

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-5056-N]

Medicare Program; Implementation of Prior Authorization for Select Services for the

Wasteful and Inappropriate Services Reduction (WISeR) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and

Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces a 6-year model focused on reducing fraud, waste (including low-value care), and abuse in Medicare fee-for-service (FFS) via the implementation of technology-enabled prior authorization processes for select services.

DATES: This notice is effective on January 1, 2026.

FOR FURTHER INFORMATION CONTACT: Kate Blackwell (844) 711-2664, Option 8 or

WISeR@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. 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 percent of total health care spending in the United States (U.S.).^{1,2} Medicare accounts for nearly one quarter of U.S. health care spending (\$1 trillion in 2023) making it an important target for identifying and reducing waste.³ The Medicare program is particularly vulnerable to wasteful spending due to the age and complexity of the Medicare population and

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.

³ 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

their disproportionately high share of health care spending compared to younger segments of the U.S. population.⁴ Additionally, the Medicare fee-for-service (FFS) payment structure may further drive waste given there is an inherent incentive in some cases for fraudulent actors to bill higher volumes of services, including those that are unnecessary or inappropriate.⁵

Key areas contributing to wasteful spending include fraudulent or abusive billing practices, as well as the delivery of services that have little or no clinical benefit, or services in which the risk of harm from the service outweighs its potential benefit.⁶ Additionally, these practices can inflict significant physical, financial, and emotional harm on beneficiaries. A 2019 study of 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 Medicare FFS beneficiaries.⁷ Such findings indicate there is a significant opportunity to better address and prevent fraud, waste, and abuse (FWA) and its negative impact on the health and well-being of beneficiaries and the fiscal sustainability of the Medicare FFS program.

The Centers for Medicare & Medicaid Services (CMS) and the Medicare Administrative Contractors (MACs) employ a variety of techniques to reduce FWA in Medicare FFS. These include publication of National and Local Coverage Determinations (NCDs and LCDs, respectively) describing the evidence-based requirements and limitations for Medicare coverage for specific medical services, procedures, or devices. Generally, prior authorization is a utilization management tool in which a health care provider requests provisional affirmation of coverage from a health care payer before medical service is furnished to a beneficiary and before a claim is submitted for payment.

⁴ 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

⁵ Knickman JR. Marchica J, and Radley DC. "Health Care Financing, Costs, and Value." Jonas and Kovner's Health Care Delivery in the United States (2023): 257.

⁶ 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

⁷ 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.

Under Medicare FFS, providers and suppliers submit a request for prior authorization (also known as pre-claim review, depending on the service type and the timing of the submission) for a limited set of specific services⁸ to their MAC. The MAC then reviews the prior authorization request based on the associated Medicare requirements such as those found in NCDs and LCDs and provides a decision, which can be either a provisional affirmation or nonaffirmation. CMS has implemented prior authorization in Medicare FFS under specific and limited initiatives, and evidence suggests doing so for these services has contributed to significant reductions in the amounts paid by CMS for these targeted services.⁹ In an effort to reduce provider burden, these initiatives do not change any medical necessity or documentation requirements. Additionally, evidence demonstrates that under the Medicare Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT), there was no adverse effect on quality of care or access to care- as demonstrated by increased emergency service use, hospitalizations (including hospitalizations for complications of end stage renal disease (ESRD)), or deaths – notwithstanding that some beneficiaries had been non-affirmed for RSNAT.¹⁰

Other payers, including Medicare Advantage (MA) plans, often employ more utilization management approaches to reduce FWA, including requiring prior authorization for a more expansive set of services. Additionally, some MA plans have prior experience 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. This work is done with certain guardrails in place. For example, 42 CFR 422.566(d) requires that an adverse medical necessity decision related to a prior authorization request must be reviewed by a

⁸ 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

⁹ 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

¹⁰ 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

physician or other health care professional with appropriate expertise before the MA plan issues the decision.

CMS conducted market research from various different MA organizations that had experience with enhanced technology-enabled prior authorization processes. The research indicated significant reductions in the decision time to prior authorization determination, particularly for affirmed prior authorization requests. Some MA plans reported decision time to prior authorization approval being almost instantaneous for services with very clear clinical coverage criteria. As a result, CMS is exploring findings from MA plans regarding enhanced technologies to examine how to efficiently, accurately, and appropriately ensure select services are provided and paid for based on clinical and evidence-based guidelines.

