United States Senate

WASHINGTON, DC 20510–6200

September 18, 2025

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Abe Sutton
Deputy Administrator and Director of
CMMI Centers for Medicare & Medicaid
Services
7500 Security Boulevard Baltimore,
Maryland 21244

Dear Administrator Oz and Director Sutton:

We write to express our alarm regarding the recently announced Wasteful and Inappropriate Service Reduction (WISeR) Model, released by the Center for Medicare and Medicaid Innovation (CMMI) on June 27, 2025. We support CMS's goals to improve value, reduce unnecessary spending, and modernize the Medicare program. Like you, we are eager to root out genuine waste, fraud, and abuse in the Medicare program. The WISeR demonstration, however, raises significant concerns that merit reconsideration of the model.

We fear that the approach of this demonstration will put up roadblocks for patients seeking necessary care using technology like artificial intelligence (AI) that Americans do not want involved in health care decisions. This amounts to importing the most unpopular elements of Medicare Advantage, namely the frequent use of prior authorization, into Traditional Medicare. As such, we urge CMS to halt implementation of this demonstration until a full analysis of the program's impact on patient access is conducted that includes input from beneficiaries and their families, consumer and patient advocates, health care providers, and suppliers. This analysis is needed to assure the program in no way undermines the Medicare guarantee.

Under the WISeR model, participants are third-party vendors who will use artificial intelligence (AI) to determine whether patients in Traditional Medicare would be covered for certain procedures. Although described as a voluntary model, WISeR is functionally mandatory for health care providers and suppliers operating in the six selected states: New Jersey, Ohio, Oklahoma, Texas, Arizona, and Washington. Clinicians that do not submit prior authorization requests for the selected services will face mandatory pre-payment medical reviews, adding administrative burden and potential care delays for people with Traditional Medicare. By classifying the model as voluntary, CMMI circumvented the traditional notice and comment

rulemaking process. This approach allowed CMS to fast track the model implementation without public input, despite the significant change to the Traditional Medicare program.

Additionally, many of the services identified as "low value" in the WISeR model have already undergone rigorous coverage review through the national or local coverage determinations, along with Food and Drug Administration (FDA)'s "safety and effectiveness thresholds," making it unclear why additional authorization steps are needed. Importantly, CMS already has established mechanisms within Traditional Medicare to protect program integrity, including pre-claims review in which providers can submit a request and receive the decision prior to claim submission; without denying or delaying patients' needed care.[1] Independent analyses find prior authorization protocols similar to those employed by Medicare Advantage plans delay care and deny necessary care, and increase burden on providers.[2] Expanding these burdens into Traditional Medicare risks harming millions of older adults: more than four in five physicians reported that patients abandon treatment due to authorization challenges with insurers.[3] Further, introducing duplicative and untested requirements risks confusing providers and patients alike, while undermining trust in Traditional Medicare.

The WISeR model's burden on physicians and other health care providers is immense, particularly for those working in small or marginalized or low-income settings. The model permits health care providers to request peer-to-peer reviews and resubmit denied authorizations; these seemingly well-intentioned safeguards simply create more work for clinicians. Most important is the lack of clarity this demonstration provides about how beneficiaries will be notified, supported, or protected if prior authorizations are denied. Without strong patient-centered protections and appeals guidance, the model could unintentionally restrict access to necessary care.

The previous Administration engaged in extensive rulemaking to reform prior authorization processes in Medicare Advantage, both to minimize patient and provider burden and place additional constraints on insurers. This Administration seemingly shares these goals, having sought voluntary commitments from insurers to address prior authorization concerns.[4] Yet, the

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1 Centers for Medicare & Medicaid Services. 2025. *Prior Authorization and Pre-Claim Review Program Statistics for Fiscal Year 2023*. Washington, DC: U.S. Department of Health and Human Services. Accessed September 8, 2025. https://www.cms.gov/files/document/pre-claim-review-program-statistics-document-fy-23.pdf

2 Office of Inspector General. 2022. *OEI-09-18-00260: Complete Report*. April. Washington, DC: U.S. Department of Health and Human Services. Accessed September 8, 2025. https://oig.hhs.gov/documents/evaluation/3150/OEI-09-18-00260-Complete%20Report.pdf

