Health and Human Services
Centers for Medicare & Medicaid Services
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Wasteful and Inappropriate Service Reduction (WISeR) Model

Request for Applications (RFA)

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1. Model Summary

This Request for Applications (RFA) invites interested parties to apply to participate in the Wasteful and Inappropriate Service Reduction (WISeR) Model, a new Center for Medicare and Medicaid Innovation (Innovation Center) model from the Centers for Medicare & Medicaid Services (CMS). Wasteful medical care spending accounts for an estimated 25% of total healthcare spending with a substantial portion being attributable to fraud, waste (including low-value services), and abuse (FWA).[1,2] The WISeR Model will test an innovative approach to addressing this issue by implementing a six-year model, in two three-year agreement periods. Under the WISeR model, CMS seeks qualified technology partners as model participants to implement and streamline the prior authorization process for select items and services that may be fraudulent, and wasteful, or of low-value to beneficiaries in Original Medicare.

Key Model Elements:

- Scope and Duration: The WISeR Model will begin on January 1, 2026, and run for two three-year agreement periods, until December 31, 2031. The scope of WISeR will include four Medicare Administrative Contractor (MAC) jurisdictions – JH, JL, JF and J15 – and six specific states within those MAC jurisdictions – New Jersey (JL), Ohio (J15), Oklahoma and Texas (JH), and Arizona and Washington (JF) – as the selected geographic areas.

- Participants: Participants in this model will be companies that apply emerging technologies to clinical and claims processing solutions and have experience and expertise managing the prior authorization process for other payers, including Medicare Advantage (MA) plans, with a demonstrated ability to apply such technology to the payment processes used under Original Medicare. Selected model participants would apply their technology solutions/products to enhance the process on both the provider/supplier and payer side and must be able to securely exchange data with MACs. For additional information on model participants, see Section 4.

- Provider/Supplier Alignment: WISeR will make the technology-enabled process available to all relevant providers and suppliers in selected regions delivering select items and services to Original Medicare beneficiaries (see Federal Register Notice Number CMS-5056-N). All Medicare-enrolled providers and suppliers in those selected regions would have the option to submit a prior authorization request on the items and services included for this model. If a provider or supplier does not submit a request prior to furnishing an included item or service, the claim for the item or service would be

[1] Speer M, McCullough JM, Fielding JE et al. Excess Medical Care Spending: The Categories, Magnitude, and Opportunity Costs of Wasteful Spending in the United States. Am J Public Health. 2020 Dec;110(12):1743-1748.
[2] Shrank WH, Rogstad TL & Parekh N. Waste in the US Health Care System: Estimated Costs and Potential for Savings. JAMA. 2019;322(15):1501–1509.

selected for further medical review by the model participant during the pre-payment period of claims processing. For additional information on impacted healthcare providers and Medicare beneficiaries, see section 5.

- Data Reporting and Sharing: A business associate relationship will be established between CMS and the model participants which will be documented through a valid business associate agreement (BAA) that complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (45 C.F.R. §§ 164.502(e), 164.504(e)). Currently, MACs also function as business associates to CMS's Medicare Fee-for-Service (FFS) health plan. CMS will develop the WISeR model's data sharing policies in compliance with all relevant HIPAA Privacy, Security, and Breach Notification Rules (45 C.F.R. Part 160 & Part 164, subparts A through E) (HIPAA Rules) and guidance applicable to the use and disclosure of protected health information (PHI), as well as CMS's overarching privacy and security framework, and all other applicable federal and state laws and regulations. CMS's privacy and security policies will govern data sharing between the model participants, the MACs, and providers/suppliers in the affected geographic regions. Model participants will be required to have access to the Federal Risk and Authorization Management Program (FedRAMP) certified workflows, follow Federal Information Security Management Act (FISMA) regulations, follow the CMS Information Systems Security & Privacy Policy (IS2P2), follow CMS Acceptable Risk Safeguards (ARS), follow CMS Authority to Operate guidelines, and enter into HIPAA BAAs with FFS Original Medicare and/or the MACs, as applicable, among other privacy and security requirements. Model participants will be required to comply with all of these requirements and to align with any changes to the program requirements throughout the model performance period.

- Payment: Payments to the model participants would be based on demonstrated reductions in spending for medically unnecessary or non-covered items or services as defined by Original Medicare local or national coverage policies, calculated as a percentage of the savings directly attributed to their model participation. For additional information on the model's payment methodology, see Section 8.

- Monitoring and Performance Measurement: WISeR model participants will be monitored, and their performance will be measured on metrics including accuracy, processing times, provider/supplier experience with the prior authorization process conducted by the model participant, and impacts on quality of care for beneficiaries included in the model. The model's monitoring strategy will follow the guiding principles of protecting beneficiaries from harm, as well as ensuring compliance with technology regulation and program regulation. CMS will also require the model participants to report data metrics on their prior authorization process, which may include, but are not

limited to, the number of affirmations and non-affirmations, time taken to reach a decision, the number of resubmissions requesting a re-review to reverse the initial determination, and instances where the model participant reverses an initial non-affirmation after re-evaluating the prior authorization request and determining that the initial decision should have been affirmed. For additional information on the model's performance measurement approach, see Section 7. For additional information on the model's monitoring approach, see Section 10.

2. Background

Wasteful medical care spending, broadly defined as spending that could be reduced or eliminated without adversely affecting quality of care or health outcomes, accounts for an estimated 25% of total healthcare spending in the United States (US).[3,4] Medicare accounts for nearly one quarter of US health care spending ($1.03 trillion dollars in 2023) making it an important area for identifying and reducing waste.[5] The Medicare program is particularly vulnerable to wasteful spending due to the age and complexity of the Medicare population and their disproportionately high share of health care services spending compared to younger segments of the US population.[6] Additionally, the fee-for-service (FFS) payment structure under Original Medicare may further drive waste given the inherent incentive to bill higher volumes of services, including those that are unnecessary or inappropriate.[7]

Key areas contributing to wasteful spending include delivery of low-value care and fraudulent or abusive billing practices. Low-value care refers to services that have little or no clinical benefit, or services in which the risk of harm from the service outweighs its potential benefit.[8] Initiatives such as Choosing Wisely® work to increase awareness of low-value care health among health care providers and numerous efforts have been implemented by specialty societies, advocacy

[3] Speer M, McCullough JM, Fielding JE et al. Excess Medical Care Spending: The Categories, Magnitude, and Opportunity Costs of Wasteful Spending in the United States. Am J Public Health. 2020 Dec;110(12):1743-1748.
[4] Shrank WH, Rogstad TL & Parekh N. Waste in the US Health Care System: Estimated Costs and Potential for Savings. JAMA. 2019;322(15):1501–1509.
[5] Martin AB, Hartman M, Washington B, Catlin A. National Health Expenditures in 2023: Faster growth as insurance coverage and utilization increased. *Health Affairs*. 2024;44(1):12-22. doi:10.1377/hlthaff.2024.01375
[6] McGough M, Claxton G, Amin K, Cox C. How do health expenditures vary across the population? Peterson-KFF: Health System Tracker. 2024 Jan; retrieved from: https://www.healthsystemtracker.org/chart-collection/health-expenditures-vary-across-population/#Share%20of%20total%20population%20and%20total%20health%20spending,%20by%20age%20group,%202021
[7] Knickman, James R., John Marchica, and David C. Radley. "Health Care Financing, Costs, and Value." Jonas and Kovner's Health Care Delivery in the United States (2023): 257.
[8] Medicare Payment Advisory Commission. *Health Care Spending and the Medicare Program: A Data Book*. 2024. Retrieved from: www.medpac.gov/wp-content/uploads/2024/07/July2024_MedPAC_DataBook_SEC.pdf

groups, and health systems to reduce delivery of these services.[9,10] Nevertheless, MedPAC estimated Original Medicare spent between $1.9 to $5.8 billion on low-value services in 2022.[11]

