



Decision

Matter of: U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services—Applicability of the Congressional Review Act to Notice Implementing the Wasteful and Inappropriate Services Reduction (WISeR) Model

File: B-337994

Date: May 12, 2026

DIGEST

On July 1, 2025, the U.S. Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) issued a notice announcing the implementation of the Wasteful and Inappropriate Services Reduction (WISeR) Model, a new process to be used in six states to evaluate whether claims for certain medical items and services comply with Medicare requirements (WISeR Model Notice or Notice).

The Congressional Review Act (CRA) requires that before a rule can take effect, an agency must submit the rule to both the House of Representatives and the Senate, as well as the Comptroller General. CRA adopts the definition of a rule under the Administrative Procedure Act (APA) but excludes certain categories of rules from coverage. We conclude that the WISeR Model Notice is a rule for purposes of CRA because it meets the APA definition of a rule, and no CRA exception applies. Among other things, the WISeR Model Notice prescribes new requirements for Original Medicare providers in selected states by mandating prior authorization or pre-payment medical review of claims for certain services. Given the nature of the changes and because they could potentially affect the determinations made on claims for the selected services, we conclude that the Notice substantially affects the rights and obligations of non-agency parties, specifically providers and beneficiaries of those services. Therefore, the Notice is a rule subject to CRA's submission requirements.

DECISION

On July 1, 2025, the U.S. Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) issued a notice announcing the

implementation of the Wasteful and Inappropriate Services Reduction (WISeR) Model,¹ a new process to be used in six states to evaluate whether claims for certain medical items and services comply with Medicare requirements.² We received a request for a decision as to whether the implementation of the WISeR Model is a rule for purposes of the Congressional Review Act (CRA).³ As discussed below, we conclude that the WISeR Model Notice is a rule subject to CRA's submission requirements.

Our practice when rendering decisions is to contact the relevant agencies to obtain factual information and their legal views on the subject of the request.⁴ Accordingly, we reached out to HHS on January 13, 2026.⁵ We received HHS's response on February 20, 2026.⁶

BACKGROUND

Original Medicare

Medicare consists of four distinct parts: Parts A, B, C, and D.⁷ Original

¹ CMS also refers to this at times as the Wasteful and Inappropriate "Service" Reduction Model. See CMS, *WISeR (Wasteful and Inappropriate Service Reduction) Model*, available at <https://www.cms.gov/priorities/innovation/innovation-models/wiser> (WISeR Website) (last visited Apr. 21, 2026).

² *Medicare Program; Implementation of Prior Authorization for Select Services for the Wasteful and Inappropriate Services Reduction (WISeR) Model*, 90 Fed. Reg. 28749 (July 1, 2025) (WISeR Model Notice or Notice).

³ Letter from Senator Ron Wyden, Senator Patty Murray, Senator Richard Blumenthal, and Senator Kirsten Gillibrand to Comptroller General (Dec. 18, 2025).

⁴ GAO, *GAO's Protocols for Legal Decisions and Opinions*, GAO-24-107329 (Washington, D.C.: Feb. 2024), available at <https://www.gao.gov/products/gao-24-107329>.

⁵ Letter from Managing Associate General Counsel for Appropriations Law, GAO, to General Counsel, HHS (Jan. 13, 2026).

⁶ Letter from Senior Counsel, HHS, to Managing Associate General Counsel for Appropriations Law, GAO (Feb. 20, 2026) (HHS Response).

⁷ CMS, *Parts of Medicare*, available at <https://www.medicare.gov/basics/get-started-with-medicare/medicare-basics/parts-of-medicare> (last visited Apr. 21, 2026).

Medicare—sometimes called Medicare Fee-for-Service (FFS)⁸—includes Part A and Part B.⁹ Part A (Hospital Insurance) “helps cover inpatient care in hospitals, skilled nursing facility care, hospice care, and home health care.”¹⁰ Part B (Medical Insurance) helps cover a range of medical services and supplies, including physician, outpatient, and some home health care, durable medical equipment, and many preventive services.¹¹ Medical providers and suppliers submit Part A and Part B claims for services and items to Medicare Administrative Contractors (MACs)—private health insurers that have specific geographic jurisdictions—which process and pay the claims.¹²

CMS and MACs employ a variety of techniques to reduce fraud, waste, and abuse in Original Medicare.¹³ These include publishing “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.”¹⁴ MACs also operate a medical review program that includes pre-payment clinical review of medical records and related information to ensure that payment is made only for services that meet all Medicare coverage, coding, billing, and medical necessity requirements.¹⁵ The MAC may use any

⁸ See CMS, *World of Medicare: Course Glossary*, available at <https://www.cms.gov/Outreach-and-Education/MLN/WBT/MLN9329634-WOM/wom/misc/glossary/index.html> (last visited Apr. 21, 2026). CMS uses the term “Medicare FFS” in the WISeR Model Notice but “Original Medicare” in other materials describing the WISeR Model. *E.g.*, WISeR Website. For consistency, we use the term “Original Medicare” in this decision.

