



Decision

Matter of: U.S. Department of Health and Human Services—Applicability of the Congressional Review Act to Policy on Adhering to the Text of the Administrative Procedure Act

File: B-337397

Date: August 27, 2025

DIGEST

On March 3, 2025, the U.S. Department of Health and Human Services (HHS) published in the *Federal Register* a policy statement titled, *Policy on Adhering to the Text of the Administrative Procedure Act* (2025 Policy Statement or Policy Statement). The 2025 Policy Statement rescinds a prior policy generally requiring HHS agencies and offices to use Administrative Procedure Act (APA) notice-and-comment procedures for rules relating to public property, loans, grants, benefits, or contracts and establishes a new policy giving HHS agencies and offices discretion whether to use notice-and-comment procedures for such rules.

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 “rule” under APA but excludes certain categories of rules from coverage. We conclude that the 2025 Policy Statement is a rule for purposes of CRA because it meets the APA definition of a rule, and no CRA exception applies. Therefore, the Policy Statement is a rule subject to CRA’s submission requirements.

DECISION

On March 3, 2025, the U.S. Department of Health and Human Services (HHS) published in the *Federal Register* a policy statement titled, *Policy on Adhering to the Text of the Administrative Procedure Act* (2025 Policy Statement or Policy Statement).¹ We received a request for a decision as to whether the Policy

¹ 90 Fed. Reg. 11029.

Statement is a rule for purposes of the Congressional Review Act (CRA).² As discussed below, we conclude that the Policy Statement 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.³ Accordingly, we reached out to HHS on April 29, 2025, and received HHS's response on June 11, 2025.⁴

BACKGROUND

The 2025 Policy Statement rescinds HHS's previous policy generally requiring the use of APA notice-and-comment rulemaking procedures for certain types of rules that APA exempts from such procedures.⁵

APA Notice-and-Comment Procedures

APA prescribes notice-and-comment procedures for certain rules.⁶ For these rules, APA generally requires agencies to publish in the *Federal Register* a notice of proposed rulemaking and provide interested persons an opportunity to participate in the rulemaking "through submission of written data, views, or arguments."⁷ The agency may promulgate a final rule only after providing notice and opportunity for comment.⁸

² Letter from Senator Ron Wyden, Ranking Member, Senate Committee on Finance, Representative Richard E. Neal, Ranking Member, House Committee on Ways and Means, and Representative Frank Pallone, Jr., Ranking Member, House Committee on Energy and Commerce, to Comptroller General (Apr. 11, 2025).

³ 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>.

⁴ Letter from Assistant General Counsel, GAO, to Acting General Counsel, HHS (Apr. 29, 2025); Email from Deputy Director of Audit Activity, Office of Assistant Secretary for Legislation, HHS, to Assistant General Counsel, GAO, *Subject: RE: GAO development letter* (June 11, 2025) (with attachments) (HHS Response).

⁵ 2025 Policy Statement, 90 Fed. Reg. at 11029.

⁶ See 5 U.S.C. § 553.

⁷ 5 U.S.C. § 553(b)–(c).

⁸ See 5 U.S.C. § 553(c).

APA exempts certain rules from these notice-and-comment procedures, including rules involving “matter[s] relating . . . to public property, loans, grants, benefits, or contracts.”⁹ APA also includes a good cause exception, which permits an agency to forgo the notice-and-comment procedures if “the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”¹⁰

Richardson Waiver

In 1970, the Secretary of Health, Education, and Welfare (the predecessor to HHS)¹¹ issued a policy statement directing agencies and offices in the department that issue rules relating to public property, loans, grants, benefits, or contracts to use APA notice-and-comment procedures notwithstanding the exemption (Richardson Waiver).¹² The Richardson Waiver further stated that APA’s good cause exception should be used sparingly, such as in emergencies and for amendments covering minor technical matters.¹³ The Richardson Waiver explained that the new policy implemented a recommendation by the Administrative Conference of the United States (ACUS), and that the public benefit from greater participation in rulemaking should outweigh any administrative inconvenience or delay caused by using the notice-and-comment procedures.¹⁴

⁹ 5 U.S.C. § 553(a)(2).

