISeR Participant shall report data metrics for monitoring and evaluation purposes related to the WISeR Participant's Prior Authorization Process that include without limitation:

1. The total number of Prior Authorizations received during the data reporting period with a detailed description of:
    i. The number of Prior Authorization Provisional Affirmations during the data reporting period; and
    ii. The number of Prior Authorization Non-Affirmations during the data reportion period; and
2. The time (e.g., Days, weeks, hours, etc.) taken for the WISeR Participant's Prior Authorization Process to reach a determination;
    i. The total number of Resubmissions for each Prior Authorization received during the data reporting window or for a previous data reporting window;
    ii. The number of reversals of the Initial Prior Authorization Determination.

Section 9.3 Provision of Certain Beneficiary-Identifiable Claims Data

A. At CMS' sole discretion based on CMS' available resources, the limitations in this Agreement, the limitations in the BAA, and applicable law, CMS and the WISeR Participant may share certain Beneficiary-identifiable data for Beneficiaries in the WISeR Jurisdiction subject to the Prior Authorization Process.
B. The Beneficiary-identifiable data includes the data and reports described in this Section 9.3.B.
    1. Detailed Beneficiary Claims Data. These data will include individual Beneficiary-identifiable Medicare FFS claims data for Select Items and Services provided to Beneficiaries within the WISeR Jurisdiction. This includes without limitation data on Medicare FFS expenditures and utilization, and Prior Authorization Process metrics (e.g., timing, Prior Authorization request determinations, Resubmissions of Prior Authorizations, etc.).
    2. Quality Performance Scoring Data. These data will include Beneficiary-identifiable data and quality performance data specific to the Prior Authorization Process.
C. The parties mutually agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by CMS.
D. The parties further agree that CMS retains all ownership rights to the data sources specified in this Agreement and shared under this Agreement and the BAA, and the WISeR Participant does not obtain any right, title, or interest in any of the data furnished by the WISeR Participant as it relates to the Prior Authorization Process.

E. The WISeR Participant represents, and in furnishing the data files specified in Section 9.3.B of this Agreement and the BAA CMS relies upon such representation, that such data files will be used solely for the purpose of carrying out the provisions of this Agreement to improve the efficiency and accuracy of Prior Authorizations, quality improvement activities, reducing health care costs for the Medicare FFS program without causing harm to Beneficiaries, identifying or reducing fraud, waste, and abuse in Medicare FFS, and such other purposes described int his Agreement. The WISeR Participant agrees not to disclosure, use, or reuse the data excepts as specified in this Agreement, the BAA, or except as CMS shall authorize in writing or as otherwise required by law. The WISeR Participant further agrees not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement and the BAA.

F. Information derived from the CMS data specified in Section 9.3.B of this Agreement and in the BAA may be shared and used within the legal confines of the WISeR Participant and its WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers and WISeR Suppliers in a manner consistent with the provisions of this Agreement and the BAA to improve the Prior Authorization Process and Beneficiary care.

G. The WISeR Participant may reuse original or derivative data without prior written authorization from CMS for quality improvement activities relating to improving health or reducing health care costs through the Prior Authorization Process, but shall not disseminate (unless required by law) any individually identifiable original or derived information from the data specified in Section 9.3.B of this Agreement to anyone who is not a HIPAA Covered Entity, a HIPAA Business Associate, a WISeR Clinician or WISeR Clinical Reviewer performing activities related to this Model, or a WISeR Provider or WISeR Supplier in treatment relationship with the subject WISeR Beneficiary. When using or disclosing PHI or personally identifiable information ("**PII**"), obtained from data specified in Section 9.3.B, the WISeR Participant must make "reasonable efforts to limit" the information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure, or request.

H. The WISeR Participant shall establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget ("**OMB**") in OMB Circular No. A-130, Appendix I – Responsibilities for Protecting and Managing Federal Information Resources (https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A130/a130revised.pdf) as well as Federal Information Processing Standard 200 entitled

"Minimum Security Requirement for Federal Information and Information Systems" (http:// (http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf); and, NIST Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" (http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf). The WISeR Participant acknowledges that the use of unsecured telecommunications, including the Internet, to transmit directly or indirectly identifiable information from the files specified in Section 9.2.B or any such derivative data files is strictly prohibited.

I. The WISeR Participant shall grant access to the data and/or the facility(ies) in which the data is maintained to the authorized representatives of CMS or Office of Inspector General of the Department of Health and Human Services ("**OIG**") for the purpose of inspecting to confirm compliance with the terms of this Agreement and the BAA.