Fraud and abuse can occur in any part of health care. Historically, areas where fraud and abuse have been frequently observed include diagnostic testing, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), genetic testing, hospice care, and laboratory testing.[12] Direct estimates of fraud within Original Medicare are difficult to calculate, but civil settlements and judgements on health care fraud under the False Claims Act in 2023 reached $1.8 billion in 2023.[13] Such levels of fraud and abuse undermine the integrity of the Original Medicare program, waste taxpayer dollars, and consume valuable medical resources. Additionally, these practices can inflict significant physical, financial, and emotional harm on beneficiaries. A 2019 study of Original Medicare claims data estimated that treatment by health care providers who were subsequently prosecuted for fraud and/or abuse contributed to as many as 6,700 premature deaths among Original Medicare beneficiaries.[14] Such findings indicate there is a significant opportunity to better address and prevent fraud and abuse and its negative impact on the health and well-being of beneficiaries and the fiscal sustainability of the Medicare program.

CMS and the Medicare Administrative Contractors (MACs) employ a variety of strategies to reduce FWA in Original Medicare. These include publication of National and Local Coverage Determinations (NCDs and LCDs, respectively) describing the requirements and limitations for Medicare coverage for specific medical services, procedures, or devices; operation of the Fraud Prevention System by CMS to identify FWA through predictive modeling and other algorithms; and implementation of prior authorization for some items, services and therapies. Prior authorization is a utilization management tool with which a healthcare provider requests provisional affirmation of coverage from a healthcare payer for review before a service is furnished to a patient and before a claim is submitted for payment.

Prior authorization is a complex topic, as existing efforts vary across Medicare Advantage plans and private payers, with varied perceptions of the process and its utility. On the

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[9]Choosing Wisely®: an initiative of the ABIM Foundation. https://www.choosingwisely.org/. Access April 28, 2025.
[10] https://www.choosingwisely.org/files/Choosing-Wisely-at-Five.pdf
[11] Medicare Payment Advisory Commission. *Health Care Spending and the Medicare Program: A Data Book*. 2024. Retrieved from: www.medpac.gov/wp-content/uploads/2024/07/July2024_MedPAC_DataBook_SEC.pdf
[12] US Department of Health and Human Services and US Department of Justice. *Annual Report of the Departments of Health and Human Services and Justice: Health Care Fraud and Abuse Control Program FY* 2023. 2024. Retrieved from: https://oig.hhs.gov/documents/hcfac/10087/HHS%20OIG%20FY%202023%20HCFAC.pdf
[13] US Department of Health and Human Services and US Department of Justice. *Annual Report of the Departments of Health and Human Services and Justice: Health Care Fraud and Abuse Control Program FY* 2023. 2024. https://oig.hhs.gov/documents/hcfac/10087/HHS%20OIG%20FY%202023%20HCFAC.pdf
[14] Nicholas LH, Hanson C, Segal JB et al. Association Between Treatment by Fraud and Abuse Perpetrators and Health Outcomes Among Medicare Beneficiaries. JAMA Intern Med. 2020;180(1):62–69.

provider/supplier side, a healthcare provider that furnishes care to patients across multiple payers may encounter different processes with different standards across those payers. On the beneficiary side, CMS is sensitive to concerns that the implementation of additional processes to reduce rates of low-value, fraudulent, or wasteful care in Original Medicare could be perceived as limitations on access to care.

Under Original Medicare, a prior authorization process is currently applied to a specific and limited set of services and items, including certain hospital outpatient department (OPD) services, repetitive, scheduled non-emergent ambulance transports (RSNAT), and certain DMEPOS items.[15] CMS implements this process under various initiatives, but evidence suggests implementing it has contributed to significant reductions in the amounts paid by CMS for the targeted services.[16] Additionally, evidence demonstrates that under the Medicare Prior Authorization Model for RSNAT, there was no adverse effect on quality of care or access to care – as measured by increased emergency service use, hospitalizations (including hospitalizations for complications of ESRD), or deaths – notwithstanding that some beneficiaries had been non-affirmed for RSNAT.[17]

Other payers often employ more extensive utilization management approaches compared to Original Medicare to reduce FWA, including requiring prior authorization for a more expansive set of services. Such approaches are likely key contributors to MA beneficiaries receiving 9.2 percent fewer low-value care services than Original Medicare beneficiaries.[18] Additionally, MA plans are working with third parties to leverage enhanced technologies, like artificial intelligence (AI), machine learning (ML), or algorithmic decision logic, to streamline and improve detection of FWA. Results from a 2025 National Association of Insurance Commissioners survey of health insurers in 16 states found 92 percent of respondents use, plan to use, or plan to explore using AI and ML and the vast majority (83 percent) are working with third party companies to incorporate AI and ML into their workflows.[19] These third-party companies offer technology solutions for a variety of payer workflows, with prior authorization workflows among the most common target.

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[15] CMS. Prior Authorization and Pre-Claim Review Initiatives. *CMS.gov.* https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives

[16] CMS. Prior Authorization and Pre-Claim Review Program Stats for Fiscal Year 2023. 2025. Retrieved from: https://www.cms.gov/files/document/pre-claim-review-program-statistics-document-fy-23.pdf

[17] Asher A, Contreary K, Haile G, and Coopersmith J. *Evaluation of the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport: Final* Report. 2021. Retrieved from: https://www.cms.gov/priorities/innovation/data-and-reports/2021/rsnat-finalevalrpt

[18] Boudreau E, Schwartz R, Schwartz AL, et al. Comparison of Low-Value Services Among Medicare Advantage and Traditional Medicare Beneficiaries. *JAMA Health Forum.* 2022;3(9):e222935.

[19] Humphreys M, Loogue S. "Update on the Artificial Intelligence (AI) / Machine Learning (ML) Surveys and Recommendations. Big Data AI Working Group Spring Meeting Materials. National Association of Insurance Commissioners. 2025. Retrieved from: https://content.naic.org/sites/default/files/national_meeting/Materials-Big-Data-AI-WG032625.pdf

CMS research identified over 30 companies offering technology-enabled solutions for utilization and revenue cycle management. Many of these companies currently use enhanced technology and technology-enabled platforms to administer their prior authorization processes to help with streamlining and shortening the time to a determination, or are planning to implement such platforms.

There is an opportunity to test enhanced prevention and detection of fraudulent, wasteful, and abusive service delivery to beneficiaries under Original Medicare through the adoption of processes and tools leveraged by the private sector, including MA plans. To that end, the WISeR model will focus on testing implementation of prior authorization and prepayment review for the specific selected items and services that would be performed by third party entities leveraging enhanced technologies, that would be paid under a novel payment approach where the model participants are compensated based on a share of averted expenditures. Further, the WISeR model would test: the speed and accuracy of new tech-assisted decision-making; the ability of participants to help patients navigate away from low-value or potentially unsafe treatments and towards clinically appropriate higher-value care through education and support to providers and suppliers; a novel payment approach that is based on paying WISeR participants a share of averted expenses in lieu of the traditional acquisition-based approach; and potential alignment with Medicare Advantage in terms of standardization, predictability, and transparency.