¹⁰ 5 U.S.C. § 553(b)(B). CRA includes its own good cause exception that allows a rule to take effect at such time as the agency determines if, like the APA exception, the “agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 808(2).

¹¹ See HHS, *HHS Historical Highlights*, available at <https://www.hhs.gov/about/historical-highlights/index.html> (last visited Aug. 25, 2025).

¹² Statement of Policy, *Public Participation in Rule Making*, 36 Fed. Reg. 2532 (Feb. 5, 1971); see *Administrative Practices and Procedures*, 47 Fed. Reg. 26860, 26860 (proposed June 22, 1982) (1982 NPRM) (describing how the Richardson Waiver was issued as a memorandum on October 12, 1970, and subsequently published in the *Federal Register*).

¹³ Richardson Waiver, 36 Fed. Reg. at 2532.

¹⁴ Richardson Waiver, 36 Fed. Reg. at 2532; see ACUS Recommendation 69-8, *Elimination of Certain Exemptions from the APA Rulemaking Requirements* (Oct. 1969), available at <https://www.acus.gov/sites/default/files/documents/69-8.pdf> (last visited Aug. 25, 2025). ACUS “is a federal agency in the executive branch charged with identifying and promoting improvements in the efficiency, adequacy, and fairness of the procedures by which federal agencies conduct regulatory programs, administer grants and benefits, protect the public interest, and perform
(continued...) ”

1982 Notice of Proposed Rulemaking

In 1982, HHS proposed, but never adopted, a rule clarifying the policy announced in the Richardson Waiver and codifying it in the agency's regulations.¹⁵ HHS reaffirmed in the proposed rule that the agency's general policy would be to ordinarily use notice-and-comment procedures for rules relating to public property, loans, grants, benefits, or contracts.¹⁶ However, HHS noted that some courts had interpreted the Richardson Waiver to require HHS to use notice-and-comment procedures for such rules unless HHS met the APA's good cause exception.¹⁷ Believing that it was not appropriate to hold HHS to that standard when the agency used notice-and-comment procedures voluntarily, HHS proposed clarifying that it could decline to use those procedures for rules relating to public property, loans, grants, benefits, or contracts if, in HHS's judgment, the delay from using such procedures would impair the attainment of program objectives or would have other disadvantages that outweighed the benefits of receiving public comment.¹⁸ The proposed regulations would also have clarified that HHS's voluntary use of notice-and-comment procedures was not intended to create any judicially enforceable rights.¹⁹

2025 Policy Statement

The 2025 Policy Statement rescinds the Richardson Waiver and establishes a new policy giving HHS agencies and offices discretion whether to use

other essential governmental functions." ACUS, *About ACUS*, available at <https://www.acus.gov/about-acus> (last visited Aug. 25, 2025).

¹⁵ 1982 NPRM, 47 Fed. Reg. at 26860; see 2025 Policy Statement, 90 Fed. Reg. at 11029.

¹⁶ 1982 NPRM, 47 Fed. Reg. at 26860.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.* In addition to the proposed provisions related to HHS's use of APA notice-and-comment procedures, the agency also proposed clarifying two additional aspects of its policy. First, the proposed regulations would explain that if HHS did not provide notice and comment prior to issuing one of the affected rules, it would ordinarily solicit comment when the rule was issued. *Id.* Second, HHS proposed to clarify that the policy was limited to the use of notice-and-comment procedures for rules relating to public property, loans, grants, benefits, or contracts, and HHS would not commit to voluntarily provide a delayed effective date for such rules as generally required by APA. *Id.*; see 5 U.S.C. § 553(d).