J. The WISeR Participant agrees that any use of CMS data in the creation of any document concerning the purpose specified in this section must adhere to CMS' current cell size suppression policy. The policy stipulates that no cell (e.g., patients, services) representing 10 or fewer Beneficiaries may be displayed. Also, no percentages or other mathematical formulas may be used if they result in the display of a cell representing 10 or fewer Beneficiaries. A cell that represents or uses percentages or other mathematical formulas to represent zero Beneficiaries must be displayed.

Article X. Participation in Evaluation, Shared Learning Activities, and Site Visits

Section 10.1 Evaluation Requirement

A. General. The WISeR Participant shall participate and cooperate in any independent evaluation activities conducted by or on behalf of CMS aimed at assessing the impact of the Model on the goals of improving quality of care and reducing fraud, waste, and abuse expenditures for the Medicare program. The WISeR Participant shall require its WISeR Clinicians and WISeR Clinical Reviewers to participate and cooperate in any such independent evaluation activities conducted by or on behalf of CMS. Termination or expiration of this Agreement shall not affect the right of CMS to evaluate WISeR.

B. Primary Data. In its evaluation activities, CMS or its designee(s) may collect qualitative and quantitative data. These data may include, but are not limited to the following sources:

1. Site visits with the WISeR Participant;
2. Surveys or interviews with WISeR Providers and WISeR Suppliers;
3. Surveys or interviews with Beneficiaries and their caregivers;
4. Focus groups of WISeR Providers and WISeR Suppliers;
5. Focus groups of Beneficiaries and their caregivers;
6. Interviews with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
7. Focus groups with the WISeR Participant, its WISeR Clinicians, its WISeR Clinical Reviewers, and their staff;
8. Direct observation of WISeR Provider and/or WISeR Supplier interactions with the WISeR Participant and its staff, and other activities related to the WISeR Participant's participation in the Model;
9. Review of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates; and
10. Surveys.

C. Secondary Data. In its evaluation activities, CMS may use data or information submitted by the WISeR Participant as well as claims submitted to CMS for Select Items and Services furnished to Beneficiaries. These data may include, but are not limited to:
    1. Claims data;
    2. Survey data from Patient Experience surveys;
    3. Medical records;
    4. Clinical data;
    5. Monitoring data (e.g., audit results, etc.); and
    6. Quality and clinical data submitted to CMS.
D. Reporting Requirements. CMS may add or modify evaluation-related reporting requirements during the Agreement Term. CMS will notify the WISeR Participant of any additions or modifications as soon as practicable or at least 30 Days prior to the Day on which such change would take effect.

Section 10.2 Shared Learning Activities

A. The WISeR Participant shall participate in CMS-sponsored learning activities designed to drive improvement and foster innovations in using technology-assisted decision-making through sharing best practices or new knowledge that emerges from participation in the Model.
B. The WISeR Participant shall actively engage in a variety of learning events, learning communities, and sharing promising tools and ideas, as well as their lessons learned.

Section 10.3 Site Visits

A. The WISeR Participant shall cooperate and require its staff to cooperate in any site visits conducted by or on behalf of CMS.
B. CMS or its designee(s) shall, to the extent practicable, schedule any site visits to the WISeR Participant no fewer than 15 Days in advance. To the extent practicable, CMS will attempt to accommodate the WISeR Participant's request for particular dates in scheduling site visits. However, the WISeR Participant may not request a date that is more than 60 Days after the date of the initial site visit notice from CMS.
C. The WISeR Participant shall ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during the site visit.
D. Notwithstanding the foregoing, CMS or its designee(s) may perform unannounced site visits at any of the WISeR Participant's office locations at any time to investigate concerns or other program integrity issues.
E. Nothing in this Agreement shall be construed to limit or otherwise prevent CMS from performing site visits permitted by applicable law or regulations.

Section 10.4 Rights in Data and Intellectual Property

A. CMS may use any data obtained pursuant to the Model to evaluate the Model and to disseminate quantitative results and successful care management techniques to other providers and suppliers and to the public. Data to be disseminated may include results of WISeR Provider and WISeR Supplier surveys, results of patient experience of care and quality of life surveys as well as measures based upon claims, medical records, and other data sources. The WISeR Participant will be permitted to comment on evaluation reports when the WISeR Participant has been specifically cited to ensure factual accuracy but may not edit conclusions or control the dissemination of reports.
B. The parties agree that by participating in the Model, the WISeR Participant grants to CMS and its designees a limited, royalty-free, worldwide, non-sublicensable, non-exclusive license on a warranty-free basis during the term of this Agreement (and for any agreed to extension thereof) in, to and under all intellectual property and information technology owned or licensable (without the consent of, or payment to, any third party) by the WISeR Participant or any of its affiliates, solely for CMS or any of its designees or affiliates to receive and use such information technology.
C. Notwithstanding any other provision in the Agreement, the parties agree that any intellectual property or information technology developed as a result of the collaborative activity under the terms of this Agreement and the requirements associated with this Model will be dealt with by appropriate written agreements