Evidence suggests prior authorization is an effective tool for reducing the delivery of and spending on targeted services. As previously mentioned, prior authorization initiatives under Original Medicare have observed reductions in spending on the targeted services. For example, the use of prior authorization for certain OPD services contributed to a decline from $51 million in the second half of 2019 to $35 million in the second half of 2023 in Medicare spending on blepharoplasty, botulinum toxin injection, panniculectomy, rhinoplasty, and vein ablation services, while maintaining a high accuracy rate.[20]

The evidence base for the use of enhanced technology in this space is nascent, but early signs of its positive impact are promising. It is estimated that AI has the potential to automate between 50 and 75 percent of the manual work involved with processing prior authorizations.[21] An example of the impact of this automation is related to the time required to process requests. Blue Cross Blue Shield of Massachusetts piloted an automated AI-enabled prior authorization tool for hip and knee procedures and reported 88 percent of requests were able to be

[20] CMS. Prior Authorization and Pre-Claim Review Program Stats for Fiscal Year 2023. 2025. Retrieved from: https://www.cms.gov/files/document/pre-claim-review-program-statistics-document-fy-23.pdf

[21] Al-Haque S, Khanna V, Mandal S, Rayasam M, Singh P. AI ushers in next-gen prior authorization in healthcare. *McKinsey & Company*. April 19, 2022. Retrieved from: https://www.mckinsey.com/industries/healthcare/our-insights/ai-ushers-in-next-gen-prior-authorization-in-healthcare

processed in real-time.[22] Another pilot explored the use of ML for prior authorization requests for lumbar spinal stenosis surgery and found the ML model had a high level of accuracy in predicting surgical recommendations compared to recommendations made by a group of physicians reviewing the same case.[23] These studies indicate AI and ML have the potential to increase the efficiency of the process and can be aligned with clinical coverage requirements.

Building on the existing CMS initiatives and the potential of incorporating enhanced technologies into these processes, the model will test the use of technology-enhanced prior authorization to ensure claims comply with Medicare documentation, coverage, payment, and coding requirements. This model will include voluntary participation by model participants with strong health technology expertise to implement the prior authorization process in Original Medicare for selected items and services in specific geographies. While not direct participants in the model, Medicare providers and suppliers furnishing selected items and services in specific geographies would be subject to prior authorization processes. WISeR will not change coverage of, or payment for, items and services in Original Medicare as prior authorization supports coverage and payment of items and services that are medically necessary.

The WISeR model's theory of change is that the implementation of prior authorization and prepayment review for selected items and services, performed by a third party (leveraging enhanced technologies) operating under a set financial arrangement can facilitate the navigation of beneficiaries away from low-value and other wasteful services that are commonly subject to FWA given that non-affirmation of payment for the planned service typically results in discussions between patients and providers for alternative pathways. In addition, the WISeR Model seeks to leverage the innovative, technology-enhanced approaches that exist in the MA and private payer space, potentially exceeding and improving Original Medicare's existing capacity and effectiveness at prior authorization.

3. Scope and Duration

The WISeR model will begin on January 1, 2026, and run for two three-year agreement periods, until December 31, 2031. The scope of WISeR will include select states in select MAC jurisdictions. The selected MAC jurisdictions for WISeR are JH, JL, JF, and J15, and the selected states are New Jersey (JL/Novitas), Ohio (J15/CGS), Oklahoma and Texas (JH/Novitas), and Arizona and Washington (JF/Noridian). CMS plans to select one model participant per included

[22] Blue Cross Blue Shield of Massachusetts. "Blue Cross Bllue Shield of Massachusetts Uses Artificial Intelligence to Speed Review Time, Automate Authorizations & Eliminate Administrative Costs." BCBS Massachusetts Newsroom. October 12, 2022. Retrieved from: https://newsroom.bluecrossma.com/2022-10-12-BLUE-CROSS-BLUE-SHIELD-OF-MASSACHUSETTS-USES-ARTIFICIAL-INTELLIGENCE-TO-SPEED-REVIEW-TIME,-AUTOMATE-AUTHORIZATIONS-ELIMINATE-ADMINISTRATIVE-COSTS

[23] De Barros A, et al. Determining Prior Authorization Approval for Lumbar Stenosis Surgery with Machine Learning. *Global Spine* J. February 8, 2023. Retrieved from: https://pmc.ncbi.nlm.nih.gov/articles/PMC11268295/

MAC jurisdiction. CMS may consider adding additional model participants, regions, and/or selected items or services in future years of the model depending on specific factors such as number of applicants or newly identified items or services.

4. WISeR Application and Participation Requirements

Application

Potential model participants that would like to participate in WISeR are required to submit an application at https://app.innovation.cms.gov/WISeR. CMS is not soliciting Letters of Intent (LOIs) from potential applicants. CMS will review completed applications against standardized criteria. Applications to participate in the model will be accepted on the basis of completeness and quality of answers. All WISeR applications must be submitted by 11:59 pm Eastern Daylight Time on July 25, 2025. CMS may not review applications submitted after the deadline.

Information regarding the WISeR application process will be available on the CMS Innovation Center website: https://www.cms.gov/priorities/innovation/innovation-models/wiser Questions that arise during the application process may be directed to WISeR mailbox: WISeR@cms.hhs.gov

Model applicants seeking to withdraw a completed application must submit an electronic withdrawal request to CMS via email to the WISeR mailbox (WISeR@cms.hhs.gov) prior to signing any agreements to participate. The request must be submitted as a PDF on the organization's letterhead and signed by an official authorized to act on behalf of the organization. It should include the applicant organization's legal name; the organization's primary point of contact; the full address of the organization; and a description of the reason for the withdrawal.

Eligibility Criteria

Model participants will be eligible to participate in WISeR if they meet the following eligibility requirements:

- Demonstrated ability to understand, interpret, apply, explain, and communicate regarding clinical coverage criteria derived from NCDs and LCDs, effectively work with payers on improving prior authorization processes, including the incorporation of enhanced technologies;
- Established processes for ensuring appropriate clinical expertise is incorporated into determinations and for ensuring that providers and suppliers have the ability to resubmit requests after non-affirmative decisions;
- Compliance with all applicable Federal data protection and security requirements including Federal Risk and Authorization Management Program (FedRAMP) certification and Federal Information Security Management Act (FISMA) requirements, and following

CMS Authority to Operate (ATO) guidelines for the connections established between the MACs and model participants;
- Compliance with HIPAA, including being able to serve as a HIPAA business associate to CMS and comply with the HIPAA Security Rule and certain provisions of the HIPAA Privacy and Breach Notification Rules, as well as other applicable privacy and security laws and CMS policies;
- Dedicated clinicians with relevant expertise and experience for the selected items and services to conduct medical reviews as appropriate; and
- Capability to offer back up options to advanced technologies, including processing requests through phone, fax, electronic portals, mail, etc.

Participation Requirements

Model participants will need to interface with the MACs and demonstrate specific capabilities to be selected for participation. CMS plans to accept one model participant per each selected MAC jurisdiction. CMS intends to accept model participants into the model based on their ability to meet the below participation requirements.