notice-and-comment procedures for matters relating to public property, loans, grants, benefits, or contracts and not requiring such procedures unless otherwise required by law.²⁰ The Policy Statement further states that “the good cause exception should be used in appropriate circumstances in accordance with” APA requirements rather than “sparingly,” as directed in the Richardson Waiver.²¹ The Policy Statement explains that the “obligations of the Richardson Waiver impose[d] costs on [HHS] and the public, [we]re contrary to the efficient operation of [HHS], and impede[d] [HHS’s] flexibility to adapt quickly to legal and policy mandates.”²²

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.²³ The report must contain a copy of the rule, “a concise general statement relating to the rule,” and the rule’s proposed effective date.²⁴ CRA allows Congress to review and disapprove rules issued by federal agencies for a period of 60 days using special procedures.²⁵ If a resolution of disapproval is enacted, then the new rule has no force or effect.²⁶

CRA adopts the definition of “rule” under 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.”²⁷ 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.²⁸

²⁰ 2025 Policy Statement, 90 Fed. Reg. at 11029.

²¹ *Id.*

²² *Id.*

²³ 5 U.S.C. § 801(a)(1)(A).

²⁴ *Id.*

²⁵ See 5 U.S.C. § 802.

²⁶ 5 U.S.C. § 801(b)(1).

²⁷ 5 U.S.C. §§ 551(4); 804(3).

²⁸ 5 U.S.C. § 804(3).

HHS did not submit a CRA report to Congress or the Comptroller General on the 2025 Policy Statement. In its response to us, HHS states that although the Policy Statement meets the APA definition of a rule, the Policy Statement is a rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties and therefore falls within CRA's third exception.²⁹

DISCUSSION

At issue here is whether the 2025 Policy Statement meets CRA's definition of rule, which adopts APA's definition of a rule with three exceptions. As explained below, we conclude that it does. In addition, we conclude that the Policy Statement does not fall within any CRA exceptions. Therefore, the Policy Statement is a rule subject to CRA's submission requirements.

The 2025 Policy Statement is a Rule Under APA

Applying APA's definition of "rule," the 2025 Policy Statement meets all of the required elements. First, the Policy Statement is an agency statement as it is an official document signed by the HHS Secretary and published by HHS in the *Federal Register*.³⁰

Second, the 2025 Policy Statement 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."³¹ The Policy Statement rescinds the Richardson Waiver "[e]ffective immediately," and establishes HHS's policy going forward with respect to using APA notice-and-comment procedures for rules relating to public property, loans, grants, benefits, or contracts.³²

Finally, the 2025 Policy Statement 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

²⁹ HHS Response, at 1.

³⁰ 2025 Policy Statement, 90 Fed. Reg. at 11029; see, e.g., B-333501, Dec. 14, 2021 (concluding that an official document published in the *Federal Register* qualified as an agency statement).

³¹ B-316048, Apr. 17, 2008.

³² See 2025 Policy Statement, 90 Fed. Reg. at 11029.

agency will exercise its discretion, among other things.³³ The Policy Statement changes HHS's official policy and alters how it will exercise its discretion with respect to when the agency will use APA notice-and-comment procedures for rules relating to public property, loans, grants, benefits, or contracts. The Policy Statement also implements APA by providing that the APA exemption waived by the Richardson Waiver now applies to HHS rulemakings; directing HHS agencies and offices to use the good cause exception in accordance with the requirements of APA rather than in the more limited situations described in the Richardson Waiver; and reaffirming that HHS will continue to follow notice-and-comment procedures when required to do so by APA.³⁴

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.³⁵ The 2025 Policy Statement describes how HHS will conduct rulemaking proceedings for rules relating to public property, loans, grants, benefits, or contracts.³⁶

Having satisfied all the required elements, the 2025 Policy Statement meets the APA definition of a rule.

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.³⁷

(1) Rule of Particular Applicability

The 2025 Policy Statement is not a rule of particular applicability.³⁸ 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

³³ B-334005, Jan. 18, 2023 (*citing Industrial Safety Equipment Association, Inc. v. Environmental Protection Agency*, 837 F.2d 1115, 1120 (D.C. Cir. 1988)).