D. Notwithstanding any other provision in the Agreement, all proprietary trade secret information and technology of the WISeR Participant that existed prior to the Effective Date of this Agreement is and shall remain the sole property of the WISeR Participant, and, except as required by federal law, shall not be released by CMS without express written consent. The regulation at 48 C.F.R. § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into the Agreement. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property right or other rights to the WISeR Participant's proprietary information or technology.

E. If the WISeR Participant maintains any information that should not be publicly disclosed because the WISeR Participant considers such information to be proprietary and confidential, the WISeR Participant acknowledges that it may submit to CMS a form, using either the template attached as Appendix C, or a form substantially the same as Appendix C, identifying specific examples of information the WISeR Participant considers to be proprietary and confidential. The WISeR Participant must notify CMS, in a form and manner to be specified by CMS, of any updates to this form. If the WISeR Participant does not submit such a form, the WISeR Participant will be deemed to have confirmed that it has no information it considers proprietary and confidential.

Section 10.5 WISeR Participant Public Release of Information

A. The WISeR Participant shall obtain prior approval from CMS during the Agreement Term and for 6 months thereafter for the publication or release of any press release, external report or statistical/analytical material that materially and substantially references the WISeR Participant's participation in the Model. External reports and statistical/analytical material may include but are not limited to papers, articles, professional publications, speeches, and testimony.

B. All external reports and statistical/analytical material that are subject to this Section 10.5 must include the following statement on the first page: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

Article XI. Compliance and Oversight

Section 11.1 WISeR Participant Compliance Plan

A. The WISeR Participant shall have a compliance plan that includes at least the following elements:

1. A designated compliance official or individual who is not legal counsel to the WISeR Participant and reports directly to the WISeR Participant's governing body;
2. Mechanisms for identifying and addressing compliance problems related to the WISeR Participant's operations and performance;
3. A method for employees or contractors of the WISeR Participant performing functions or services related to this Model to anonymously report suspected problems related to the WISeR Participant's compliance official;
4. Compliance training for the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers; and
5. A requirement for the WISeR Participant to report probable violations of law to an appropriate law enforcement agency.

B. The WISeR Participant shall ensure that its compliance plan is in compliance with all applicable laws and regulations. The WISeR Participant shall periodically update its compliance plan to reflect changes in those laws and regulations.

Section 11.2 CMS Monitoring and Oversight Activities

A. CMS shall conduct monitoring activities to assess compliance by the WISeR Participant and its WISeR Clinicians and WISeR Clinical Reviewers with the terms of this Agreement. Such monitoring activities may include, but are not limited to:
   1. Claims analyses to identify fraudulent behavior or program integrity risks such as efforts to manipulate Prior Authorization Process accuracy and efficiency;
   2. Claims and appeals data to identify fraudulent behavior or program integrity risks, including data between the WISeR Participant and any MAC;
   3. Review of documents from the WISeR Participant, WISeR Clinicians, WISeR Clinical Reviewers, WISeR Providers, and WISeR Suppliers, including surveys and questionnaires;
   4. Review and audits of the WISeR Participant's Enhanced Technology, including without limitation, reliance on artificial intelligence, machine learning capabilities, and its impact on the timing and accuracy of Prior Authorization determinations, denial rates, affirmation rates, resubmission rates, and other data related to such Enhanced Technology;
   5. Review and audits of the WISeR Participant's Pre-Payment Review processes performed by its WISeR Clinicians and WISeR Clinical Reviewers, and the impact on the timing and accuracy of Pre-Payment Review determinations, denial rates, affirmation rates, resubmission rates, and other data related to such reviews;
   6. Interviews with Beneficiaries and their caregivers;

7. Audits of data related to the Prior Authorization Process, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant;
8. Audits of data related to Pre-Payment Review, including without limitation, timing and accuracy of determinations, denial rates, affirmation rates, and resubmission rates, and other data from the WISeR Participant; and
9. Site visits to the WISeR Participant.

B. In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including, without limitation, all Medicare claims submitted for items and/or services furnished to Beneficiaries.

C. In conducting monitoring and oversight activities, CMS or its designee(s) may use any relevant data or information including, without limitation, all Prior Authorization requests, Pre-Payment Review activities, determinations, and resubmissions submitted for items and/or services furnished to Beneficiaries.