3 American Medical Association. 2025. "Physicians Concerned AI Increases Prior Authorization Denials." February 24. Accessed September 8, 2025. https://www.ama-assn.org/press-center/ama-press-releases/physicians-concerned-ai-increases-prior-authorization-denials

4 Centers for Medicare & Medicaid Services; U.S. Department of Health and Human Services. 2025. "HHS Secretary Kennedy, CMS Administrator Oz Secure Industry Pledge to Fix Broken Prior Authorization System." June 23. Washington, DC. Accessed September 8, 2025. https://www.cms.gov/newsroom/press-releases/hhs-secretary-kennedy-cms-administrator-oz-secure-industry-pledge-fix-broken-prior-authorization

WISeR model introduces these same burdens and new prior authorization mandates in a space that has existing coverage determination processes, including pre-payment review. Further, the WISeR model was developed without clear evidence, patient centered principles, and input from affected groups and their advocates, namely patients, providers, suppliers and states.

Under WISeR, third-party vendors will be responsible for reviewing prior authorization requests.[5] These vendors will employ artificial intelligence (AI) tools along with clinical review to determine medical necessity.[6] The deployment of AI tools to determine prior authorization requests has led to spikes in denial rates in the past: even with humans left in the loop, increased denials happened in part because reviewers were incentivized to strictly adhere to the tools' recommendations.[7] This risk for such bias in WISeR seems high given that participants/vendors will "*only* be compensated if they reduce wasteful, inappropriate care, receiving a percentage of the savings associated with their reviews."[8] This creates a financial conflict of interest and raises serious concerns about clinical oversight, accountability, and transparency in the AI tools used to determine medical necessity.

In light of the above, we urge CMS to stop implementation of the WISeR model to allow for formal notice and comment rulemaking and meaningful engagement of all affected groups. We also ask for CMS to evaluate the WISeR model's potential impact on provider burden and patient care access, particularly in rural and underserved areas and clarify oversight mechanisms for the third-party vendor, including transparency in AI decision making and appeals process. To that end, please respond to the following questions by November 1, 2025:

1. What criteria did CMS use to select New Jersey, Ohio, Oklahoma, Texas, Arizona, and Washington for participation in the WISeR model?
    a. Please detail how CMS conducted outreach to states which are required to participate, and how did CMS assess each selected state's readiness to implement the WISeR model, particularly regarding provider infrastructure, claims systems, and patient access.
    b. What steps is CMS taking to monitor and address any disproportionate impacts on providers or beneficiaries in the selected states/regions?

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5 Centers for Medicare & Medicaid Services. 2025. "WISeR (Wasteful and Inappropriate Service Reduction) Model." Accessed September 8, 2025. https://www.cms.gov/priorities/innovation/innovation-models/wiser

6 https://www.cms.gov/priorities/innovation/innovation-models/wiser

7 United States Senate, Permanent Subcommittee on Investigations. 2024. *Majority Staff Report on Medicare Advantage Insurers' Refusal of Care for Vulnerable Seniors*. Washington, DC. October 17. Accessed September 12, 2025. https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf (US Senate PSI 2024, 4, 23).

8 Centers for Medicare & Medicaid Services, *WISeR Model Frequently Asked Questions* (Washington, DC: U.S. Department of Health and Human Services, 2025), accessed September 8, 2025, https://www.cms.gov/priorities/innovation/files/document/wiser-model-frequently-asked-questions Emphasis added.