³⁴ See 2025 Policy Statement, 90 Fed. Reg. at 11029.

³⁵ B-337059, May 28, 2025.

³⁶ See 2025 Policy Statement, 90 Fed. Reg. at 11029.

³⁷ 5 U.S.C. § 804(3).

³⁸ See 5 U.S.C. § 804(3)(A).

specific to those persons or entities.³⁹ In contrast, we have concluded that procedures governing agency proceedings are rules of general applicability. For example, in B-329926, Sept. 10, 2018, we concluded that certain Social Security Administration evidentiary rules applying to all disability adjudication proceedings at the hearing and appeal levels were rules of general applicability.

Here, the 2025 Policy Statement is not addressed to specific, identified persons or entities, and instead prescribes a policy for conducting rulemaking proceedings for all rules relating to public property, loans, grants, benefits, or contracts. Therefore, the Policy Statement is a rule of general applicability.

(2) Rule of Agency Management or Personnel

The 2025 Policy Statement is not a rule of agency management or personnel.⁴⁰ This exception applies to rules relating to “purely internal agency matters.”⁴¹ These include rules related to controlling, directing, or supervising internal management issues,⁴² as well as rules related to personnel issues like pay, leave, or benefits.⁴³ The 2025 Policy Statement involves neither internal management nor personnel issues. Rather, it changes HHS’s policy regarding public participation in certain HHS rulemakings.

This conclusion is consistent with our previous decisions examining other rules that affected agency proceedings involving non-agency parties, in which we determined that those rules did not relate to agency management or personnel.⁴⁴ For example, in B-329916, we concluded that an Internal Revenue Service (IRS) announcement that it would verify health insurance coverage requirements at the time taxpayers filed their individual tax returns rather than after their returns were accepted did not constitute a rule relating to agency management or personnel because the announcement did not primarily relate to agency management or personnel, but rather imposed different requirements on taxpayers.⁴⁵ Similarly here, the Policy

³⁹ See, e.g., B-337059, May 28, 2025; B-334146, June 5, 2023.

⁴⁰ See 5 U.S.C. § 804(3)(B).

⁴¹ B-336512, Aug. 29, 2024 (*quoting* B-335142, May 1, 2024).

⁴² B-336512, Aug. 29, 2024.

⁴³ B-335115, Sept. 26, 2023; B-334221, Feb. 9, 2023.

⁴⁴ See B-329926, Sept. 10, 2018 (involving a rule governing Social Security Administration adjudicators’ use of information from the Internet in claims proceedings).

⁴⁵ B-329916, May 17, 2018.

Statement does not primarily relate to agency management or personnel because it changes public participation in HHS rulemakings. Therefore, it does not meet the second exception.

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

Lastly, the 2025 Policy Statement is not a rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.⁴⁶

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,”⁴⁷ which some courts have limited to rules that do not have a substantial impact on non-agency parties.⁴⁸ The purpose of the APA exception is to ensure “that agencies retain latitude in organizing their internal operations.”⁴⁹ 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, including the conduct of agency proceedings.⁵⁰ These include rules addressing the submission of information to an agency by non-agency parties, rules that affect how the agency reviews that information, and rules that affect the type or timing of actions the agency will take based on that submission.⁵¹

The 2025 Policy Statement qualifies as a rule of agency organization, procedure, or practice. The Policy Statement addresses HHS’s rulemaking procedures for rules relating to public property, loans, grants, benefits, or contracts. In particular, the Policy Statement gives HHS agencies and offices discretion whether to use APA

⁴⁶ See 5 U.S.C. § 804(3)(C).

⁴⁷ 5 U.S.C. § 553(b)(A).

⁴⁸ 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)).

⁴⁹ *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980).

⁵⁰ B-329926, Sept. 10, 2018.