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 such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) of the Act 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 waive such provisions of 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 will waive any portion of these sections as well as any portion of 42 CFR 410.20(d), which implements section 1869(h) of the Act, and 42 CFR 414.234, which implements section 1834(a)(15) of the Act, that could be construed to limit our ability to conduct prior authorization for other items or services or that could be construed to restrict what entity performs said 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.

II. Provisions of the Notice

A. Model Specifications

We plan to implement a 6-year model test (the Wasteful and Inappropriate Services Reduction (WISeR) Model), in two 3-year agreement periods, with companies that have experience implementing technology-enhanced prior authorization with other payers, including MA plans, as model participants. Under the model, participants will implement and streamline prior authorizations to ensure that select services that are provided and paid for are clinically appropriate, evidence-based, and consistent with Medicare FFS requirements. We envision that implementing the review process while leveraging enhanced technologies would identify when such services are medically unnecessary, that model participants will support providers and suppliers in navigating beneficiaries towards more clinically appropriate or higher value care when appropriate and will streamline the prior authorization process for providers and suppliers.

This model will be tested in 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), Ohio (J15), Oklahoma and Texas (JH), and Arizona and Washington (JF).). These MAC jurisdictions and states were selected based on various evaluability and operational criteria. Evaluability criteria included: (1) MAC jurisdictions that allow for within-MAC comparisons between test and comparison states; (2) selected states with adequate volume to provide sufficiently precise impact estimates; (3) MAC jurisdictions with skin and tissue substitute LCDs to assess effectiveness, as well as one MAC jurisdiction without existing skin and tissue substitute LCDs to increase generalizability¹¹; and (4) geographic diversity. Operational criteria used for geographic selection included: (1) MAC jurisdictions that have existing skin and tissue substitute LCDs; and (2) states that also meet the evaluation criteria and have the highest volume

¹¹ Not all MAC jurisdictions have an active skin and tissue substitute LCD in place at this time. Skin and tissue substitutes are a selected service in WISeR only in states and MAC jurisdictions that have an active skin and tissue substitute LCD in place.

of services by highest historical claim paid amount. The model will begin on January 1, 2026, in the selected states.

The WISeR model will focus on testing the implementation of prior authorization and pre-payment review for specific selected services that will 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 technology-assisted decision-making; WISeR participants' ability to help patients navigate away from low-value or potentially unsafe treatments and towards clinically appropriate higher-value care through provider/supplier education; 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 MA in terms of standardization, predictability, and transparency. We plan that model participants will use a technology-assisted prior authorization process to help ensure that all relevant clinical and medical documentation requirements are met before services are rendered to beneficiaries and before claims are submitted for payment, and to help navigate patients towards alternatives when appropriate. This process will further help ensure that claims comply with existing Medicare documentation, coverage, payment, and coding requirements.

In general, this model will require the same information and clinical documentation that is already required to support Medicare FFS payment but earlier in the process, namely, prior to the service being furnished. Prior authorization allows providers and suppliers to address potential issues with claims prior to rendering services, including potentially navigating beneficiaries to more effective or appropriate alternative care, and reduces the likelihood that a furnished service is not covered. Implementing a process that leverages enhanced technology will streamline the claim review and adjudication process. The model will not change payment or coverage for the selected services in the model.

Beginning January 1, 2026, the prior authorization process under this model will be

implemented in the selected states on the following items and services with affiliated NCDs or LCDs:

- 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 excluding facet joint injections

(L39015, L33906, L39036, L39240, L39242, L36920, L38994, L39054)

• Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture

(VCF) (L33569, L34106, L34228, L38201, L34976, L35130, L38737, L38213)

• Cervical Fusion (L39741, L39799, L39770, L39758, L39762, L39793, L39773,

L39788)

- Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee (NCD 150.9)
 - Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea (L38276, L38307,

L38398, L38387, L38310, L38312, L38385, L38528)

- 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 (LCDs below) – only applicable to MAC jurisdictions and

states that have an active LCD in place

++ Application of Bioengineered Skin Substitutes to Lower Extremity Chronic

++ Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (L36690)

We selected these services based on several factors. We considered for inclusion services for which there is existing evidence of potential FWA, including alignment with definitions and evidence around services defined as low-value by Schwartz et al.;¹² concerns around and prior reports^{13, 14} of fraud, waste, and abuse from the Department of Health and Human Services' (HHS) Office of Inspector General (OIG), Department of Justice (DOJ), the Medicare Comprehensive Error Rate Testing (CERT) program, and other sources; and services already subject to prior authorization in MA at the time. We considered patient safety concerns, including both excluding services that are inpatient only, or pose a substantial risk to patients if services are delayed. We also considered for inclusion services where opportunity exists to support the model test, including services with publicly available NCDs or LCDs, and cost savings opportunity. CMS may add additional services in future years.