⁹ CMS, *Parts of Medicare*.

¹⁰ *Id.*

¹¹ *Id.* Medicare Part C (Medicare Advantage) is a Medicare-approved plan from a private company that “offers an alternative to Original Medicare for . . . health and drug needs,” and Part D (Drug Coverage) helps cover the cost of prescription drugs. *Id.*

¹² CMS, *What’s a MAC*, available at <https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac> (last visited Apr. 21, 2026). For simplicity, we refer to both providers and suppliers as “providers,” and to both services and items as “services” in this decision.

¹³ WISeR Model Notice, 90 Fed. Reg. at 28749.

¹⁴ *Id.*

¹⁵ CMS, *Medical Review and Education*, available at <https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/medical-review-and-education> (last visited Apr. 21, 2026).

relevant information they deem necessary to conduct the review, including documentation submitted with the claim and additional information they request from the provider.¹⁶ However, only a small percentage of claims are subject to such pre-payment review.¹⁷ CMS pays MACs for pre-payment reviews based on the MACs' costs to review the claims.¹⁸

Claims are generally submitted to the MACs after the services are rendered, though certain services require prior authorization before the service is provided to the beneficiary.¹⁹ For those services, providers submit a request for prior authorization to the MAC, and the MAC reviews the request based on the associated Medicare requirements, such as those found in NCDs and LCDs, and provides a decision, which can be either provisional affirmation or non-affirmation.²⁰

WISeR Model Notice

On July 1, 2025, CMS issued the Notice announcing the implementation of the WISeR Model, a new process to evaluate claims for certain medical services under Original Medicare.²¹ The Notice explains that the WISeR Model will be tested for a six-year period beginning on January 1, 2026, in six states.²² According to CMS, the 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”—referred to as “model participants.”²³ The model participants will implement an optional prior authorization process for the selected services to ensure they “are clinically appropriate,

¹⁶ *Id.*

¹⁷ See GAO, *Medicare: Claim Review Programs Could Be Improved with Additional Prepayment Reviews and Better Data*, GAO-16-394 (Washington, D.C.: Apr. 2016), at 2, available at <https://www.gao.gov/products/gao-16-394> (noting that “[l]ess than one percent of claims undergo” pre-payment or post-payment manual review).

¹⁸ *Id.* at 2–3.

¹⁹ See WISeR Model Notice, 90 Fed. Reg. at 28749–51; CMS, *Prior Authorization and Pre-Claim Review Initiatives*, available at <https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives> (last visited Apr. 21, 2026).

²⁰ WISeR Model Notice, 90 Fed. Reg. at 28750.

²¹ WISeR Model Notice, 90 Fed. Reg. at 28749.

²² *Id.* at 28749–50. The six states are New Jersey, Ohio, Oklahoma, Texas, Arizona, and Washington. *Id.* at 28750.

²³ *Id.* at 28750–51.

evidence-based, and consistent with Medicare . . . requirements.”²⁴ CMS stated that it envisions that the model’s use of enhanced technology will streamline the process and identify when services are medically unnecessary, thereby supporting providers in navigating beneficiaries towards more clinically appropriate or higher value care.²⁵

The Notice states that for the selected services, providers will have the option to: (1) submit a request for prior authorization with supporting documentation to the relevant model participant; (2) submit a request for prior authorization with supporting documentation to the MAC (which will send the request to the model participant); or (3) perform the service without requesting prior authorization and then submit a claim, which will be subject to pre-payment medical review by the model participant and may involve requests for supporting documentation.²⁶

Under options 1 or 2 described above, if the provider opts to seek prior authorization from either the model participant directly or via the MAC, the model participant will review the request and issue a provisional affirmation or non-affirmation.²⁷ If the model participant provisionally affirms the request, the associated claim will generally be paid by the MAC.²⁸ On the other hand, claims associated with a non-affirmed request will be denied by the MAC, and the denial would be subject to the existing administrative appeals process.²⁹

Under option 3, if the provider opts to furnish the service without requesting prior authorization and then submits a claim to the MAC, the MAC will flag the claim for pre-payment medical review, to be performed by the model participant.³⁰ The model

²⁴ *Id.* at 28750.

