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RE: Opposition to Implementation of the WISeR Model in Medicare Fee-for-Service

Dear Dr. Oz and Mr. Sutton:

On behalf of the Regulatory Relief Coalition (RRC), we write to express our strong concerns about the Centers for Medicare & Medicaid Services' (CMS) implementation of the Wasteful and Inappropriate Service Reduction (WISeR) Model in the Medicare Fee-for-Service (FFS) program. The RRC is a coalition of national physician specialty organizations seeking to reduce regulatory burdens that interfere with patient care. Our recent activities focus on ensuring that utilization review policies are not a barrier to timely and necessary access to care for the patients we serve.

Implementation of the WISeR Model is completely inconsistent with the Administration's commitment to reducing the administrative burden of federal regulatory and other administrative requirements. The overwhelming evidence is that prior authorization (PA) imposes extraordinary administrative burdens on providers and significantly interferes with the efficient delivery of healthcare services to patients, including Medicare beneficiaries enrolled in Medicare Advantage. For example, a physician survey conducted by RRC found, among other things, that:

- Eighty-two percent of respondents state that PA always (37%) or often (45%) delays access to necessary care;
- Wait times can be lengthy: For most physicians (74%), it takes between 2 to 14 days to obtain PA, and for 15%, this process can take 15 to more than 31 days;
- Thirty two percent (32%) of respondents report that patients often abandon treatment and 50% report that patients sometimes abandon treatment;
- Overwhelmingly (87%), physicians report that PA has a significant (40%) or somewhat (47%) negative impact on patient clinical outcomes;
- The burden associated with PA for physicians and their staff is high or extremely high (92%); and
- Ultimately, most services are approved, with one-third of physicians getting approved 90% or more of the time.



Another recent national medical group practice survey¹ found the following:

- 89% of medical practices find PA "very or extremely burdensome."
- 92% of medical practices "hired or redistributed staff to work on PA due to the increase in requests."
- 83% of practices said a top challenge is PA for routinely approved items and services.
- 97% of medical practices reported that patients "experienced delays or denials for medically necessary care due to prior authorization requirements."

Thus, the available evidence indicates that PA is among the most burdensome of administrative processes imposed by payers on providers. In light of this evidence, we believe that implementation of the WISeR Model clearly contradicts the Administration's goal to put patients over paperwork. In fact, CMS recently urged private insurers to commit to a set of actions intended to *reduce* the use of PA.² The implementation of the WISeR Model altogether negates these efforts.

In addition, we question the legality of the WISeR Model. There is no general authority for PA in Medicare FFS, and PA historically has not been used in Medicare FFS without explicit statutory authorization.³ Section 1395(hh) of the Medicare Act specifically provides:

No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the <u>Secretary</u> by regulation.

To the extent that the WISeR Model clearly changes a substantive legal standard regarding the payment for services, it is inconsistent with this statutory mandate unless implemented through regulation.

Moreover, Congress has specifically addressed the requirements that must be met for any "voluntary" request for a prior determination with regard to physicians' services. Under Section 1869(h)(1)(B)(i), a physician who chooses to submit a request for a prior determination must obtain the consent of the beneficiary, and, under Section 1869(h)(2) the Secretary is required to establish criterion regarding which services are eligible for prior determination "by regulation." Perhaps most importantly, Section 1869(h)(6)(B)(ii) states: "Failure to seek a prior determination under this subsection with respect to physicians' service shall not be taken into account in [the administrative or judicial review of a claim for the service subsequently submitted by the physician." By contrast, under the proposed WISER demonstration, if a physician fails to request PA for a service subject to the demonstration project, any subsequent claim filed by the physician is subject to special prepayment medical review. In light of the detailed statutory provisions governing voluntary prior determination for physicians' services, we believe that implementation of the WISER program as currently proposed poses serious legal issues.

¹ See https://www.mgma.com/getkaiasset/423e0368-b834-467c-a6c3-53f4d759a490/2023%20MGMA%20Regulatory%20Burden%20Report%20FINAL.pdf.

² These include, for example, limiting the scope of claims subject to prior authorization, providing simple explanations and easy-to-access assistance for prior authorization determinations, and guaranteeing that PA denials based on medical necessity for clinical factors are reviewed by a qualified clinician. *Health Plans Take Action to Simplify Prior Authorization*. AHIP. June 23, 2025. https://www.ahip.org/news/press-releases/health-plans-take-action-to-simplify-prior-authorization.

³ For example, 42 U.S.C. § 1395m(a)(15) was enacted specifically to allow for prior authorization in the program only for durable medical equipment, prosthetics, orthotics, and supplies. {D1188964.DOCX / 5 }

We are also extremely concerned about those provisions of the WISeR Model under which participating third-party vendors are to be paid based upon the volume or amounts of the claims they deny. This payment mechanism provides a clear financial incentive for such vendors to deny PA for medically necessary services, jeopardizing Medicare patients' access to critical medical and related facility services. The Medicare Anti-Kickback Law strictly prohibits the payment of incentives to induce overutilization of Medicare services; we believe that the payment of incentives to deny care is equally unjustifiable outside the managed care context, which is subject to regulatory limits. We note that the Medicare Act specifically precludes "qualified independent contractors" that are engaged to reconsider initial determinations made by Medicare contractors, from being compensated in a manner that is "contingent on any decision rendered by the contractor or by any reviewing professional." Contractors that preauthorize payment of claims, as well as those that review initial determinations, should be precluded from receiving compensation based on their decisions. The integrity of the claims review process depends on this precedent.

Finally, we do not believe that the WISeR Model includes sufficient transparency, accountability, and oversight mechanisms to ensure that stakeholders have any real insight into how PA determinations are made. It is critical that, if CMS moves forward with this model, it should establish transparency requirements necessary to ensure that algorithms are not used to obfuscate denials of medically necessary care and should put in place a mechanism for regular audits of participating vendors.

For these reasons, we strongly urge CMS to reconsider implementation of the WISeR Model in the Medicare FFS program and to instead focus on reforming and streamlining PA requirements, thereby eliminating existing barriers to the delivery of medically necessary services to all beneficiaries.

Sincerely,

American Academy of Neurology
American Academy of Ophthalmology
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Rheumatology
American Gastroenterological Association
American Osteopathic Association
Association for Clinical Oncology
Congress of Neurological Surgeons
Medical Group Management Association
The Society for Cardiovascular Angiography and Interventions

cc: Stephanie Carlton

Deputy Administrator and Chief of Staff Centers for Medicare & Medicaid Services

Chris Klomp
Deputy Administrator and Director
Center for Medicare

⁴ See 42 CFR Section 422.208. {D1188964.DOCX / 5 }