⁵¹ 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)).

notice-and-comment procedures when promulgating those rules, in contrast to the previous policy generally requiring such procedures.⁵²

However, the 2025 Policy Statement substantially affects the rights or obligations of non-agency parties. To satisfy this element of the exception, a rule must not alter the rights or interests of non-agency parties, though it may alter the manner in which parties present themselves or their viewpoints to the agency.⁵³

With respect to rules affecting non-agency parties' submission of information in an agency proceeding, our previous decisions distinguish between rules that merely affect the manner in which parties submit that information, which fall within the exception, and rules that create a new right to submit information that could affect the agency's decision, which do not. For example, in B-329916, May 17, 2018, we examined an IRS announcement that the agency was changing its process for reviewing tax returns for compliance with certain statutory reporting requirements. Previously, IRS assessed compliance after the taxpayer filed a return, IRS processed the return, and the taxpayer paid taxes due or received a refund.⁵⁴ IRS announced that it would begin verifying compliance at the time of filing and would no longer accept noncompliant returns.⁵⁵ We concluded that this rule fell within the exception because it merely shifted the timing of IRS's verification of compliance and neither changed the substantive standards used by IRS to evaluate compliance nor affected the rights or obligations of taxpayers.⁵⁶

Similarly, in B-336217, Aug. 6, 2024, we considered a letter issued by the Board of Governors of the Federal Reserve System (FRB) modifying and clarifying the process by which state member banks sought, and FRB granted, supervisory nonobjection for certain crypto-asset-related activities. These modifications included changes affecting the submission of information by the banks, such as: changing the process for certain banks that were required to notify FRB by establishing a 30-day deadline for such notification; clarifying the types of risk FRB would focus on in its review; communicating that FRB might seek additional information from banks; and clarifying that notification in accordance with the letter would also serve as notification required by a separate FRB letter.⁵⁷ We concluded that while these

⁵² 2025 Policy Statement, 90 Fed. Reg. at 11029.

⁵³ See B-336217, Aug. 6, 2024 (*citing* B-329916, May 17, 2018; B-281575, Jan. 20, 1999; *Batterton*, 648 F.2d at 707).

⁵⁴ B-329916, May 17, 2018.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ B-336217, Aug. 6, 2024.

changes might affect the manner in which the banks presented themselves and their viewpoints to FRB by adjusting the timing or type of information submitted to the agency, the changes did not substantially affect the banks' rights or obligations because they neither impacted the banks' ability to engage in the relevant activities nor affected the standards by which FRB would evaluate their compliance with applicable laws and regulations.⁵⁸

In contrast, in B-281575, Jan. 20, 1999, we reviewed the Environmental Protection Agency's (EPA) interim guidance for investigating discrimination complaints related to EPA permits. In particular, the guidance departed from existing EPA procedures by requiring EPA to make an initial finding of whether there were discriminatory effects associated with the relevant permit, and, if so, notify the permit recipient and complainant and afford the recipient an opportunity to respond.⁵⁹ We concluded that 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.⁶⁰

Courts have also considered the reverse situation—namely when an agency revokes procedures providing non-agency parties with notice and an opportunity to submit information in an agency proceeding—and similarly concluded that those changes substantially impacted the non-agency parties.⁶¹ For instance, in *Brown Express*, the Interstate Commerce Commission (ICC) decided to end its practice of notifying other competing carriers when a carrier filed a petition for emergency temporary authority to provide services to a particular area.⁶² The court determined that the ICC's decision risked the agency not obtaining relevant information, that this risk could result in serious economic consequences to those affected, and that the decision had a substantial impact on the industry.⁶³

There are clear distinctions between the rules discussed in these two lines of decisions. The rules in B-329916 and B-336217 involved changes to previously established procedures for non-agency parties to submit information in agency proceedings. The changes affected those parties insofar as they changed the manner in which the parties submitted that information but did not alter their rights or obligations. Conversely, the rules in B-281575 and *Brown Express* involved the

⁵⁸ *Id.*

⁵⁹ B-281575, Jan. 20, 1999.