2. Section 1871of the Social Security Act calls for notice-and-comment rulemaking for changes to any substantive condition of payment. Please explain why notice-and-comment rulemaking was not followed for the WISeR model, and how CMS is working with physicians who are effectively required to participate in the six selected states.
3. Please describe the following regarding CMS's collaboration with participants on AI:
    a. What types of AI tools will CMS accept from participants? What are possible use examples of AI tools currently in use by private companies to explain the types of technology CMS is soliciting as part of WISeR?
    b. How will WISeR work with participants as they update and/or improve their tool over time?
    c. What transparency and oversight mechanisms will CMS adopt to ensure that vendor use of AI in medical necessity determinations is accurate, accountable, and unbiased?
    d. Does CMS have an AI governance framework or group? If so, what are its key values, inputs, and components? If such a framework or group does exist, how is it applied to the development and deployment of AI tools through WISeR?
    e. How will CMS ensure that AI tools used in WISeR are independently validated, free from discriminatory or harmful algorithmic bias, automation bias, and subject to public reporting of their accuracy, appeals outcomes and retraining protocols?
    f. Automation bias is typically defined as the uncritical acceptance of an AI-driven suggestion or decision. How are model participants, physicians, and patients in selected states empowered to fight automation bias and, when relevant, dispute the output of an AI system?
    g. Which safety measures will CMS require to ensure that patient data used by vendors including data processed by AI tools remain fully HIPAA compliant and/or prevent misuse or unauthorized secondary use of patient information?
    h. Are there other companies who use participants' AI tools? If so, for whom and which population groups (Medicare, commercial, etc.)?
4. What kind of support and training for participants will be provided by CMS, in particular case managers and physician medical reviewers?
5. How will CMS support beneficiary questions? Will the State Health Insurance Assistance Programs, or SHIPs, be trained to provide support to beneficiaries subject to WISeR?
6. What safeguards will CMS establish to guarantee that AI determinations under WISeR cannot override sound clinical judgement? How will CMS ensure that human clinical reviewers retain ultimate authority in disputed cases?
7. How will the CMS Regional Offices work with beneficiaries and health care providers, state governments to provide support and address questions related to WISeR?
8. How does CMS plan to structure vendor compensation to avoid perverse incentives that reward denial of care, and how will CMS hold participants financially accountable when denial rates exceed reasonable thresholds?

9. Will CMS confirm that an approved prior authorization under WISeR constitutes a binding guarantee of payment for services provided as authorized and medically necessary, with no risk of retroactive denials or recoupments?
10. What assessment has CMS conducted of the additional administrative burden WISeR will place on providers, specifically small, rural and underserved practices and will that analysis be made public?
11. What specific timelines will CMS require for expedited and standard prior authorization requests under WISeR and how will CMS ensure that these timelines align with clinical best practices and protect beneficiaries from harmful delays in care?
12. How will Medicare beneficiaries be notified and supported if their prior authorization requests are denied and what safeguards will CMS implement to ensure access to medically necessary care is not delayed or denied?
13. How will CMMI track access to care for people with Traditional Medicare?
14. Please provide a list of all Medicare Advantage Organizations (MAOs) or vendors who also contract with MAOs that are selected as participants in WISeR.

CMS should be a responsible steward of taxpayer funds, and we are aligned with the agency's stated goal to root out waste, fraud, and abuse across federal health care programs. Yet, we believe all CMMI models must be implemented in a transparent, evidence-based, and patient-centered manner. The WISeR model as currently designed risks undermining those goals and imposing significant new burdens on beneficiaries who need treatment and already busy clinicians without adequate engagement and safeguards.

We urge CMS to reconsider not proceeding with the WISeR demonstration. We look forward to your timely response to the questions outlined above which are critical to ensuring that WISeR does not undermine access to necessary care, compromise patient protections or place undue burdens on providers.

Sincerely,

Ron Wyden
United States Senator
Ranking Member, Committee on Finance

Kirsten Gillibrand
United States Senator
Ranking Member, Special Committee on Aging

Richard Blumenthal
United States Senator
Ranking Member, Permanent
Subcommittee on
Investigations

Bernard Sanders
United States Senator

Mark R. Warner
United States Senator

Elizabeth Warren
United States Senator

Jeffrey A. Merkley
United States Senator

Tammy Baldwin
United States Senator

Jack Reed
United States Senator

Jeanne Shaheen
United States Senator

Patty Murray
United States Senator

Cory A. Booker
United States Senator

Sheldon Whitehouse
United States Senator

Tina Smith
United States Senator

Ruben Gallego
United States Senator

Andy Kim
United States Senator

Tammy Duckworth
United States Senator

Amy Klobuchar
United States Senator