All approved model applicants will be required to sign an agreement with the CMS Innovation Center. Examples of participation requirements that may be included in the agreement governing WISeR Model participation may include the following:

- Ability to interpret and apply clinical coverage criteria derived from NCDs and LCDs;
- Use of enhanced technologies to improve the prior authorization process (i.e. artificial intelligence, machine learning, algorithmic decision logic, etc.)
    - Specifically, enhanced technologies may be used for affirmation.
    - For non-affirmed decisions, model participants must use human clinicians with relevant clinical expertise for the selected items and services for medical review.
- Established processes for ensuring appropriate clinical expertise are incorporated into prior authorization, for communicating affirmed and non-affirmed determinations to the providers/suppliers and MACs, and for ensuring that providers/suppliers have the ability to resubmit requests following non-affirmative decisions;
- Ability to conduct peer-to-peer clinical review of resubmitted requests, including discussion of evidence-based guidelines and navigation towards more clinically appropriate care if the prior authorization request is non-affirmed;
- Compliance with all applicable Federal data protection and security requirements including FISMA requirements, FedRAMP certification, CMS Information Systems Security & Privacy Policy (IS2P2), CMS Acceptable Risk Safeguards (ARS), CMS ATO Guidelines; compliance with the HIPAA Rules and other applicable privacy and security laws, as well as CMS's overarching privacy and security framework. A business associate relationship will be established with model participants which will be documented

through a valid BAA. The BAA delineates and restricts the authorized uses and disclosures of PHI by the business associate. A business associate may use or disclose PHI solely in accordance with the provisions of the BAA or as required by applicable law. The business associate is directly liable for compliance with the HIPAA Security Rule and certain provisions of the HIPAA Privacy and Breach Notification Rules, and must comply with the CMS Risk Management Handbook (RMH) Chapter 8 Incident Response requiring reporting of any data/security incident immediately, or within one hour of being made aware of an incident to the CMS Service Desk, by calling 1-800-562-1963 and the WISeR model team via the Help Desk.

- Compliance with applicable nondiscrimination requirements to avoid illegal discrimination based on disability, including Section 504 of the Rehabilitation Act of 1973.
- Access to dedicated clinicians with relevant expertise and experience to assist with prior authorization and conduct medical reviews, e.g., a board-certified orthopedic surgeon to review resubmissions related to knee arthroscopy;
- Capability to offer back up options to advanced technologies, including processing requests through phone, fax, electronic portals, mail, etc.;
- Streamline the process for clinicians and CMS, aiming to reduce administrative burden, and the ability to process valid requests in a timely manner;
- Report on quality measures and performance metrics as specified in Section 7 below;
- Ability to provide documentation that the model participant's ownership interest will not create a clear conflict of interest;
- Ability to disclose any and all relevant financial interests; any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; any outstanding debts owed to a Federal health care program, including any debts owed or to any agency of the federal government; whether any individuals employed by, or entities engaged by, the company are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; any instances of criminal conduct; and any instances of bankruptcy;
- Ability to establish a conflict of interest policy that applies to members of the WISeR participant's governing body which includes, but is not limited to, requiring each member of the governing body to regularly disclose relevant financial interests;
- Ability to establish a process to disclose and resolve any conflicts of interest that arise; and
- Prohibition on model participants selling items or services or engaging in any behavior to Medicare enrolled providers/suppliers to obtain prior authorization affirmations or non-affirmations.

5. Beneficiary and Provider/Supplier Involvement

Overview

Providers and suppliers in the model's selected geographic regions will submit prior authorization requests to the model participants (either directly or via the MACs) for certain selected items and services furnished to Original Medicare beneficiaries.

Beneficiary Involvement

Individual beneficiaries will not be assigned to a particular participant. However, beneficiaries who are enrolled in Original Medicare and are seeking with their healthcare provider to receive one of the items or services included in the model located in a selected region will be subject to the prior authorization process under the model.

Under this model, we will work to limit any adverse impact on beneficiaries and to educate beneficiaries and their caregivers (if applicable) about the process. If the provider or supplier receives a non-affirmed decision because the item or service was determined to not be medically necessary, the healthcare provider will be required to notify the beneficiary and issue an Advanced Beneficiary Notice of Non-coverage (ABN) prior to performing the item or service if it is expected that payment would be denied.

Beneficiaries will continue to have all applicable administrative appeal rights in Original Medicare.

Provider/Supplier Involvement

Any healthcare provider or supplier that furnishes and bills Part B selected items or services to beneficiaries in Original Medicare in the model's geographic regions will have the model process available to them.

Under this model, providers and suppliers in selected geographic regions who intend to furnish an included item or service will have the option to submit that item or service for prior authorization with the model participant for their region. Providers and suppliers may submit directly to the model participant or may submit via their MAC (who would route the request to the participant). Providers and suppliers may opt to not submit a request for prior authorization for a selected item or service. If the provider or supplier does not submit an included item or service for prior authorization and submits a claim for payment directly, that claim would be flagged by the MAC and routed to the participant for prepayment medical review, where the participant or MAC may request provider/supplier documentation to support the necessity of the care provided prior to paying the claim.

Furthermore, we are exploring implementation of "gold carding" which is a process to exempt compliant providers/suppliers from the prior authorization process and expanded pre-payment review processes. Such an exemption acknowledges providers'/suppliers' resource limitations and reduces burden for compliant providers while enforcing prior authorization for aberrant billers, meeting our fiduciary obligation to protect the Original Medicare Trust Funds. We would likely leverage and align with existing exemptions policies in place for the CMS' OPD prior authorization program. A provider/supplier would be exempt from prior authorization if they achieve a prior authorization provisional affirmation threshold of 90 percent during a periodic assessment, thereby demonstrating a sufficient understanding of the requirements for submitting an accurate claim; 100percent compliance is not necessary as there could be unintentional or sporadic errors that could occur that are not deliberate and/or a result of issues out of the provider's/supplier's control. We would withdraw an exemption if evidence became available, based on a review of claims, that the provider/supplier has begun to submit claims that are not payable based on Original Medicare's billing, coding, or payment requirements during a periodic assessment.

Providers and suppliers will continue to have all applicable administrative appeal rights in Original Medicare.

6. Prior Authorization Process and Selected Items and Services

Process

Starting January 1, 2026, a provider or supplier in a model test region that plans to furnish a selected item or service to a beneficiary in Original Medicare will have the option of submitting a prior authorization request to either the model participant assigned to the provider's and supplier's test region or the MAC that they usually work with, which the MAC would then route to the model participant. The provider or supplier will submit all relevant documentation to support Original Medicare coverage of the selected items or services (as dictated in statute, regulation, NCD, or LCD) along with the prior authorization request.

Of note, the provider or supplier is not required to submit a prior authorization request for a selected item or service and may choose not to engage in the prior authorization process for a selected item or service. In the event that a provider or supplier does not submit a prior authorization request for a selected item or service, the claim for said item or service would be subject to pre-payment medical review where the participant or MAC may request provider documentation to support the necessity of the care provided prior to paying the claim. Providers typically have 45 calendar days to respond to MAC documentation requests with the total review process varying from weeks to months. Documentation requests from model

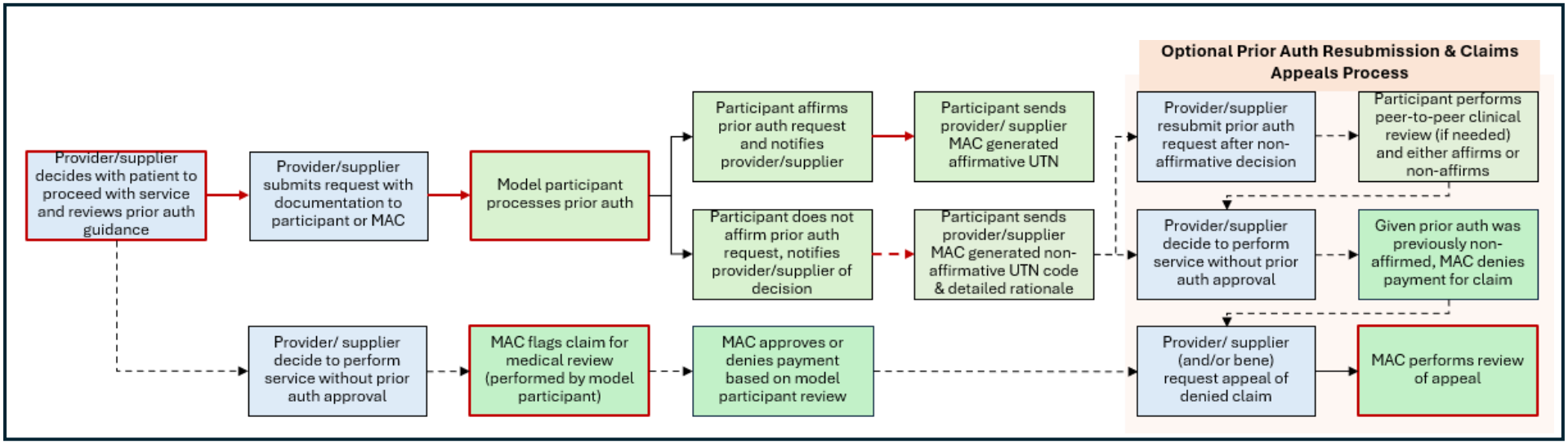
participants will have equivalent allowed response times as documentation requests from MACs.