D. Nothing in this Agreement limits or otherwise prevents CMS from monitoring the WISeR Participant for compliance as permitted by applicable law or regulations.

E. CMS may conduct monitoring activities pursuant to this Article XI for up to two calendar years after the effective date of termination or expiration of this Agreement.

Section 11.3 Compliance with Monitoring and Oversight Activities

A. The WISeR Participant shall cooperate with, and require its WISeR Clinicians and WISeR Clinical Reviewers to cooperate with, all CMS monitoring and oversight requests and activities.

B. The WISeR Participant shall ensure it has sufficient access to all records, data, and information necessary to comply with the monitoring activities described in this Agreement. As necessary, the WISeR Participant shall request this information from any WISeR Clinician, or any WISeR Clinical Reviewer, or individual performing functions or providing services related to WISeR.

Section 11.4 Compliance with Laws

A. Agreement to Comply

1. The WISeR Participant shall comply with, and shall require all WISeR Clinicians and WISeR Clinical Reviewers to comply with, the applicable terms of the Agreement and all applicable statutes, regulations, and guidance, including without limitation: (a) federal criminal laws; (b) the Social Security Act (Public Law 74-271); (c) Title XVIII of the Act; (d) the False Claims Act (31 U.S.C. § 3729 et seq.); (e) the antikickback statute (42 U.S.C. § 1320a-7b(b)); (f) the civil monetary penalties law (42 U.S.C. § 1320a-7a); (g) the federal

physician self-referral law (42 U.S.C. § 1395nn); and (h) any applicable State laws.

2. This Agreement does not waive any obligation of the WISeR Participant to comply with the terms of any other CMS contract, agreement, model, or demonstration.

B. Reservation of Rights

1. Nothing contained in this Agreement or in the application process for WISeR constitutes a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS Office of the Inspector General, or CMS of any right to institute any proceeding or action for violations of any statutes, rules, or regulations administered by the government, or to prevent or limit the rights of the government to obtain relief under any other federal statutes or regulations, or on account of any violation of the Agreement or any other provision of law. This Agreement does not bind any government agency except CMS and the Agreement binds CMS only to the extent provided in this Agreement.
2. The failure by CMS to require performance of any provision of this Agreement does not affect CMS' right to require performance at any time thereafter, nor does a waiver of any breach or default of the Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

C. Office of Inspector General of the Department of Health and Human Services (OIG) Authority. None of the provisions of this Agreement limit or restrict the OIG's authority to audit, evaluate, investigate, or inspect the WISeR Participant or its WISeR Clinicians or its WISeR Clinical Reviewers.

D. Other Government Authority. None of the provisions of this Agreement limit or restrict any other government authority that is permitted by law to audit, evaluate, investigate, or inspect the WISeR Participant.

Section 11.5 Applicable Statutes, Regulations, Manuals, and Documents

In addition to all referenced statutes, regulations, manuals, and documents, the following statutes, regulations, manuals, and documents apply to this Agreement and are hereby incorporated by reference.

A. Financial management and internal controls (e.g., the Federal Managers' Financial Integrity Act of 1982 (FMFIA), the Chief Financial Officers' Act of 1990, etc.);
B. Federal Information Security Management Act of 2014 (FISMA);
C. Privacy and information technology requirements (Privacy Act of 1974, Information Technology Management Reform Act of 1996);

D. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191);
E. Rehabilitation Act of 1973 (including section 508, Accessibility Standards);
F. Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248);
G. Administrative Simplification Compliance Act of 2002 (Public Law 107-105);
H. Benefit Improvement and Protection Act of 2000 (Public Law 106-554);
I. Executive Order 13410, to the extent practicable, Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs;

Medicare manuals (e.g., internet only manuals – IOMs) to administer CMS programs. In the event of any conflict, this Agreement shall have precedence over the IOMs located at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index;

Article XII. Audits and Record Retention

Section 12.1 Right to Audit and Inspect

The WISeR Participant agrees that the government (including CMS, HHS, and the Comptroller General or their designees) has the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the WISeR Participant that pertain to the following:

A. The WISeR Participant's compliance with the terms of this Agreement, including provisions that require the WISeR Participant to impose duties or requirements on its WISeR Clinicians and its WISeR Clinical Reviewers;
B. Whether the WISeR Clinicians and WISeR Clinical Reviewers complied with the duties and requirements imposed on them by the WISeR Participant pursuant to the terms of this Agreement;
C. The quality of services performed under this Agreement;
D. Any activity by the WISeR Participant that may pose a potential risk of harm to Beneficiaries or a vulnerability to the integrity of the Model test;
E. The WISeR Participant's right to WISeR Payments;
F. The ability of the WISeR Participant to repay amounts owed to CMS under this Agreement;
G. The WISeR Participant's financial arrangements.