Prior to the start of the model and throughout the duration of the model, we will conduct outreach and education to Medicare-enrolled providers and suppliers, beneficiaries, and the model participants through such methods as open-door forums, frequently asked questions (FAQs) on our website, other website postings, and educational materials issued by the MACs. Traditionally, utilization management tools such as technology-enabled prior authorization are widely used in the MA and commercial payer space but applied in limited cases in the Medicare FFS program. For this reason, the WISeR model would ensure that there is rigorous communication and education between the MACs and the model participants to seamlessly interface with one another, reduce health care provider burden, and avoid Medicare beneficiary

 ¹³ HHS Office of the Inspector General. "Medicare Part B Payments for Skin Substitutes." HHS OIG Work Plan. Available at: https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000894.asp
¹⁴ HHS Office of the Inspector General. "Audits of Medicare Payments for Spinal Pain Management Services." HHS OIG Work Plan. Available at: https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000583.asp

¹² Schwartz, A.L., Landon, B.E., and Elshaug, A.G. (2014). Measuring Low-Value Care in Medicare. JAMA Intern Med. 174(7):1067-1076. doi:10.1001/jamainternmed.2014.1541

harm. Additional information about the WISeR model is available on the CMS website [https://www.cms.gov/priorities/innovation/innovation-models/wiser].

B. Prior Authorization Process Under WISeR

Under the WISeR model, a Medicare-enrolled provider/supplier will have the opportunity to submit a request for prior authorization to either the MAC or the model participant,¹⁵ along with documentation to support Medicare coverage of a selected service included in the model as defined in the statute, regulation, NCD and/or LCD. After receipt of this documentation, the model participant will be required to make every effort to conduct a review and notify the provider/supplier of their decision on a prior authorization request within the timeframe specified by CMS for an initial submission. Submitting a prior authorization request will be voluntary; however, if the provider/supplier does not submit a request, their claim will be subject to prepayment medical review by model participants that may involve requests for documentation to support the medical necessity of the targeted item or service (see Scenario 3 for further details).

To be provisionally affirmed, the request for prior authorization must meet all applicable coverage, coding, and documentation requirements found in statutes, rules, NCDs, and LCDs for the select service. A provisional affirmation is a preliminary finding that a future claim submitted to Medicare for the service likely meets 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 are met, and the claim was billed and submitted correctly.

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. Requests for expedited review will need to include justification for why the standard timeframe would not be appropriate. If the MAC or model participant determines that the request

¹⁵ The model participant would be required to offer options for providers and suppliers to submit prior authorization requests that would be consistent with standardized submission approaches recognized by CMS, including an electronic portal.

does not substantiate the need for an expedited review, they will provide notification that the request will not be expedited and communicate a decision within the regular timeframe. As we plan to initially target nonemergent services only, we expect requests for expedited reviews to be extremely rare.

For a non-affirmed request where the service has yet to be provided and a claim has yet to be submitted, the provider/supplier has unlimited opportunities to resubmit a prior authorization request to the model participant or MAC. When resubmitting the request to the model participant or MAC, the provider or supplier would have the opportunity to request a peerto-peer review to inform the new determination. A non-affirmed prior authorization decision does not prevent the provider/supplier from submitting a claim. However, submission of such a claim would be denied by the MAC and would constitute an initial determination, which would be subject to the administrative appeals process. The existing claims appeals process would not change under the model. See 42 CFR part 405, Subpart I. This would be a further opportunity to challenge the coverage decision.

The following describes how WISeR will address three potential scenarios under the model:

Scenario 1: A Medicare-enrolled provider/supplier submits a prior authorization request to the model participant. The model participant will make a decision of affirmation or nonaffirmation based on its review of the prior authorization request and relevant supporting documentation. If the model participant determines provisional affirmation, then the model participant will provide notification to the provider/supplier and coordinate with the MAC to generate a unique tracking number (UTN) to inform payment determination when the claim is submitted. The provider/supplier will need to include the UTN on the claim when billing for applicable services. If the model participant determines a non-affirmative prior authorization, they will provide the provider/supplier with a detailed reason for the non-affirmative decision and work with the MAC to generate an UTN that is associated with the non- affirmative decision. After reviewing the information provided, the provider/supplier should consider if there is additional documentation or other rationale that could address the non-affirmation decision and can resubmit the prior authorization request an unlimited number of times. If a claim with a non-affirmed prior authorization request is submitted, the MAC will deny the claim. The provider/supplier may then appeal the claim denial with the MAC under existing appeals procedures.

Scenario 2: A Medicare-enrolled provider/supplier submits a prior authorization request to the MAC. When the MAC receives the prior authorization request and supporting documentation from the provider or supplier, the MAC will route the prior authorization request to the model participant to conduct the prior authorization. After that, the same process as outlined in scenario 1 will be followed.

Scenario 3: A Medicare-enrolled provider or supplier performs a selected service without requesting prior authorization. As noted previously, submitting a prior authorization request is voluntary. In this scenario, the provider or supplier submits the claim to the MAC without seeking prior authorization. The MAC then flags the claim for pre-payment medical review to be performed by the model participant; the model participant would request documentation from the provider/supplier to support medical necessity for the claim. After receipt of all relevant documentation, the model participant will conduct a medical review, which could include leveraging technology and clinician review, and communicate the decision to the MAC. The MAC will then process the claim in accordance with the model participant's decision. If the claim is denied for payment, the provider/supplier and beneficiary may request an appeal and will have full administrative appeal rights. This appeal would follow the existing Medicare FFS claim appeal process.

Under the model, we will work to avoid any adverse impact on beneficiaries or providers/suppliers and to educate stakeholders about the model. We will hold model participants accountable for the accuracy and timeliness of prior authorization determinations through quality adjustments to model payments and we will also monitor for downstream impacts on quality and outcomes. If a prior authorization request is not affirmed, and the claim is still submitted by the provider or supplier, the claim will be denied and the providers/suppliers as well as beneficiaries will retain their administrative appeal rights.

CMS is also 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 Medicare Trust Fund. We would likely leverage and align with existing exemptions policies in place for the CMS' OPD prior authorization program. A provider/supplier could 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. Under such an approach, 100 percent compliance may not be necessary as there could be unintentional or sporadic errors that could occur that are not deliberate or a result of issues out of the provider's/supplier's control. We could withdraw an exemption if evidence became available, based on a review of claims, that the provider/supplier had begun to submit claims that are not payable based on FFS Medicare's billing, coding, or payment requirements during a periodic assessment.

Given the model participants in WISeR will be third-party entities, CMS privacy and security policies will govern data sharing under the model. Model participants will be required to comply with all applicable data privacy and security laws, including relevant provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules (45 CFR parts 160 and 164, subparts A through E) (HIPAA Rules). By performing prior authorization functions on behalf of the Medicare FFS health plan that involve protected health information (PHI), the model participants will be serving as business associates (see 45 CFR 160.103). A business associate relationship will be established between CMS's Medicare FFS health plan and the model participants which will be documented through valid business associate agreements (BAA) that comply with the requirements of the HIPAA Privacy Rule (see 45 CFR 164.502(e) and 164.504(e)). Currently, MACs also function as business associates to CMS's Medicare FFS health plan. CMS will develop the WISeR model's data sharing policies in compliance with the HIPAA Rules and all relevant HIPAA guidance applicable to the use and disclosure of PHI, as well as CMS's overarching privacy and security framework, and other applicable federal laws and regulations.

Additional information is available on the WISeR website at https://www.cms.gov/priorities/innovation/innovation-models/wiser .

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act, as added by section 3021 of the Affordable Care Act, states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of such models under this section. Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Dr. Mehmet Oz, having reviewed and approved this document, authorizes Chyana Woodyard who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard, Federal Register Liaison, Centers for Medicare & Medicaid Services. [FR Doc. 2025-12195 Filed: 6/27/2025 4:15 pm; Publication Date: 7/1/2025]