After receiving a prior authorization request, either directly from the provider/supplier or routed through the MAC, the model participant will then conduct the prior authorization review. A human clinician with relevant clinical expertise for selected items and services must review every non-affirmation determination, although this requirement does not apply to affirmations. To be provisionally affirmed, the request for prior authorization must meet all applicable rules and policies, including any NCD or LCD requirements. A provisional affirmation is a preliminary finding that a future claim submitted to Original Medicare for the service likely meets Original Medicare's coverage, coding, and payment requirements. Claims for which there is an associated provisional affirmation decision will be paid in full, so long as all of the applicable Medicare coverage and clinical documentation requirements are met, and the claim was billed and submitted correctly. After receipt of all relevant documentation, a timely decision will be made, and the model participant will provide notification to the MAC, the provider/supplier, and to the beneficiary. A provider/supplier may request an expedited review when the model's standard timeframe for making a prior authorization decision could jeopardize the life or health of the beneficiary. Since we plan to initially target nonemergent services only, we expect requests for expedited reviews to be extremely rare.

If a prior authorization request is non-affirmed and the item or service has yet to be provided or billed, the provider or supplier will have unlimited opportunities to resubmit the request. When resubmitting the request to the model participant or MAC, the provider or supplier will have the opportunity to request a peer-to-peer review to inform the new determination. A non-affirmed prior authorization decision does not prevent the provider/supplier from furnishing the item or service and submitting a claim. Submission of a claim with a non-affirmed prior authorization decision and subsequent denial by the MAC would constitute an initial payment determination which would be subject to administrative appeals (See 42 C.F.R. part 405, subpart I).

While the model participant would take on most of the requirements of the prior authorization process for this model, the MACs would still need to be included in this process to assist with front-end provider communication and outreach, receiving and routing prior authorization requests and documentation, and performing claims appeals and billing operations, including generating affirmative and/or non-affirmative unique tracking codes, etc. Please see Figure 1 for a visual flow chart of the anticipated prior authorization process under WISeR.

Figure 1: Prior Authorization Process Flow Chart



Selected Items and Services

The WISeR model's impact on care delivery will be focused on implementing prior authorization for a selected set of items and services, but it will not impact the actual care processes of delivering that item or service after an affirmation is made. The WISeR model will be implemented for particular items and services in phases that fulfill certain criteria described below. To streamline implementation, the model will start with a limited set of items and services in its initial performance year – allowing all parties involved to work through operational and integration activities – before expanding to additional items or services in future years.

Service/Item Selection Criteria

The selection of items and services for inclusion in the WISeR model is a key component of the model's design. The Innovation Center considered multiple factors when selecting items and services for inclusion, to balance across several policy goals, provider/supplier concerns, and operational feasibility. Key principles that govern item/service selection for the model include:

Leveraging Existing Evidence

Prior authorization is a complex topic, as existing efforts vary across MA plans and private payers, with varied perceptions of the process and its utility. CMS considered inclusion of items and services that are already subject to prior authorization by other payers, including MA plans, which will help promote multi-payer alignment.

Similarly, we have included items and services that have existing publicly available coverage requirements specified in statutes, regulations, NCDs, or LCDs. The availability of existing coverage requirements helps support the policy goal of ensuring clinically appropriate care is delivered, thereby reducing the provision of services that are considered inappropriate or unnecessary. The model will prioritize including items and services that have national coverage criteria, e.g., an NCD. If an NCD does not exist for an item or service, the model will use LCDs that have been implemented more broadly across the country by MACs. For selected services with LCDs, the selected service would only apply to regions with an active LCD in place, e.g., skin and tissue substitutes would be a selected service only in selected regions with an active skin and tissue substitute LCD in place.

Clinical guidelines and literature, as used in development and/or cited in the NCD or LCD, as well as internal and external stakeholder discussions, also informed the selection of items and services. Where possible, items and services were chosen to align with generally defined low-value care as described in literature[24] and initiatives, such as the American Board of Internal

[24] Schwartz AL, Landon BE, Elshaug AG et al. Measuring Low-Value Care in Medicare. *JAMA Intern Med*. 2014;174(7):1067-1076.

Medicine Foundation's Choosing Wisely® campaign aimed at promoting more evidence-based care.

Patient Safety

Patient safety is a key concern for CMS in two ways. First, one of the motivating factors behind the model would be to ensure more clinically appropriate care is being delivered, thereby reducing the provision of services that may be potentially low-value and inappropriate to beneficiaries in Original Medicare. Beneficiaries who undergo a medically unnecessary service or procedure may experience avoidable harm, particularly if it is an invasive surgery or procedure.[25] As mentioned above, we will address this policy goal by considering services have existing publicly available coverage criteria, including extant regulations, NCDs, or LCDs.

Second, the implementation of WISeR could have negative consequences for beneficiaries if the process delays or prevents medically necessary care. As such, we are seeking to exclude items or services that could pose a risk to the patient if care is delayed. To prevent delays in medically necessary care, included items and services ideally are elective (non-emergent), do not occur solely in the inpatient setting, and would not be generally first line diagnostics or treatments for a medical condition.

Furthermore, we aim to target standalone services to reduce the operational complexity associated with managing frequent repetitive services, e.g., weekly physical therapy visits, or multiple related prior authorization requests ("bundling"), e.g., in oncology (a care plan can often have genetic testing, chemotherapy, radiation oncology, surgery, etc.), for which prior authorization may inhibit care.

Opportunity

As described earlier, WISeR builds on a limited number of existing programs in Original Medicare. We are not selecting items or services that are already subject to prior authorization or pre-claim review under an existing Original Medicare program to avoid redundancy. In certain cases, the items and services chosen for this model will augment or complement existing requirements in Original Medicare.

Similarly, we are focusing on selecting items and services that are of sufficient volume or dollar value to be impactful, supporting the feasibility of the model test. The cost of the item or service should be greater than the cost associated with performing a prior authorization request for the item or service, and sufficient volume is needed to ensure adequate power, evaluability, and impact. Data analytics on utilization and spending of potential items or services have also

[25] Chalmers K, Gopinath V, Brownlee S et al. Adverse Events and Hospital-Acquired Conditions Associated With Potential Low-Value Care in Medicare Beneficiaries. *JAMA Health Forum*. 2021;2(7):e211719.

informed selection with the goal of targeting services with the highest impact to produce cost savings.

Lastly, we reviewed reports and investigations exposing areas of fraud, waste, including low-value care, and abuse in Original Medicare. A few specific services with NCDs and LCDs were chosen if they were a known source of potential waste or have been defined as low-value care in literature. Other chosen services could be vulnerable to FWA, especially if they tend to be more costly, elective services that are not first-line and may have limited evidence.

Furthermore, given the desire to leverage enhanced technology in this model, some items/services selected would be more amenable to automation and require less manual, medical review to complete affirmations.