⁶⁰ *Id.*

⁶¹ See *Brown Express*, 607 F.2d at 702–03.

⁶² *Id.* at 697–98.

⁶³ *Id.* at 702–03.

wholesale creation or termination of a non-agency party's right to receive notice of potential agency action and to submit information to the agency to inform the agency's determination and potentially affect the outcome of the proceeding. Therefore, the rules establishing or rescinding those procedures substantially affected the rights or obligations of the non-agency parties.

Here, the 2025 Policy Statement falls within the category of rules not subject to the exception. The previously applicable Richardson Waiver, like the rule at issue in B-281575, required notice to affected non-agency parties and an opportunity for those parties to submit information and views to inform the agency's decision. Specifically, the Richardson Waiver established a policy generally requiring HHS to use APA notice-and-comment procedures for otherwise exempt rules relating to public property, loans, grants, benefits, or contracts. These procedures require an agency to publish a notice of proposed rulemaking for such rules and provide interested persons an opportunity to comment on the proposed rule,⁶⁴ thereby affording "affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and . . . afford[ing] the agency a chance to avoid errors and make a more informed decision."⁶⁵ Failure to follow such procedures can result in a reviewing court setting aside or vacating the rule.⁶⁶ And even though APA exempts rules covered by the Richardson Waiver from the notice-and-comment procedures, courts have determined that the Richardson Waiver subjected such rules to those procedures notwithstanding the exemption.⁶⁷

The 2025 Policy Statement rescinds the Richardson Waiver, meaning that the public will no longer have a judicially enforceable right to notice and opportunity to

⁶⁴ See 5 U.S.C. § 553(b)–(c).

⁶⁵ *Mann Construction, Inc. v. United States*, 27 F.4th 1138, 1142 (6th Cir. 2022) (quoting *Azar v. Allina Health Services*, 587 U.S. 566, 582 (2019)).

⁶⁶ See, e.g., *Mann Construction*, 27 F.4th at 1148.

⁶⁷ E.g., *Mt. Diablo Hospital District v. Bowen*, 860 F.2d 951, 956 n.6 (9th Cir. 1988) ("Under 5 U.S.C. § 553(a)(2), rulemaking relating to public benefits is exempt from the notice and comment rulemaking requirements of § 553(b), (c). In 1971, however, the Secretary waived the public benefits exception. Rules promulgated by the Secretary after 1971 are therefore subject to the normal section 553 requirements.") (internal citations omitted); *Buschmann v. Schweiker*, 676 F.2d 352, 356 n.4 (9th Cir. 1982) ("Although 5 U.S.C. § 553(a)(2) would have exempted the rulemaking procedure now in dispute, the then Secretary . . . , in a policy statement . . . , required all agencies and offices in his department to utilize the public participation procedures of § 553. The Secretary does not contest his legal obligation to comply with § 553 procedures."); *Humana of South Carolina, Inc. v. Califano*, 590 F.2d 1070, 1084 (D.C. Cir. 1978) ("Cognizant of the prudence . . . of allowing public input in the wide variety of rulemaking covered by [s]ection 553(a)(2), (continued...)");

comment on such rules unless similar procedures are required by another statute. Like the rule in *Brown Express*, the Policy Statement eliminates non-agency parties' right to notice of agency proceedings and opportunity to submit information that could affect the agency's decisions—in this case, HHS rules that could impact those non-agency parties.⁶⁸ Accordingly, we conclude that the Policy Statement substantially affects the rights of non-agency parties.

In its response, HHS states that the 2025 Policy Statement does not substantially affect the rights or obligations of non-agency parties because APA does not confer the right to comment on the categories of rules affected.⁶⁹ In support, HHS cites *Azar v. Allina Health Services*, in which the Supreme Court stated that “[w]hile the APA requires many other agencies to offer public notice and a comment period before adopting new regulations, it does not apply to public benefit programs like Medicare.”⁷⁰ HHS further states that intervening law has rendered the Richardson Waiver largely obsolete, pointing to a provision in the Office of Federal Procurement Policy Act requiring notice-and-comment rulemaking for certain procurement rules.⁷¹

HHS is correct that APA does not require agencies to provide an opportunity for public comment for the relevant categories of rules. But as discussed above, courts have determined that the Richardson Waiver imposed such requirements on HHS, and invalidated rules within those categories when HHS failed to follow APA notice-and-comment procedures.⁷² HHS has also contested the impact of the

the Secretary in 1971 elected to waive the exemption and to submit to the normal requirements of the [APA], and regulations promulgated since that time are subject to mandatory rulemaking procedures.”) (internal citations omitted).

HHS acknowledged the courts' interpretation in the 1982 NPRM, which proposed, but did not adopt, changes to the policy that would have afforded HHS officials more discretion whether to use notice-and-comment procedures and explained that the revised policy would not establish judicially enforceable rights. 1982 NPRM, 47 Fed. Reg. at 26860.

⁶⁸ Cf. 1982 NPRM, 47 Fed. Reg. at 26860 (“Proposed rules have frequently been modified . . . on the basis of public comment prior to issuance of final rules.”).

⁶⁹ HHS Response, at 1.

⁷⁰ *Azar*, 587 U.S. at 569 (citing 5 U.S.C. § 553(a)(2)); HHS Response, at 1.

⁷¹ HHS Response, at 1 (citing 41 U.S.C. § 1707(a)(1)).

⁷² See *Buschmann*, 676 F.2d at 356 n.4, 358. And although, as HHS indicates, the Supreme Court noted the APA exemption in *Azar*, the Court also acknowledged the Richardson Waiver immediately thereafter, stating that “[s]oon enough, though, the government volunteered to follow the informal notice-and-comment rulemaking
(continued...)

Richardson Waiver in more recent litigation, but the courts have either expressed skepticism with those assertions⁷³ or rejected them outright.⁷⁴

In addition, HHS's statement regarding the obsolescence of the Richardson Waiver is belied by the 2025 Policy Statement itself, which states that the "obligations of the Richardson Waiver impose[d] costs on [HHS] and the public, [we]re contrary to the efficient operation of [HHS], and impede[d] [HHS's] flexibility to adapt quickly to legal and policy mandates."⁷⁵ These statements indicate that the Richardson Waiver continued to impact HHS rulemakings and these impacts were the reason for its rescission.

Based on the foregoing, the 2025 Policy Statement does not meet CRA's third exception.

CONCLUSION

The 2025 Policy Statement is a rule for purposes of CRA because it meets the definition of a rule under APA and no CRA exception applies. Therefore, the Policy Statement is subject to CRA's requirement that it be submitted to Congress and the Comptroller General before it can take effect.



Edda Emmanuelli Perez
General Counsel

procedures found in the APA when proceeding under the Medicare Act." *Azar*, 587 U.S. at 566 (citing *Clarian Health West, LLC v. Hargan*, 878 F.3d 346, 356–57 (D.C. Cir. 2017)).

⁷³ *Clarian Health West*, 878 F.3d at 356–57 ("[The government] appears to contest the assertion that th[e] [Richardson] [W]aiver binds the agency. The [g]overnment provides no basis for this argument, however, and it fails to address this court's and the Supreme Court's cases treating this or other such waivers as binding.") (internal citations omitted).

⁷⁴ *Commonwealth of Massachusetts v. National Institutes of Health*, 770 F. Supp. 3d 277, 313–15 (D. Mass. 2025) ("Defendants state that despite the Secretary's explicit statement otherwise, the grant exception in the APA continues to apply, and thus the Rate Change Notice is entirely exempt from notice-and-comment rulemaking. . . . In light of the weight of precedent, the waiver of the grant exception is binding and cannot be summarily disregarded.").

⁷⁵ 90 Fed. Reg. at 11029.