²⁵ *Id.*

²⁶ WISeR Model Notice, 90 Fed. Reg. at 28751–52.

²⁷ *Id.* In its press release on the WISeR Model issued shortly before the Notice, CMS clarified that while technology will support the review process, final decisions on non-affirmations will be made by licensed clinicians. CMS, *CMS Launches New Model to Target Wasteful, Inappropriate Services in Original Medicare* (June 27, 2025), available at <https://www.cms.gov/newsroom/press-releases/cms-launches-new-model-target-wasteful-inappropriate-services-original-medicare> (WISeR Press Release) (last visited Apr. 21, 2026).

²⁸ WISeR Model Notice, 90 Fed. Reg. at 28752.

²⁹ *Id.* The Notice clarifies that providers will have unlimited opportunities to resubmit a non-affirmed prior authorization request and may request peer-to-peer review to inform the new determination. *Id.*

³⁰ WISeR Model Notice, 90 Fed. Reg. at 28751–52.

participant will request documentation from the provider to support the medical necessity of the claim, conduct a medical review, and then communicate its decision to the MAC, which will approve or deny the claim based on the model participant's decision.³¹ If the MAC denies the claim, the denial would be subject to the existing appeals process.³²

The Notice states that the WISeR Model does "not change any medical necessity or documentation requirements" and "will require the same information and clinical documentation that is already required to support Medicare . . . payment but earlier in the process, namely, prior to the service being furnished."³³ The Notice further states that the WISeR Model "will not change payment or coverage for the selected services."³⁴

Regarding the model participants themselves, the Notice states that CMS will implement two three-year agreement periods with participants, which will be companies that have experience using technology-enhanced prior authorization with other payers, including Part C Medicare Advantage plans.³⁵ The participants will be paid under a "novel payment approach," where they will be compensated based on a share of averted expenses from reducing unnecessary or non-covered services in lieu of the traditional acquisition-based approach.³⁶

The Notice states that the WISeR Model is being implemented under section 1115A of the Social Security Act, 42 U.S.C. § 1315a, which, according to the Notice, "authorizes the [HHS] Secretary to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of

³¹ *Id.* at 28752.

³² *Id.*

³³ WISeR Model Notice, 90 Fed. Reg. at 28750–51.

³⁴ *Id.* at 28751; see WISeR Press Release ("The WISeR Model will not change Medicare coverage or payment criteria. Health care coverage for Original Medicare beneficiaries remains the same, and beneficiaries retain the freedom to seek care from their provider . . . of choice.").

³⁵ WISeR Model Notice, 90 Fed. Reg. at 28750.

³⁶ *Id.* at 28751; WISeR Press Release (clarifying that "[m]odel participants will receive payments based on their ability to reduce unnecessary or non-covered services" and that "[p]articipants' payments will be adjusted based on their performance against established quality and process measures that measure the model participants' ability to support faster decision-making for providers and suppliers and improve provider, supplier and beneficiary experience with the prior authorization process").

care furnished to Medicare, Medicaid, and Children’s Health Insurance Program beneficiaries” and allows the Secretary to waive certain statutory requirements as may be necessary to test the models.³⁷ The Notice states that pursuant to this authority, the agency is waiving specific statutory and regulatory provisions that could be construed as limiting its ability to conduct prior authorization or that could be construed to restrict what entity performs such prior authorization.³⁸

Congressional Review Act (CRA)

CRA, enacted in 1996 to strengthen congressional oversight of agency rulemaking, requires federal agencies to submit a report on each new rule to both houses of Congress and the Comptroller General for review before the rule can take effect.³⁹ The report must contain a copy of the rule, “a concise general statement relating to the rule,” and the rule’s proposed effective date.⁴⁰ CRA allows Congress to review and disapprove rules issued by federal agencies for a period of 60 days using special procedures.⁴¹ If a resolution of disapproval is enacted, then the new rule has no force or effect.⁴²

CRA adopts the definition of a rule under the Administrative Procedure Act (APA), which states that a rule is “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency.”⁴³ However, CRA excludes three categories of APA rules from coverage: (1) rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.⁴⁴

HHS did not submit a CRA report to Congress or the Comptroller General on the WISeR Model Notice. In its response to us, HHS stated that, in its view, the WISeR

³⁷ WISeR Model Notice, 90 Fed. Reg. at 28750; see 42 U.S.C. § 1315a(a)(1), (d).

³⁸ WISeR Model Notice, 90 Fed. Reg. at 28750.