Items and Services Included in Performance Year 1

The following table shows the items and services planned for initial inclusion.

Table 1: Items and Services Planned for Initial Performance Year (subject to change) *

Service Category (with 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)
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 (L39741, L39762, L39793) *Excluding codes already included in OPD*
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 Lumbar Spinal Stenosis (NCD 150.13)
Skin and Tissue Substitutes • Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041) • Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (L36690)

*The final list of services included in the model's initial performance year will be included in the agreement the model participant signs with CMS. This model will align with any changes made to the NCDs or LCDs by CMS or the MACs, e.g., implementation of the new proposed LCDs related to skin and tissue substitutes. As mentioned earlier, skin and tissue substitutes would be a selected service only in selected regions that have an active skin and tissue substitute LCD in place.

7. Performance Measurement

In order to preserve or enhance the quality of care in line with statutory obligations, and to ensure that Original Medicare beneficiaries continue to receive timely, high-quality care, CMS will assess the impact of WISeR on quality of care, including clinical outcomes and the quality of care furnished to individuals. We expect that the implementation of technology-enhanced prior authorization by WISeR participants will benefit the Original Medicare beneficiaries in selected geographies by reducing the provision of low-value or harmful services in a manner inconsistent with Medicare coverage criteria. Consequently, we expect that beneficiaries will be more likely to receive safer, more effective, or higher-value alternatives to the selected items and services.

Under the auspices of the WISeR Model implementation, CMS will assess the quality of the prior authorization processes implemented by model participants, gather data on provider/supplier and beneficiary experience, and monitor changes in downstream clinical outcomes that could be impacted by reductions in the selected items and services. Below, we provide additional details regarding these three key quality domains. Additionally, the impact of WISeR on the quality of care will be further assessed via the model evaluation, which is described in Section 11.

Process Quality

As model participants implement their processes for prior authorization and medical review, determinations must be timely and consistent with Original Medicare coverage criteria. High-quality processes promote the timely delivery of medically appropriate services to beneficiaries, while low-quality processes could potentially result in negative consequences for beneficiaries (e.g., delayed or forgone care) and for Medicare (e.g., improper payments). In order to minimize these risks and hold model participants accountable for the efficiency and accuracy of their processes, CMS will adjust payments to model participants (see Section 8) for performance on a set of process quality measures. Favorable performance on these metrics will be necessary in order to receive the full payment amount described in Section 8; unfavorable performance will result in downward adjustments to model payments and could potentially result in corrective action as further described in Section 10.

One of the process quality measures will be based on audits monitoring participants' compliance with Original Medicare coverage criteria when making determinations. Audit results indicating a high rate of improper determinations will result in downward adjustments to the quality score and may also result in corrective action (see Section 10). In addition to conducting regular audits, CMS would measure process quality using data collected from model participants and other administrative sources (e.g., MACs), such as prior authorization request volume, processing time, and affirmations/non-affirmations; frequency and outcomes of resubmissions; suitability of model participants' documentation; frequency at which providers

or suppliers provide and bill non-affirmed items or services and appeal claim denials; and the outcomes of such appeals. To the extent feasible, we will seek to align our metrics with those used by MA plans and other private payers to assess procedural efficiency.

Provider/Supplier and Beneficiary Experience

While providers, suppliers, and Original Medicare beneficiaries will not be model participants, it is essential to assess the impact of WISeR on the entities and individuals interacting with the model. Prompt, clear communication from the model participant to providers or suppliers regarding prior authorization request submissions, determinations, and rationales would minimize provider burden associated with WISeR and should also minimize delays or disruptions in the provision of covered items and services to beneficiaries. To this end, CMS will either field or require model participants to field a questionnaire assessing experiences of providers, suppliers, and beneficiaries engaging with WISeR participants' processes. This survey will be modeled after satisfaction surveys and questionnaires commonly used within health care (e.g., Press Ganey surveys) and include question categories focused on ease of submitting requests, clarity of requirements concerning information and documentation to be included in the request, timeliness of response, and clarity of the reasons for the determination (i.e., affirmation or non-affirmation). If participants ultimately field the survey, they may have discretion over some operational decisions (e.g. the survey mode). However, as select measures from the survey will contribute to the quality score used to adjust model payments, CMS would require the inclusion of certain content to ensure comparable and rigorous quality assessment across all model participants.

Clinical Quality Outcomes

To assess the impact of the model on clinical quality, CMS will monitor broad clinical outcomes that could be impacted by the reduction in the delivery of the model's selected items and services. Given the diversity in the clinical areas represented in the items and services selected, assessing quality for each item or service area is infeasible, especially as validated quality measures are not available for all selected items and services. Instead, the model will include measures of clinical outcomes that are further downstream in the care delivery pathway. Examples of quality measures that may be assessed include indicators that a clinical issue targeted by the model's selected items or services persists, such as use of relevant alternative services (e.g., increase in surgery or new prescriptions for pain medications due to prior authorization non-affirmation of selected pain management services). Further downstream, CMS may assess outcomes such as rates of adverse events, unplanned hospitalizations, emergency department utilization, or mortality. This broader approach to assessing quality allows for a more parsimonious set of measures while still assessing the impacts of the model on quality on a broad scale.

8. Payment Design

Payment Design

Payments to WISeR model participants will be based on the demonstrated reductions in spending for medically unnecessary or non-covered services, as defined by the Original Medicare LCD or NCD. For each of the selected items and services, a participant will receive a percentage of the reduction in expenditures, or savings, that can be directly attributed to the prior authorization review process in their applicable region. These savings will be calculated from requests that did not result in a paid claim (i.e., non-affirmations not followed by an affirmed resubmission or a successfully appealed claim denial), multiplied by the average claim-level payments for historical regional claims submitted with the applicable item(s)/service(s) during the prior 12 months (adjusted for performance year pricing). The use of total claim payments in the savings calculation (as opposed to claim-line payments for the eligible CPT®/HCPCS codes) is intended to accurately depict the total revenue impact, including secondary or add-on services that are regularly billed and reimbursed along with the primary procedure or service codes.

Initially, model participants will receive model payments for non-affirmations that were not subsequently resubmitted and affirmed during the initial 120-day window. A model participant will only be paid for one non-affirmation involving the same beneficiary, item/service, and provider/supplier within a period of 120 calendar days. For instance, if a provider/supplier resubmitted a request twice within 120 days of an initial non-affirmation and neither resubmission was affirmed, the model participant would receive a single payment for the series of non-affirmations, not three separate payments. Payments for non-affirmations will be held for up to one year if the associated request is resubmitted, to ensure that the initial non-affirmation was upheld in the subsequent determination(s). In the event that a provider/supplier performs and bills for a non-affirmed item or service and successfully appeals the denial of the associated claim, the model payment associated with that record will be clawed back from the participant once the claim payment is processed.

As detailed above, model payments will be based on a percentage of the observed cost savings that can be directly attributed to prevention of medically unnecessary or non-covered items or services. Additionally, payments will be subject to an annual quality adjustment based on an aggregated score of the participant's performance across each of the defined quality metrics. As poor-quality performance will result in downward adjustment of model payments, this adjustment will be critical in enforcing the defined quality metrics and minimizing any adverse incentives related to WISeR participation.

Finally, given that WISeR participants will make determinations based on the same coverage criteria that are currently available and used by the MACs to assess medical necessity and

coverage, it is likely that a portion of the savings attributed to WISeR participants would otherwise have been captured by the MACs during prepayment reviews or post-payment audits. To account for this counterfactual, the Innovation Center will utilize historical claims data (pre-implementation) by item/service and region to determine the baseline medical necessity denial rate. This baseline rate will then be applied as a discount to the total savings attributed to each record. For example, if three percent of claims for a selected item or service were historically denied by the MACs for medical necessity reasons, the cost savings attributed to each prevented item or service will be reduced by three percent.