Section 12.2 Maintenance of Records

The WISeR Participant shall maintain and shall give the government (including CMS, HHS, and the Comptroller General or their designees) access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs,

quality performance measures, and financial arrangements) sufficient to enable the audit, evaluation, inspection, or investigation of the Model, including the subjects identified in Section 11.2. The WISeR Participant shall maintain such books, contracts, records, documents, and other evidence for a period of six years from the expiration or termination of this Agreement or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:

A. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the WISeR Participant at least 30 Days before expiration of the six-year period described above; or
B. There has been a termination, dispute, or allegation of fraud or similar fault against the WISeR Participant in which case the records shall be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

Article XIII. Remedial Action and Termination

Section 13.1 Grounds for Remedial Action

A. CMS may take remedial action against the WISeR Participant if CMS determines that the WISeR Participant:
    1. Has failed to comply with any applicable term of the Agreement or any Medicare program requirement, rule, or regulation;
    2. Has failed to comply with the American with Disabilities Act of 1990, 42 U.S.C. § 12101 *et seq*. (1990);
    3. Has failed to comply with the WISeR Participant's Corrective Action Plan (CAP), the monitoring or auditing plan, or both, developed by CMS for the WISeR Participant, or other remedial action imposed by CMS, if applicable;
    4. Has taken any action that threatens the health or safety of a Beneficiary, including a WISeR Beneficiary;
    5. Has failed to rectify deficiencies following any remedial action;
    6. Has undergone a Change in Control that renders it ineligible for participation in the Model or presents a program integrity risk;
    7. Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model or any requirement of the Medicare program;
    8. Has failed to pay amounts owed to CMS by the date specified in a demand letter;
    9. Has failed to pay a WISeR Recoupment;

10. Has a conflict of interest; or
11. Poses significant program integrity risks, including but not limited to:
    i. Is subject to sanctions or other actions of a federal, state, or local government agency;
    ii. Is subject to investigation or action by HHS (including, but not limited to OIG and CMS) or the Department of Justice due to an allegation of fraud or similar misconduct, including but not limited to being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

Section 13.2 Types of Remedial Action

A. If grounds for remedial action exist, CMS may take one or more of the following actions:
    1. Notify the WISeR Participant of the violation;
    2. Require the WISeR Participant to provide additional information to CMS or its designees;
    3. Conduct site visits, interview WISeR Providers and/or WISeR Suppliers, interview Beneficiaries, or take other actions to gather information;
    4. Place the WISeR Participant on a monitoring and/or auditing plan developed by CMS;
    5. Require the WISeR Participant to not use a WISeR Clinician or WISeR Clinical Reviewer for Medical Review, immediately or within a timeframe specified by CMS;
    6. Withhold, deny, or recoup WISeR Payments;
    7. Withhold, deny, or recoup any Advance WISeR Payments;
    8. Suspend or terminate the WISeR Participant's ability to perform its Prior Authorization Process on new requests;
    9. Require a CAP from the WISeR Participant that is acceptable to CMS. If CMS requires a CAP from the WISeR Participant, the following requirements apply:
        i. The WISeR Participant shall submit a CAP to CMS for approval by a deadline established by CMS:
        ii. CMS must approve the WISeR Participant's CAP;
        iii. The CAP must address what actions the WISeR Participant will take within a specified time period to ensure that all deficiencies will be corrected and that the WISeR Participant will be in compliance with the terms of this Agreement; and

iv. If the WISeR Participant does not comply with the terms of the CAP within the specified period of time, CMS may take additional remedial actions or terminate the Agreement or Agreement Performance Period in accordance with Section 13.3.

B. CMS may impose additional remedial actions, including but not limited to terminating the Agreement or Agreement Performance Period pursuant to Section 13.3, if CMS determines that the WISeR Participant's efforts to address noncompliance or other grounds for remedial action were insufficient.

Section 13.3 Termination by CMS

CMS may immediately or with advance notice terminate the Agreement or Agreement Performance Period if:

A. CMS determines that it no longer has the funds to support the Model;
B. CMS modifies or terminates the Model pursuant to section 1115A(b)(3)(B) of the Act;
C. CMS offers the WISeR Participant an amendment to this Agreement pursuant to Section 1.4, and the WISeR Participant does not sign such amendment by the date specified by CMS;
D. CMS determines that any grounds for remedial action exist;
E. CMS determines that the WISeR Participant has failed to submit, obtain approval for, implement, or fully comply with the terms of a CAP;
F. CMS determines that the WISeR Participant has failed to demonstrate improved performance following any remedial action imposed by CMS;
G. The WISeR Participant has a conflict of interest that cannot be resolved;
H. The WISeR Participant has not executed a valid BAA; or
I. The WISeR Participant assigns or purports to assign any of the rights or obligations under the Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

Section 13.4 Termination of the Agreement Performance Period by WISeR Participant

The WISeR Participant may terminate the Agreement Performance Period upon advance written notice to CMS. Such notice must specify the effective date of the termination, which must be at least 90 Days after the date of the notice.

Section 13.5 Financial Settlement Upon Termination

If CMS terminates the Agreement or the Agreement Performance Period is terminated by either party, CMS shall conduct settlement for the entire Performance Year in which the Agreement is terminated in accordance with Article VIII of the Agreement.

Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination

If the Agreement or Agreement Performance Period is terminated under Section 13.3 or Section 13.4, the WISeR Participant shall provide written notice of the termination to all WISeR Providers and WISeR Suppliers in its WISeR Jurisdiction. The WISeR Participant shall deliver such written notice no later than 45 Days before the effective date of termination unless a different date is specified by CMS. The WISeR Participant shall include in such notices any content specified by CMS.

Article XIV. Limitation on Review and Dispute Resolution

Section 14.1 Limitations on Review

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

A. The selection of organizations, sites, or participants to test models selected for testing or expansion under section 1115A of the Act, including the decision by CMS to terminate the Agreement or Agreement Performance Period;
B. The elements, parameters, scope, and duration of such models for testing or dissemination;
C. Determinations regarding budget neutrality under section 1115A(b)(3);
D. The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B);
E. Determinations about expansion of the duration and scope of a model under section 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection (c);
F. The selection of quality performance standards by CMS;
G. The methodology applied to calculate Regional Benchmarks, WISeR Discount, AQS, and WISeR Payments;
H. The methodology used to calculate the WISeR Participant's WISeR Payment; and
I. The methodology used to calculate the WISeR Recoupment.

Section 14.2 Dispute Resolution

A. Right to Reconsideration. The WISeR Participant may request reconsideration of a determination made by CMS pursuant to the Agreement only if such reconsideration is not precluded by section 1115A(d)(2) of the Act or the Agreement.
    1. Such a request for reconsideration by the WISeR Participant must satisfy the following criteria:

i. The request must be submitted to a designee of CMS ("**Reconsideration Official**") who –
    a. Is authorized to receive such requests;
    b. Did not participate in the determination that is the subject of the reconsideration request; and
    c. May be, but does not have to be, an Inferior Officer.
ii. The request must include a copy of the initial determination issued by CMS and contain a detailed, written explanation of the basis for the dispute, including supporting documentation;
iii. The request must be made within 30 Days of the date of the initial determination for which reconsideration is being requested and
iv. The request must be delivered via email to CMS at InnovationModelsReconsideration@cms.hhs.gov or at such other address specified by CMS.

2. Requests that do not meet the requirements of Section 14.2.A.1 will be denied.
3. Within 15 Days of receiving a request for reconsideration, the parties will be sent a written acknowledgement of receipt of the reconsideration request. Such an acknowledgement will set forth:
    i. The review procedures; and
    ii. A briefing schedule that permits each party to submit written briefs, including any evidence or documentation in support of the party's position for consideration by the Reconsideration Official.

B. Standards for Reconsideration
1. The parties shall proceed diligently with the performance of this Agreement during the course of any dispute arising under the Agreement.
2. The reconsideration will consist of a review of documentation that is submitted timely and in accordance with the standards specified by the Reconsideration Official.
3. The burden of proof is on the WISeR Participant to demonstrate to the Reconsideration Official with clear and convincing evidence that the determination is inconsistent with the terms of the Agreement.

C. Reconsideration Determination
1. The reconsideration determination will be based only upon:
    i. Position papers and supporting documentation that are timely submitted to the Reconsideration Official and meet the standards for submission under Section 14.2.B.2; and

ii. Documents and data that were timely submitted to CMS in the required format before the agency made the determination that is the subject of the reconsideration request.

2. The Reconsideration Official will issue to CMS and the WISeR Participant a written notification of the reconsideration determination ("**Reconsideration Determination**"). Absent unusual circumstances, the Reconsideration Determination will be issued within 60 Days of receipt of timely filed position papers and supporting documentation.
3. The Reconsideration Determination is final and binding 30 Days after its issuance, unless the WISeR Participant or CMS timely requests review of the Reconsideration Determination in accordance with Sections 14.2.D.1 and 2.

D. CMS Administrator Review. The WISeR Participant or CMS may request CMS Administrator review of the Reconsideration Determination.

1. The request must be made via email to InnovationModelsReconsideration@cms.hhs.gov or such other address as specified by CMS within 30 Days after the date of the Reconsideration Determination.
2. The request must include a copy of the Reconsideration Determination and a detailed, written explanation of why the WISeR Participant or CMS disagrees with the Reconsideration Determination.
3. Within 30 business days after receiving a request for review, the CMS Administrator (or a delegate acting on behalf of the CMS Administrator) will determine whether the request for review is granted or denied. The CMS Administrator will promptly send the parties written acknowledgement of receipt of the request for review. Such an acknowledgement will set forth:
    i. Whether the request for review is granted or denied; and
    ii. If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.
4. If the request for review is denied, the Reconsideration Determination is final and binding as of the date the request for review is denied.
5. If the request for review is granted:
    i. The record for review will consist of timely submitted briefs and the evidence contained in the record of the proceedings before the Reconsideration Official. The CMS Administrator will not consider documentation submitted for review other than documents and date described in Section 14.2.B.2;

ii. The CMS Administrator will review the record and issue to CMS and to the WISeR Participant a written determination; and
iii. The written determination of the CMS Administrator is final and binding.

E. Effect of Dispute Resolution. The dispute resolution process under this Agreement shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

Article XV. Miscellaneous

Section 15.1 Agency Notifications and Submission of Reports

A. For a notice or other communication required under this Agreement to be valid, it must be in writing.
B. Unless otherwise specified in this Agreement or stated in writing after the Effective Date, all notifications and reports required under this Agreement must be submitted to the parties at the addresses set forth below:

CMS:
WISeR Model
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop: WB-06-05
Baltimore, MD 21244
Email: WISeR@cms.hhs.gov

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

Section 15.2 Notice of Bankruptcy

A. If the WISeR Participant has filed a bankruptcy petition, whether voluntary or involuntary, the WISeR Participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the WISeR Participant under the terms of each model tested under section 1115A of the Act in which the WISeR Participant is participating or has participated and all administrative or judicial review proceedings related to any payments under such models have been fully and finally resolved.

B. The notice of bankruptcy must be sent by certified mail no later than 5 Days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the WISeR Participant is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the WISeR Participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the WISeR Participant and CMS have been fully and finally resolved with respect to that model.

C. The notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3-01-24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices.

Section 15.3 Severability

In the event that any one or more of the provisions of this Agreement is, for any reason, held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had never been included in the Agreement, unless the deletion of such provision or provisions would result in such a material change to the Agreement so as to cause continued participation under the terms of this Agreement to be unreasonable.

Section 15.4 Entire Agreement; Amendment

This Agreement, including all appendices, constitutes the entire agreement between the parties. The parties may amend this Agreement or any appendix hereto at any time by mutual written consent; provided, however, that CMS may amend this Agreement or any appendix hereto in writing without the consent of the WISeR Participant as specified in this Agreement or any appendix hereto, or for good cause or as necessary to comply with applicable federal

or state law, regulatory requirements, accreditation standards, or licensing guidelines or rules. To the extent practicable, CMS shall provide the WISeR Participant with 30 Days' advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

Section 15.5 Survival

Expiration or termination of this Agreement by CMS shall not affect the rights and obligations of the parties accrued prior to the effective date of the expiration or termination of this Agreement, except as provided in this Agreement. The rights and duties under the following sections of this Agreement shall survive the expiration or termination of this Agreement and apply thereafter:

Article VIII. Payment;
Article IX. Data Sharing and Reports;
Section 10.1 Evaluation Requirements;
Section 10.4 Rights in Data and Intellectual Property;
Section 10.5 WISeR Participant Public Release of Information;
Section 11.3 Compliance with Monitoring and Oversight Activities;
Article XII. Audits and Record Retention;
Section 13.5 Financial Settlement Upon Termination;
Section 13.6 Notifications to WISeR Providers and WISeR Suppliers upon Termination;
Section 14.1 Limitations on Review;
Section 15.2 Notice of Bankruptcy;
Section 15.5 Survival; and
Section 15.7 Prohibition on Assignment.

Section 15.6 Precedence

If any provision of this Agreement conflicts with a provision of any document incorporated herein by reference, the provision of this Agreement shall prevail.

Section 15.7 Prohibition on Assignment

Except with the prior written consent of CMS, the WISeR Participant shall not transfer, including by merger (whether the WISeR Participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under this Agreement; (2) any right that it has to satisfy a condition under this Agreement; (3) any remedy that it has under this Agreement; or (4) any obligation imposed on it under this Agreement. The WISeR Participant shall provide CMS 90 Days' advance written notice of any such proposed transfer. This obligation remains in effect until final payment by or to the WISeR Participant has been made under this Agreement. CMS may condition its consent to transfer on full payment of any amounts owed by the WISeR Participant under this Agreement or owed to CMS by the

proposed assignee. Any purported transfer in violation of this Section is voidable at the discretion of CMS.

Section 15.8 Certification

The WISeR Participant executive signing this Agreement certifies to the best of his or her knowledge, information, and belief that the WISeR Participant satisfies the requirements of Section 3.1.A, that all WISeR Clinicians and WISeR Clinical Reviewers satisfy the requirements of Section 3.4, and that he or she is authorized by the WISeR Participant to execute this Agreement and to legally bind the WISeR Participant to its terms and conditions.

Section 15.9 Execution in Counterpart

This Agreement and any amendments hereto may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof. This Agreement and any amendments hereto may be signed by autopen or electronic signature (e.g., DocuSign or similar electronic signature technology) and may be transmitted by electronic means. Copies of this Agreement and any amendments hereto that are so executed and delivered have the same force and effect as if executed with handwritten signatures and physically delivered.

[SIGNATURE PAGE FOLLOWS]

Each party is signing this Agreement on the date stated opposite that party's signature. If a party signs but fails to date a signature, the date that the other party receives the signing party's signature will be deemed to be the date that the signing party signed the Agreement.

WISeR Participant: Zyter Inc.

WISeR ID: WISeR-00081

(b)(6)

Date: 2025-10-10 10:13:25

By: _____

(b)(6)

Name of Authorized Signatory

(b)(6)

Title

CMS:

Date: 2025-10-15 10:07:15

By: _____

Arrah Tabe-Bedward

Name of Authorized Signatory

CMS Executive

Appendices

Appendix A: Select Items and Services

Appendix B: Quality Measures

Appendix C: WISeR Participant Proprietary and Confidential Information

Appendix A: Select Items and Services

CMS uses Covered Services that correspond to the LCDs and NCDs identified in the Table 1 below ("**Select Items and Services**") to determine whether the WISeR Provider's and/or WISeR Supplier's Medicare claim is subject to the Prior Authorization Process for Performance Year 1. The WISeR Participant performs its Prior Authorization Process for each Select Item or Service identified in a Prior Authorization request within its WISeR Jurisdiction.

CMS may unilaterally revise the Select Items and Services identified in Table 1 prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any revisions to the Select Items and Services for a Performance Period prior to the start of the Performance Period in which such change will take effect.

Table 1

Select Items and Services	Associated NCD/LCDs
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)	NCD 160.7 NCD 230.18 NCD 160.19 NCD 160.24 NCD 160.18
Induced Lesions of Nerve Tracts	NCD 160.1
Epidural Steroid Injections for Pain Management	L39015, L39242, L36920
Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L34106, L38201, L35130
Cervical Fusion Excluding codes already included in OPD	L39741, L39762, L39793
Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee	NCD 150.9

Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea	L38307, L38312, L38385
Incontinence Control Devices	NCD 230.10
Diagnosis and Treatment of Impotence	NCD 230.4
Percutaneous Image-Guided Lumbar Decompression for Spinal Stenosis	NCD 150.13
Skin and Tissue Substitutes • Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds • Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities	L35041 L36690

Appendix B: Quality Measures

Consistent with Article VII and the WISeR Data Reporting Guide, CMS shall use the following WISeR Performance Measure Set for purposes of calculating the AQS of the WISeR Participant for Performance Year 1. CMS will also use the following WISeR Performance Measure Set for purposes of monitoring and evaluating the overall performance of the WISeR Participant during the Model.

CMS may update the quality measures identified in the WISeR Performance Measure Set prior to the start of any Performance Period during the Model. CMS shall notify the WISeR Participant in writing of any updates for a Performance Period prior to the start of the Performance Period in which such change will take effect.

WISeR Performance Measure Set

Domain	First Applicable Performance Period	Data Source	Measurement Frequency
Timeliness of Determinations	PP1	WISeR Participant-Reported	Quarterly
Accuracy of Determinations	PP1	CMS Audit of WISeR Participant-Reported Data	Quarterly

Appendix C: WISeR Participant Proprietary and Confidential Information

The following are specific examples, without limitation, of what the WISeR Participant considers proprietary and confidential information currently maintained by the WISeR Participant that should not be publicly disclosed:

1) RFA submission documents

2)

3)

4)

In accordance with Section 10.4 of the Agreement, this information shall not be released by CMS without the express written consent of the WISeR Participant except as required by federal law.