³⁹ 5 U.S.C. § 801(a)(1)(A).

⁴⁰ *Id.*

⁴¹ See 5 U.S.C. § 802.

⁴² 5 U.S.C. § 801(b)(1).

⁴³ 5 U.S.C. §§ 551(4); 804(3).

⁴⁴ 5 U.S.C. § 804(3).

Model Notice is a guidance document and the CRA does not apply to guidance documents.⁴⁵

DISCUSSION

At issue here is whether the WISeR Model Notice meets CRA's definition of a rule, which adopts APA's definition of a rule with three exceptions. As explained below, we conclude that the Notice meets the APA definition, and no exceptions apply. Therefore, the Notice is a rule subject to CRA's submission requirements.

The WISeR Model Notice is a Rule under APA

Applying APA's definition of a rule, the WISeR Model Notice meets all of the required elements. First, the Notice is an agency statement as it is an official document approved by the CMS Administrator and published by CMS in the *Federal Register*.⁴⁶ Second, the WISeR Model Notice is of future effect. An agency action of future effect is one "concerned with policy considerations for the future rather than the evaluation of past or present conduct."⁴⁷ The Notice was published on July 1, 2025, and announced the future implementation of the WISeR Model beginning on January 1, 2026.⁴⁸

Finally, the WISeR Model Notice implements and prescribes law or policy and describes agency procedure and practice requirements. An agency statement implements, interprets, or prescribes law or policy when the action creates new regulations, changes regulatory requirements or official policy, or alters how the agency will exercise its discretion, among other things.⁴⁹ The WISeR Model Notice prescribes and implements new requirements for Original Medicare providers in selected states by mandating prior authorization or pre-payment medical review of

⁴⁵ HHS Response, at 1. HHS indicated that although it did not submit the WISeR Model Notice to Congress under the CRA procedures, it informally notified individual member offices and certain committees. *Id.* As we have noted in previous decisions, such informal notification does not meet CRA's reporting requirements. B-330811, July 15, 2019; B-323772, Sept. 4, 2012.

⁴⁶ WISeR Model Notice, 90 Fed. Reg. at 28753; see, e.g., B-337397, Aug. 27, 2025 (concluding that an HHS document signed by the HHS Secretary and published in the *Federal Register* qualified as an agency statement).

⁴⁷ B-316048, Apr. 17, 2008, at 3.

⁴⁸ WISeR Model Notice, 90 Fed. Reg. at 28750.

⁴⁹ B-334005, Jan. 18, 2023 (citing *Industrial Safety Equipment Association, Inc. v. Environmental Protection Agency*, 837 F.2d 1115, 1120 (D.C. Cir. 1988)).

claims for certain services.⁵⁰ The Notice also prescribes and implements a new policy of having such claims reviewed by model participants—companies using enhanced technology, like AI or machine learning—and prescribes a new payment approach for those participants based on averted Medicare expenditures.⁵¹ In addition, the Notice implements section 1115A of the Social Security Act by establishing the WISeR Model pursuant to that section and using its authority to waive certain statutory and regulatory provisions.⁵²

An agency statement describes agency organization, procedure, or practice requirements when the statement discusses the internal operations of an agency, including statements that govern the conduct of agency proceedings.⁵³ The WISeR Model Notice describes new procedures for the submission and processing of Original Medicare claims for certain services in selected states. In addition, the Notice outlines the method by which companies participating in the model will be compensated by CMS. Therefore, the Notice also describes agency organization, procedure, or practice requirements.

Having satisfied all the required elements, the WISeR Model Notice meets the APA definition of a rule.

HHS stated in its response that it did not submit the WISeR Model Notice because it is a guidance document and CRA does not apply to guidance documents.⁵⁴ We have addressed in previous decisions HHS's position that guidance documents are not rules under CRA and rejected that interpretation.⁵⁵ For example, we previously examined an HHS Information Memorandum informing states that HHS would use its statutory authority to waive certain requirements of the Temporary Assistance for Needy Families (TANF) program to allow states to test various strategies, policies, and procedures designed to improve employment outcomes for needy families.⁵⁶ The Information Memorandum also set forth requirements that had to be met for a waiver request to be considered by HHS.⁵⁷ HHS stated that the Information Memorandum was a non-binding guidance document and that guidance documents

⁵⁰ WISeR Model Notice, 90 Fed. Reg. at 28750–52.

⁵¹ *Id.* at 28751–52.

⁵² *Id.* at 28750.

⁵³ B-337059, May 28, 2025.

⁵⁴ HHS Response, at 1.

⁵⁵ See B-330811, July 15, 2019; B-323772, Sept. 4, 2012.

⁵⁶ B-323772, Sept. 4, 2012.

⁵⁷ *Id.*

do not need to be submitted as rules under CRA.⁵⁸ We rejected this position, noting that the APA definition of a rule “is expansive and specifically includes documents that implement or interpret law or policy.”⁵⁹ We also cited previous GAO decisions in which we concluded that “agency guidance, including guidance characterized as non-binding, constitutes a rule under the CRA.”⁶⁰ Finally, we pointed to relevant CRA legislative history listing guidance documents as an example of APA rules.⁶¹

Like the Information Memorandum at issue in B-323772, Sept. 4, 2012, the WISeR Model Notice implements a new policy and prescribes new procedures for non-agency parties.

As discussed above, the Notice satisfies all the elements of the APA rule definition and is a rule under APA, regardless of whether it is a guidance document.

CRA Exceptions

We must next determine whether any of CRA’s three exceptions apply. CRA provides for three types of rules that are not subject to its requirements: (1) rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.⁶²

(1) Rule of Particular Applicability

The WISeR Model Notice is not a rule of particular applicability.⁶³ Such rules are addressed to specific, identified persons or entities and determine actions those persons or entities may or may not take, considering the facts and circumstances specific to those persons or entities.⁶⁴ In determining whether a rule is one of general or particular applicability, we have noted that a rule need not apply to the population as a whole to be considered a rule of general applicability; rather, all that

⁵⁸ *Id.*

⁵⁹ *Id.* at 5; see 5 U.S.C. § 551(4).

⁶⁰ B-323772, Sept. 4, 2012, at 5 (*citing* B-281575, Jan. 20, 1999).

⁶¹ *Id.* (*citing* 142 Cong. Rec. S3687 (daily ed. Apr. 18, 1996) (statement for the record by Sens. Nickles, Reid and Stevens); 142 Cong. Rec. H3005 (daily ed. Mar. 28, 1996) (statement of Rep. McIntosh)).

⁶² 5 U.S.C. § 804(3).

⁶³ See 5 U.S.C. § 804(3)(A).

⁶⁴ See, e.g., B-337059, May 28, 2025; B-334146, June 5, 2023.

is required is that the rule has general applicability within its intended range, regardless of the magnitude of the range.⁶⁵ In particular, we have determined that a rule is one of general applicability even if the rule is limited to a specific geographic area, so long as the rule does not apply to specific, identified persons or entities.⁶⁶

Although the WISeR Model Notice announces the implementation of the model in six states, the Notice is not addressed to specific, identified persons or entities. Instead, the Notice applies to all providers of the specified services in those states, as well as the model participants. Therefore, the Notice is a rule of general applicability.

(2) Rule of Agency Management or Personnel

The WISeR Model Notice is not a rule of agency management or personnel.⁶⁷ This exception applies to rules relating to “purely internal agency matters.”⁶⁸ These include rules related to controlling, directing, or supervising internal management issues,⁶⁹ as well as rules related to personnel issues like pay, leave, or benefits.⁷⁰ In contrast, we have determined that rules affecting agency proceedings with non-agency parties do not fall within this exception.⁷¹ For example, in B-337397, Aug. 27, 2025, we concluded that an HHS policy statement rescinding a prior policy generally requiring APA notice-and-comment procedures for certain rules did not fall within the exception because the policy statement changed public participation in

⁶⁵ *E.g.*, B-287557, May 14, 2001.

⁶⁶ See B-337059, May 28, 2025 (concluding that a rule adopting a management strategy for barred owls in specific areas of three states was a not a rule of particular applicability because it was not addressed to specific identified persons or entities and applied to all federal, state, or tribal government agencies, or private landowners, implementing barred owl management); B-238859, Oct. 23, 2017 (concluding that a rule applying to a specific national forest was not a rule of particular applicability because it applied to all persons or entities using the forest).

⁶⁷ See 5 U.S.C. § 804(3)(B).

⁶⁸ B-336512, Aug. 29, 2024, at 7 (*quoting* B-335142, May 1, 2024) (internal quotation marks omitted).

⁶⁹ *Id.*

⁷⁰ B-335115, Sept. 26, 2023; B-334221, Feb. 9, 2023.

⁷¹ See B-337397, Aug. 27, 2025; see B-329916, May 17, 2018.

certain HHS rulemakings and therefore did not relate primarily to agency management or personnel.⁷²

The WISeR Model Notice involves neither internal management nor personnel issues. Instead, the Notice establishes new claims procedures for providers of the specified services in specific states. The Notice also establishes a new process by which such claims will be reviewed by model participants and prescribes a new payment approach for those participants.⁷³ Therefore, the Notice does not meet this exception.

(3) Rule of Agency Organization, Procedure, or Practice That Does Not Substantially Affect Non-Agency Parties

The WISeR Model Notice is not a rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.⁷⁴

We have previously explained that this exception was modeled on the APA exception to notice-and-comment rulemaking requirements for “rules of agency organization, procedure, or practice,”⁷⁵ which some courts have limited to rules that do not have a substantial impact on non-agency parties.⁷⁶ The purpose of the APA exception is “to ensure that agencies retain latitude in organizing their internal operations.”⁷⁷ Following this interpretation in the CRA context, we have only applied CRA’s third exception to rules that primarily focus on an agency’s internal operations.⁷⁸

Rules of agency organization, procedure, or practice include rules addressing the submission of information to an agency by non-agency parties, rules that affect how

⁷² B-337397, Aug. 27, 2025.

⁷³ See B-335142, May 1, 2024 (concluding that a rule requiring agencies to designate a labor advisor to improve contractor implementation of and compliance with labor requirements fell within the exception, in part, because the rule did not “primarily relate to . . . contractors or other third parties,” and did “not provide any guidance, impose requirements on, or directions to, agency contractors”).

⁷⁴ See 5 U.S.C. § 804(3)(C).

⁷⁵ 5 U.S.C. § 553(b)(A).

⁷⁶ B-336217, Aug. 6, 2024; see B-329916, May 17, 2018 (*citing Brown Express, Inc. v. United States*, 607 F.2d 695, 702 (5th Cir. 1979)).

⁷⁷ *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980).

⁷⁸ B-329926, Sept. 10, 2018.

the agency reviews that information, and rules that affect the type or timing of actions the agency will take based on that submission.⁷⁹ The WISeR Model Notice qualifies as a rule of agency organization, procedure, or practice because it establishes new procedures for submitting and processing Medicare claims for certain services in specific states.

However, the Notice substantially affects the rights or obligations of non-agency parties. Rules that satisfy this exception do not alter the rights or interests of non-agency parties, though they may alter the manner in which parties present themselves or their viewpoints to the agency.⁸⁰

In particular, we have determined that rules that could affect the outcome of an agency proceeding substantially affect non-agency parties and do not fall within the exception.⁸¹ This includes changes to important procedural rights that could affect the outcome, even if they do not alter the substantive criteria used by the agency to make a decision.⁸² For example, we reviewed an HHS Policy Statement that rescinded a previous policy of generally requiring the use of APA notice-and-comment procedures for otherwise exempt rules relating to public property, loans, grants, benefits, or contracts.⁸³ We noted that the Policy Statement eliminated the public's right to notice and an opportunity to submit information that

⁷⁹ B-336217, Aug. 6, 2024 (*citing* B-329916, May 17, 2018; *JEM Broadcasting Co. v. FCC*, 22 F.3d 320, 326–28 (D.C. Cir. 1994)).

⁸⁰ See B-336217, Aug. 6, 2024 (*citing* B-329916, May 17, 2018; B-281575, Jan. 20, 1999; *Batterton*, 648 F.2d at 707).

⁸¹ See, e.g., B-335488, Oct. 18, 2023 (concluding that a Department of Transportation (DOT) Notice of Funding Opportunity defining eligibility requirements, selection criteria, and funding ranges for three existing DOT programs substantially affected the rights and obligations of non-agency parties); B-330811, July 15, 2019 (concluding that guidance issued by HHS and the Department of the Treasury providing requirements that a state must meet for approval of a waiver from certain Patient Protection and Affordable Care Act requirements affected the states' obligations); B-323772, Sept. 4, 2012 (concluding that an HHS Information Memorandum setting criteria for states applying for waivers from certain TANF program requirements affected states' obligations).

⁸² See B-337397, Aug. 27, 2025; B-281575, Jan. 20, 1999.

⁸³ B-337397, Aug. 27, 2025.

could affect HHS's rulemaking decisions.⁸⁴ Accordingly, we concluded that the Policy Statement substantially affected the rights of non-agency parties.⁸⁵

Further, in B-281575, Jan. 20, 1999, we reviewed Environmental Protection Agency (EPA) interim guidance for investigating discrimination complaints related to EPA permits. The guidance, in part, significantly departed from existing EPA procedures by requiring EPA to make an initial finding as to whether there were discriminatory effects associated with the relevant permit, and, if so, to notify the permit recipient and complainant and afford the recipient an opportunity to rebut EPA's finding, propose a plan to mitigate the disparate impact, or seek to demonstrate that there was a legitimate interest that justified the decision to proceed notwithstanding the discriminatory effect.⁸⁶ We concluded that by providing for an initial finding of discriminatory effects and allowing permit recipients to provide input at that stage—including justifications for the discriminatory effects—the guidance gave permit “recipients significant rights that they did not previously possess for obtaining dismissal of [a] complaint,” and thereby affected the rights and duties of recipients, complainants, and the affected population.⁸⁷

Similarly, courts have determined that a change in decision maker substantially affects the rights and interests of non-agency parties. For example, in *National Association of Home Health Agencies v. Schweiker*, the U.S Court of Appeals for the D.C. Circuit examined the HHS Secretary's administrative instruction regarding Medicare reimbursement for certain home health agencies.⁸⁸ Prior to the instruction, those home health agencies had the option of submitting claims for Medicare reimbursement directly to the Secretary or to an intermediary contracted by HHS.⁸⁹ The administrative instruction directed the relevant home health agencies to begin using intermediaries for all Medicare reimbursement determinations and payments, eliminating the option of seeking reimbursement from the Secretary.⁹⁰ The court determined that the instruction substantially affected the rights and interests of the affected home health agencies because it eliminated their right to deal directly with

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ B-281575, Jan. 20, 1999.

⁸⁷ *Id.*

⁸⁸ *National Ass'n of Home Health Agencies v. Schweiker*, 690 F.2d 932, 934 (D.C. Cir. 1982) (*Home Health Agencies*).

⁸⁹ *Id.* at 934–35.

⁹⁰ *Id.* at 935.

the Secretary.⁹¹ In a more recent opinion, the D.C. Circuit emphasized that “[t]he crucial element of *Home Health Agencies* is . . . which staffers have decision[-]making authority.”⁹²

Similar to the administrative instruction at issue in *Home Health Agencies*, the WISeR Model Notice effectively transfers decision-making authority for certain Medicare reimbursement claims, in this case from the MACs to the model participants. Although the MACs will continue to approve or deny claims, they are bound by the determinations of the model participants for claims related to the specified services. With respect to claims that are submitted for prior authorization, those that are provisionally affirmed by the model participant “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.”⁹³ In contrast, if the model participant does not affirm the prior authorization request, “the MAC will deny the [subsequent] claim.”⁹⁴ For claims not submitted for prior authorization, the model participant will perform a pre-payment medical review and communicate its decision to the MAC, and “[t]he MAC will then process the claim in accordance with the model participant’s decision.”⁹⁵

Not only does the WISeR Model Notice effectively transfer decision-making authority over certain claims from the MACs to the model participants, that change could potentially affect whether claims are approved or denied given the participants’ novel approach to reviewing claims and their compensation structure. Specifically, the model participants will use advanced technologies, like AI and machine learning, to determine whether the relevant services are medically necessary and providers should be reimbursed.⁹⁶ In addition, the participants will be compensated based on their ability to reduce payments for unnecessary or non-covered services⁹⁷; in other words, model payments will be “calculated from requests that did not result in a paid

⁹¹ *Id.* at 949.

⁹² *James V. Hurson Associates v. Glickman*, 229 F.3d 277, 282 (D.C. Cir. 2000).

⁹³ WISeR Model Notice, 90 Fed. Reg. at 28752.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *See id.* at 28751.

⁹⁷ *See id.* at 28750–51.

claim.”⁹⁸ This differs from the payment structure for MACs, which are paid based on the costs of reviewing claims.⁹⁹

Several medical organizations raised concerns to CMS that the WISeR Model’s use of advanced technologies to review claims and the model participant compensation structure could result in inappropriate denials.¹⁰⁰ For example, the American Medical Association (AMA) stated that “AI and other automated tools raise significant risks if not governed properly” and “[o]utdated, incomplete, or biased training data can lead to false positives, inappropriate denials, or unfair patterns of flagging services for certain patient populations.”¹⁰¹ With respect to the compensation structure, AMA stated that “[w]hen third-party entities are paid based on the volume of denied services, there is a clear risk that care that is medically necessary for certain patients will be inappropriately denied in pursuit of savings.”¹⁰²

⁹⁸ CMS, *Wasteful and Inappropriate Service Reduction (WISeR) Model Provider Factsheet*, at 3 available at <https://www.cms.gov/priorities/innovation/files/wiser-provider-fact-sheet.pdf> (last visited Apr. 21, 2026).

⁹⁹ GAO-16-394, at 2–3. Other claim review contractors, called Recovery Auditors, are paid on a contingent basis, but these contractors only review claims post-payment—as opposed to the pre-payment review model participants will conduct—and are paid based on recovered overpayments. *Id.* at 2, 10.

¹⁰⁰ See Letter from CEO/Executive Vice President, American Medical Association, to Deputy Administrator and Director, CMS, at 3 (July 16, 2025) (AMA Letter), available at <https://searchf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/lfcts.zip/2025-7-16-Letter-to-Sutton-re-WISer-Model-v2.pdf> (last visited Apr. 21, 2026); Letter from Senior Vice President, Public Policy Analysis and Development, American Hospital Association, to Deputy Administrator and Director, CMS (Oct. 23, 2025), available at <https://www.aha.org/lettercomment/2025-10-23-aha-comments-cms-wiser-model> (last visited Apr. 21, 2026).

CRA’s legislative history supports considering the views of affected non-agency parties about the impact of the action at issue when determining whether the third CRA exception applies. See 142 Cong. Rec. H3005 (daily ed. Mar. 28, 1996) (statement of Rep. McIntosh) (“[T]his exception should be read narrowly and resolved in favor of non[-]agency parties who can demonstrate that the rule will have a nontrivial effect on their rights or obligations.”).

¹⁰¹ AMA Letter, at 3.

¹⁰² *Id.*

AMA therefore included a number of recommendations to mitigate these concerns.¹⁰³

Part of the purpose of the WISeR Model is to test “the speed and accuracy of new technology-assisted decision-making,”¹⁰⁴ and it is unclear what the ultimate effects of the model will be on coverage determinations in practice. In addition, we note that CMS has included measures to reduce inaccuracy, such as requiring that final non-affirmation decisions be made by licensed clinicians.¹⁰⁵ However, because the purpose of our CRA determinations is to identify whether an action is a rule and should have been submitted to Congress before it took effect, we must assess the potential effects of the rule before they occur, not at some later time when those effects become known.¹⁰⁶

In this case, the WISeR Model Notice transfers decision-making authority over certain Medicare claims to different entities that will use new technology-assisted processes to evaluate claims and will be compensated based on reducing Medicare expenditures. Given the nature of these changes and because they could potentially affect the determinations made on claims for the selected services, we conclude that the Notice substantially affects the rights and obligations of non-agency parties, specifically providers and beneficiaries of the selected services in the six states covered by the model.

HHS states in its response that its voluntary models do not alter or affect the rights of any party under any statute absent a voluntary decision to participate in the model and that the WISeR Model does not change substantive Medicare eligibility, coding, coverage, or payment requirements.¹⁰⁷

However, despite HHS’s characterization and the fact that a third-party’s participation as a model participant may be voluntary, provider participation in the WISeR Model is largely involuntary. Providers in the six states must use the model procedures for claims related to the selected services, including having those claims adjudicated by a model participant.¹⁰⁸ The only choice such providers appear to

¹⁰³ *Id.* at 3–4.

¹⁰⁴ WISeR Model Notice, 90 Fed. Reg. at 28751.

¹⁰⁵ See WISeR Press Release.

¹⁰⁶ B.334032.2, Apr. 5, 2023.

¹⁰⁷ HHS Response, at 1.

¹⁰⁸ See WISeR Model Notice, 90 Fed. Reg. at 28751–52. The Notice states that CMS was “exploring implementation of ‘gold carding’ which is a process to exempt compliant providers/suppliers from the prior authorization process and expanded
(continued...)

have is the option to submit a prior authorization request for the service—not required previously—or to have their claim subject to pre-payment medical review by a model participant—a process previously applied to only a small number of claims.¹⁰⁹ And as discussed above, the changes to the claims procedures—including the transfer of decision-making authority to the model participants, the processes they will use to evaluate claims, and their compensation structure—could potentially affect the outcome of claims decisions, notwithstanding that the WISeR Model Notice does not purport to change substantive Medicare eligibility, coding, coverage, or payment requirements. Accordingly, we conclude that the Notice substantially affects the rights and obligations of non-agency parties and does not fall within the third CRA exception.

CONCLUSION

The WISeR Model Notice is a rule for purposes of CRA because it meets the definition of a rule under APA and no CRA exception applies. Therefore, the Notice is subject to CRA’s requirement that it be submitted to Congress and the Comptroller General before it can take effect.



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pre-payment review processes,” but the Notice did not implement such a system. See *id.* at 28752.

¹⁰⁹ See *id.* at 28751; GAO-16-394, at 2.