9. Data Reporting and Sharing

Data Sharing Requirements

A business associate relationship will be established between CMS and the model participants which will be documented through a valid business associate agreement (BAA) that complies 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). Currently, MACs also function as business associates to CMS's Medicare Fee-for-Service health plan. CMS would develop the WISeR model's data sharing policies in compliance with all relevant HIPAA Rules and guidance applicable to the use and disclosure of PHI, as well as CMS's overarching privacy and security framework, and all other applicable federal and state laws and regulations. CMS's privacy and security policies will govern data sharing between the model participants, the MACs, and providers/suppliers in the affected geographic regions. Model participants will be required to have access to the Federal Risk and Authorization Management Program (FedRAMP) certified workflows, follow Federal Information Security Management Act (FISMA) regulations, follow CMS Information Systems Security & Privacy Policy (IS2P2), follow CMS Acceptable Risk Safeguards (ARS), follow CMS Authority to Operate guidelines, and enter into HIPAA BAAs with FFS Original Medicare and/or the MACs, as applicable, among other privacy and security requirements. Model participants must also follow the CMS Risk Management Handbook (RMH) Chapter 8 Incident Response, which requires reporting any data/security incident immediately, or within one hour, of being made aware of an incident to the CMS Service Desk, by calling (1- 800) 562-1963 and to the WISeR model team. Model participants would be required to comply with all of these requirements and to align with any changes to the program requirements throughout the model performance period.

Data sharing with providers

Providers and suppliers will receive data from the model participants or the MACs, depending on the route of submission the provider or supplier selects, in the form of the affirmation or non-affirmation of each request. CMS will provide instructions to the model participants as to the specific data that should be collected from providers and suppliers and the data that should

be included in communications back to the provider and supplier. The communication of data with providers and suppliers will occur in accordance with the HIPAA Rules and other applicable privacy and security laws, as well as CMS privacy and security policies. Providers and suppliers will not receive any other WISeR model-related data.

Data reporting to CMS

Under 42 C.F.R. § 403.1110(b), CMS will require model participants to report data metrics for monitoring and evaluation purposes related to their prior authorization processes. These metrics may include, but are not limited to, the number of affirmations and non-affirmations, time taken to reach a decision, the number of resubmissions requesting a re-review to reverse the initial determination, and instances where the model participant reverses an initial non-affirmation after re-evaluating the prior authorization request and determining that the initial decision should have been affirmed. CMS will provide a template for model participants to use when reporting these data to CMS. Model participants will also be required to report to CMS the data collected via the provider/supplier and beneficiary experience surveys they will be required to administer. The model participants' communication of data with CMS will need to occur in accordance with the HIPAA Rules and other applicable privacy and security laws, as well as CMS privacy and security policies.

10. Participation Monitoring, Auditing, and Termination Strategy

The Innovation Center will closely monitor the model throughout its duration. The purpose of monitoring is to ensure the model is implemented safely and appropriately, and that adequate patient and program integrity safeguards are in place. The Innovation Center will ensure that model participants have built or are building the capacity and infrastructure to implement the prior authorization process in an efficient and improved manner that follows all guidelines and that access to care is not negatively impacted.

The following principles guide the WISeR model's monitoring strategy:

- **Protecting beneficiaries from harm**. Prevent and mitigate potential model-related activities that may put at undue risk the health and safety of beneficiaries. This includes ensuring that WISeR Model participants are not increasing non-affirmations for clinically appropriate, medically necessary items or services that could cause harm to beneficiaries. CMS would require participating models to report data metrics for monitoring and evaluation purposes related to their processes. These metrics may include, but are not limited to, the number of affirmations and non-affirmations, time taken to reach a decision, the number of resubmissions requesting a re-review to reverse the initial determination, and instances where the model participant reverses an initial non-affirmation after re-evaluating the prior authorization request and determining that the initial decision should have been affirmed.

- **Technology regulation.** Ensure model participants are complying with all regulatory requirements that promote interoperability while implementing WISeR. All model participants would need to align with and support the applicable provisions of the CMS Interoperability and Prior Authorization final rule (CMS-0057-F) including use of API technology meeting the technical requirements and HHS-adopted data standards specified in the rule, notice obligations to providers and suppliers concerning determinations, mandates for payers to respond to requests within specified timeframes, and requirements to publicly disclose metrics related to their processes to promote transparency.[26] Safeguards would be put in place such that the prior authorization process is not solely conducted by enhanced technology and that rigorous clinical oversight is conducted for non-affirmations.
- **Ensuring program compliance**. Ensure that WISeR participants comply with the terms of the model.

CMS may conduct comprehensive annual audits to model participants related to compliance with the participation agreement and more limited targeted or ad-hoc audits as necessary. This includes requiring and auditing data submitted by WISeR participants on their model operations, quality metrics (as outlined in section 7), and annual attestations confirming program compliance.

Noncompliance with the agreement terms and Medicare standards will be associated with appropriate remedial actions including but not limited to: participant education; requesting a corrective action plan (CAP) detailing how the WISeR participant will rectify a violation; withholding or denying model payments; and termination from the model. Generally, noncompliance will trigger appropriate actions based on the type of issue, severity of the noncompliance, and the participant's compliance record while in the model. All such CMS actions will have associated procedures.

CMS reserves the right to terminate a WISeR participant's participation at any time during the term of the model for reasons associated with poor performance, program integrity issues, non-compliance with the terms and conditions of the model agreement, or as otherwise specified in the model agreement or required by section 1115A(b)(3)(B) of the Social Security Act.

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[26] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Process for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program. 89 FR 8758. February 8, 2024. Retrieved from: https://www.federalregister.gov/documents/2024/02/08/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability

11. Evaluation

All participants will be required to cooperate with CMS efforts to conduct an independent, federally funded evaluation of the model, which may include completion of surveys and participation in interviews, site visits, and other activities that CMS determines necessary to conduct a comprehensive evaluation. The evaluation results will be used to inform CMS about the potential for the model to meet statutory requirements for expansion under 1115A authority, including the impact of the model on total cost of care and quality.

12. Authority to Test the Model

To implement this model, the Innovation Center will leverage its section 1115A waiver authority to ensure CMS' ability to conduct prior authorization on items and services not currently included under existing prior authorization requirements in Original Medicare. Section 1115A of the Social Security Act (the Act) authorizes the Secretary to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care furnished to Medicare, Medicaid and Children's Health Insurance Program beneficiaries. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain requirements of Titles XI and XVIII of the Act and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

For this model, consistent with this standard, we will consider waiving sections 1834(a)(15) and 1869(h) of the Act that limit our ability to conduct prior authorization. While these provisions are specific to durable medical equipment and physician services, we would consider waiving in our model test any portion of these sections as well as any portion of 42 C.F.R. § 410.20(d), which implements section 1869(h) of the Act, that could be construed to limit our ability to conduct prior authorization.

We have determined that the implementation of this model does not require the waiver of any fraud and abuse law, including sections 1128A, 1128B, and 1877 of the Act. Thus, providers and suppliers affected by this model must comply with all applicable fraud and abuse laws.

13. Merit-Based Incentive Payment System (MIPS) Alternative Payment Model (APM) and Advanced APM Status

This model is not expected to qualify as an Advanced APM or as MIPS APM. Given this model would neither directly impact the payment for the items and services selected for the model in

the event that requests are affirmed and the items and services performed, nor hold clinicians directly accountable for costs or quality of the selected items and services, the model would not meet the Quality Payment Program's requirements to qualify as an Advanced Alternative Payment Model and would not impact providers' MIPS status or associated reporting requirements.

14. Program Overlaps and Synergies

WISeR is not a Shared Savings model. There is no beneficiary alignment to this model. This model does not hold participants accountable for the total cost of care. There are no rules in the model that govern how providers can participate or how providers can participate in other models. There are no rules in the model that govern how beneficiaries can participate or how beneficiaries can participate in other models.

We do not anticipate prohibiting entities that participate in WISeR from participating in other models, nor do we anticipate prohibiting entities that participate in other models from participating in WISeR.

This model would not include changes to claims payment rules, but rather would enhance enforcement of existing payment rules, and as such would not impact the payment mechanisms of other models. However, as described in Section 8, the WISeR payment methodology would account for expenditures that would have been averted in the absence of the model based on regular MAC processes.

15. Application Template

The Wasteful and Inappropriate Services Reduction (WISeR) Application Template

Thank you for your interest in participating in the Center for Medicare and Medicaid Innovation's Wasteful and Inappropriate Services Reduction (WISeR) Model. This application template is intended for use by prospective model participants interested in applying to the model.

The PDF version of this application is for reference only. Applicants interested in submitting an application are required to submit their application using the WISeR Application Portal. A link to the application can be found here: https://app.innovation.cms.gov/WISeR. Submission of the PDF version of this application will not be accepted.

All WISeR applications must be submitted by 11:59 pm Eastern Daylight Time on July 25, 2025. The Centers for Medicare & Medicaid Services (CMS) may not review applications submitted after the deadline.

Refer to the Request for Applications (RFA) on the Innovation Center website [https://www.cms.gov/priorities/innovation/innovation-models/wiser] for further details regarding participation requirements and application submission criteria. Applications will be reviewed for completion of all required fields and a signed and dated application certification.

CMS will safeguard the information provided in accordance with the Privacy Act of 1974, as amended (5 U.S.C. § 552a). For more information, please see the CMS Privacy Policy at https://www.cms.gov/privacy. CMS provides no opinion on the legality of any contractual or financial arrangement that the applicant may disclose, propose, or document in this application. The receipt by CMS of any such information in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules, or regulations, and will not preclude CMS, HHS, the HHS Office of Inspector General, a law enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules, and regulations.

For questions regarding WISeR or the WISeR application process, email WISeR@cms.hhs.gov

Applicant Information

1. Legal Name of Applicant:

   The legal entity identified here as the applicant must be the same legal entity that would execute a contractual agreement with CMS upon acceptance into the model.

2. Doing Business As (DBA) Name(s) (if different from Legal Name):

3. Where is your organization located?

   Provide street address, city, and state for all locations

4. Taxpayer Identification Number (TIN):

5. Which of the following best characterizes your company or organization?
   i. Not-for-profit organization (non-academic)
   ii. Not-for-profit academic or research institution
   iii. For-profit business
   iv. Other (explain)

6. Briefly describe your company/organization's general function and purpose, including, but not limited to mission/values, services, and clientele.

7. Please indicate which MAC jurisdiction(s) your organization would prefer to operate in?
   i. JH Novitas
   ii. J15 CGS
   iii. JL Novitas
   iv. JF Noridian

Ownership Interest

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

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

Contact Information

Primary Point of Contact (POC)
Name:
POC Title:
POC Street Address:
POC City:
POC State:
POC ZIP Code:
POC Phone: Extension:
POC Email:

Secondary Point of Contact (POC)
Name:
POC Title:
POC Street Address:
POC City:
POC State:
POC ZIP Code:
POC Phone: Extension:
POC Email:

Tertiary Point of Contact (POC)
Name:
POC Title:
POC Street Address:
POC City:
POC State:
POC ZIP Code:
POC Phone: Extension:
POC Email:

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

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

Individual or entity	Federal, State, or Tribal Agency or Licensing Body	Description of Infraction (including date)	Resolution Status (including date)

For reference, enforcement actions include criminal, civil, or administrative legal actions relating to fraud and other alleged violations of law, initiated or investigated by the Health and Human Services Office of Inspector General and its law enforcement partners.
Failure to disclose any of the information described above could be grounds for application denial or, if selected for participation in WISeR, immediate termination from the model.

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

Narratives

1. Describe your experience working with Medicare Advantage plans, or other payers, on prior authorization. What Medicare Advantage plans or other health insurance plans has the company worked with and what functions did/does the company perform for the plan(s)?

2. Describe your experience with health care-specific data, including experiences with and knowledge in applying prior authorizations, pre-payment reviews, and implementing coverage determinations set by health care plans and/or CMS (e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs)). Describe your experience with administrative claims data from CMS or other payers/plans.
    a. Be specific in any experience interfacing with Medicare Administrative Contractors (MACs).
    b. Does your company or organization have any authorizations or certifications to monitor compliance with data security standards with federal agencies (e.g., Federal Risk and Authorization Management Program (FedRAMP)? Please provide documentation of any relevant authorizations or certifications.
    c. How does your company or organization monitor and monitor compliance with the HIPAA Privacy, Security, and Breach Rules, if applicable, and other privacy and security laws? Please also describe your response plan in the event of a data incident or breach.

3. Describe your clinical experience in medical reviews for coverage determinations and peer-to-peer reviews for resubmissions. Describe your company/organization's arrangement or staffing structure to access dedicated clinicians with relevant experience and expertise to conduct medical reviews to support clinically sound coverage determination decisions.

4. Describe your company's integration with Electronic Health Record (EHR) platforms to deploy prior authorizations.
    a. Please also include a list of EHR platforms your application or suite is compatible with.
    b. Briefly describe your company's ongoing or future plans to support payers and the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) including, but not limited to, use of Application Programming Interface (API) technology meeting the technical requirements and HHS-adopted data standards specified in the rule, increased data sharing, and reducing overall payer, healthcare provider, and patient burden through improvements to prior authorization practices and data exchange practices.

5. Describe your experience in training Artificial Intelligence (AI) and/or Machine Learning ML) models on complex data sets and coverage determinations, including the type of data utilized for training purposes. Describe the AI algorithm(s) and framework(s) you plan to use to implement WISeR for the selected items and services in conjunction with the MACs. Describe how your company/organization's approach and AI tools or software will uniquely meet the goals of WISeR, particularly in improving the use of technology to streamline the prior authorization process for patients, providers, and payers.
    a. Describe your approach to verify, validate, secure and regulate your company's enhanced technology software to ensure ethical and high-quality utilization management metrics are met.
    b. Describe how your company/organization's approach, tools, and software will manage potential adverse effects of automation and AI.

6. Does your company or organization have any earned accreditations or certifications in acknowledgement to commitment to quality in health care services (e.g., The National Committee to Quality Assurance (NCQA), Utilization Review Accreditation Commission (URAC))? If yes, please provide documentation of relevant accreditations or certifications. Be sure the expiration or renewal date in included in this documentation.

7. Please describe your company/organization's approach to ethics, compliance, and quality standards to ensure the safety, ethics, and partnership support for patients, providers, and payers.
    a. Please provide any details related to approaches and quality assurance to utilization management decision making, complaints and grievances, claims billing, and claim dispute issues.
    b. Please provide any details related to approaches to ensure compliance with state and federal regulations.

8. Please provide a brief savings estimate your company/organization expects in relation to the selected items and services and geographic regions/MAC jurisdictions included in WISeR.

9. Please provide a timeline and implementation plan including internal actions required for readiness to interface with MACs and access sensitive Medicare beneficiary data, in accordance with HIPAA and other applicable privacy and security laws.

APPLICATION CERTIFICATION: I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.

Company/Organization Name:

Certifying Individual (Please Print):

Title:

Signature: _____ Date: