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July 15, 2019

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services and Department of the Treasury—
Applicability of the Congressional Review Act to State Relief and
Empowerment Waivers*

This responds to your request for our legal opinion as to whether guidance issued by the Department of Health and Human Services (HHS) and the Department of the Treasury (Treasury) on October 22, 2018, entitled “State Relief and Empowerment Waivers” (2018 Guidance), is a rule for purposes of the Congressional Review Act (CRA). Letter from Ranking Member of the Committee on Finance, United States Senate, and Chairman of the Committee on Energy and Commerce, House of Representatives, to Comptroller General (Feb. 6, 2019). The 2018 Guidance at issue relates to section 1332 of the Patient Protection and Affordable Care Act (PPACA) and its implementing regulations. Pub. L. No. 111-148, § 1332, 124 Stat. 119, 203–206 (Mar. 23, 2010) (*classified at* 42 U.S.C. § 18052); 45 C.F.R. pt. 155. For the reasons discussed below, we conclude that the 2018 Guidance is a rule under the CRA, which requires that it be submitted to Congress for review.

Our practice when rendering opinions is to contact the relevant agencies and obtain their legal views on the subject of the request. GAO, *Procedures and Practices for Legal Decisions and Opinions*, GAO-06-1064SP (Washington, D.C.: Sept. 2006), available at www.gao.gov/products/GAO-06-1064SP. We contacted HHS and Treasury to obtain the agencies’ views. Letter from Managing Associate General Counsel, GAO, to General Counsel, HHS (Mar. 4, 2019); Letter from Managing Associate General Counsel, GAO, to General Counsel, Treasury (Mar. 4, 2019). We received a response

on March 22, 2019. Letter from General Counsel, HHS, to Managing Associate General Counsel, GAO (Mar. 22, 2019) (HHS Letter).¹

BACKGROUND

PPACA requires that most United States citizens and legal residents maintain health coverage that meets minimum requirements. 42 U.S.C. § 18021. PPACA also requires the establishment of exchanges in every state so that individuals and small businesses can purchase such coverage and contains requirements for exchange functions, such as maintaining web portals for individuals and small businesses to access the exchange and call centers to provide customer service. 42 U.S.C. § 18003(a).² In addition, PPACA provides for premium tax credits and cost-sharing reductions for eligible individuals, among other things. 26 U.S.C. § 36B.

Section 1332 of the statute permits states to seek federal approval to waive certain key requirements under the law. See 42 U.S.C. § 18052. For example, section 1332 authorizes HHS and Treasury to approve state proposals to waive PPACA requirements related to, among other things, the maintenance of insurance coverage for individuals, exchange functions, and subsidies for exchange coverage. 42 U.S.C. § 18052(a)(2). PPACA requires that state 1332 proposals meet four approval criteria. Specifically, a state proposal must demonstrate that the waiver will result in coverage that is at least as comprehensive, at least as affordable, and available to at least a comparable number of residents as would have been provided without the waiver, and that the waiver will not increase the federal deficit. 42 U.S.C. § 18052(b)(1)(A)–(D).³

PPACA required that the Secretaries of HHS and Treasury promulgate regulations relating to waivers under section 1332 of PPACA. 42 U.S.C. § 18052(a)(4)(B). The regulations were required to include processes for (1) public notice and comment at the state level sufficient to ensure a meaningful level of public input, (2) the submission of an application that ensures the disclosure of the provisions of law that the state involved seeks to waive, (3) additional public notice and comment after the application is received, (4) a process for the submission of periodic reports concerning implementation of the program under the waiver, and (5) periodic evaluation of the program under the waiver. *Id.* HHS and Treasury issued such regulations on

¹ Treasury deferred to HHS's response.

² Under PPACA, states may elect to establish and operate an exchange, known as a state-based exchange, or allow HHS to do so within the state, known as a federally facilitated exchange. 42 U.S.C. § 18041(b).

³ For more information on PPACA and section 1332, see GAO, *Patient Protection and Affordable Care Act: Information on Approval Process for State Innovation Waivers*, GAO-16-637R (Washington, D.C.: July 6, 2016).

February 27, 2012. *Application, Review, and Reporting Process for Waivers for State Innovation*, 77 Fed. Reg. 11700 (Feb. 27, 2012) (codified at 45 C.F.R. pt. 155).⁴

On December 16, 2015, HHS and Treasury issued guidance prescribing what a state needs to demonstrate for a waiver proposal to meet the statutory criteria under section 1332 of PPACA and how the proposed waiver will be evaluated. *Waivers for State Innovation*, 80 Fed. Reg. 78131 (Dec. 16, 2015) (2015 Guidance). For example, the 2015 Guidance provided that assessment of whether the proposal meets the coverage and affordability criteria must take into account effects across different groups of state residents, such that even if a state could demonstrate that the waiver would provide coverage to a comparable number of residents overall, it would not be approved if it reduced coverage for vulnerable groups, like low-income or elderly individuals. *Id.* at 78132.⁵

In 2018, the Departments issued new guidance superseding the 2015 Guidance. 83 Fed. Reg. 53575 (Oct. 24, 2018). According to HHS and Treasury, the Departments reviewed the 2015 Guidance in accordance with Executive Order 13765 issued in January 2017, which, among other things, called for executive branch agencies with responsibilities under PPACA to “exercise all authority and discretion available to them to provide greater flexibility to states and cooperate with them in implementing healthcare programs.” *Id.* at 53584 (citing Exec. Order No. 13765, *Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal*, 82 Fed. Reg. 8351 (Jan. 24, 2017)). As a result of this review, HHS issued updated guidance revising the agency’s policies implementing the statutory criteria for a section 1332 waiver. In particular, the 2018 Guidance changed the analysis of comprehensiveness and affordability articulated in the 2015 Guidance. For example, as noted above, the 2015 Guidance prohibited approval of a section 1332 waiver of a state plan that made coverage less comprehensive or affordable for vulnerable groups of residents; whereas, the 2018 Guidance provides that while analysis will continue to consider effects on all categories of residents, the revision gives states more flexibility to decide that improvements in comprehensiveness and affordability for state residents as a whole offset any small detrimental effects for particular residents. 83 Fed. Reg. at 53578. In addition to providing new interpretations for certain provisions of the 1332 waiver criteria, like the 2015 Guidance, the 2018 Guidance explains how the Departments will evaluate each of the statutory requirements for a section 1332 waiver and what a state must include and demonstrate in its waiver proposal to comply with each criterion.

CRA, enacted in 1996 to strengthen congressional oversight of agency rulemaking, requires all federal agencies, including independent regulatory agencies, to submit a report on each new rule to both Houses of Congress and to the Comptroller General before it can take effect. 5 U.S.C. § 801(a)(1). The report must contain a copy of the

⁴ The 2012 regulations were submitted to GAO as a rule pursuant to CRA.

⁵ The Departments did not submit the 2015 Guidance under CRA. GAO has not been asked to determine whether the 2015 Guidance is a rule under CRA.

rule, “a concise general statement relating to the rule,” and the rule’s proposed effective date. 5 U.S.C. § 801(a)(1)(A). In addition, the agency must submit to the Comptroller General a complete copy of the cost-benefit analysis of the rule, if any, and information concerning the agency’s actions relevant to specific procedural rulemaking requirements set forth in various statutes and executive orders governing the regulatory process. 5 U.S.C. § 801(a)(1)(B).

CRA adopts the definition of rule under the Administrative Procedure Act (APA), 5 U.S.C. § 551(4), 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.” 5 U.S.C. § 804(3). CRA excludes three categories of 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. 5 U.S.C. § 804(3).

Neither HHS nor Treasury sent a CRA report on the 2018 Guidance to Congress or the Comptroller General.

ANALYSIS

To determine whether the 2018 Guidance is a rule subject to review under CRA, we first address whether the Guidance meets the APA definition of a rule. As explained below, we conclude that it does. The next step, then, is to determine whether any of the CRA exceptions apply. We conclude that they do not.

We can readily conclude that the 2018 Guidance meets the APA definition of a rule upon which the CRA relies. First, the 2018 Guidance is an agency statement, as it was issued by HHS and Treasury announcing supplementary information about the requirements that must be met for the approval of a State Innovation Waiver. Second, the Guidance is of future effect, as the Departments state in the 2018 Guidance that the document will be in effect on the date of publication and will be applicable for section 1332 waivers submitted after the publication date of the 2018 Guidance. Finally, the Guidance is designed to implement, interpret, or prescribe law or policy as it provides interpretations of the section 1332 criteria, sets forth what states need to provide to demonstrate that a waiver proposal meets these statutory criteria, and how the proposed waiver will be evaluated.

In 2012, we examined a substantially similar issue to the one presented here and concluded that an Information Memorandum issued by HHS concerning the Temporary Assistance for Needy Families (TANF) program was a rule for purposes of CRA. B-323772, Sept. 4, 2012. The TANF program was established by section 402 of the Social Security Act, and provides federal funding to states for both traditional welfare case assistance as well as a variety of other benefits and services to meet the needs of low-income families and children. 42 U.S.C. § 601. Section 1115 of the Social Security Act provides HHS with the authority to waive compliance with the requirements of section 402 in cases of experimental, pilot, or demonstration projects that HHS

determines are likely to assist in promoting the objectives of TANF.⁶ 42 U.S.C. § 1315. The HHS Information Memorandum at issue in our 2012 opinion sets forth requirements that must be met for a waiver request to be considered by HHS. We held that the HHS Information Memorandum was concerned with authorizing demonstration projects in the future, rather than evaluation of past or present demonstration projects, and thus was prospective in nature. We also found that because the Information Memorandum stated that HHS will use its statutory authority to consider waiver requests and set out requirements that waiver requests must meet, it was designed to implement, interpret, or prescribe law or policy. Like the HHS Information Memorandum at issue in our 2012 decision, the 2018 Guidance at issue here meets the definition of a rule.

We next consider whether the 2018 Guidance falls within one of the exceptions enumerated in CRA. 5 U.S.C. § 804(3)(A)–(C). In this case, the 2018 Guidance is clearly a rule of general and not particular applicability, as it applies to all states. Additionally, the Guidance is not a rule relating to agency management or personnel. In that regard, our 2012 opinion regarding HHS’s Information Memorandum is instructive. See B-323772, at 4. There, we found that the Information Memorandum did not relate to agency management or personnel since it applied to the states.

With respect to the final exception—for rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties—the Guidance issued by HHS and Treasury provides requirements that a state must meet for a waiver proposal to be approved. For that reason, these requirements affect the obligations of states, which are non-agency parties. Our 2012 opinion is again instructive. There, we determined that because the Information Memorandum set out the criteria by which states may apply for waivers from certain obligations of the states, the Information Memorandum affected the rights and obligations of third parties and therefore did not fall under CRA’s third exception. We similarly find here that the 2018 Guidance does not fall under CRA’s third exception.

We requested the views of the General Counsels of HHS and Treasury on whether the 2018 Guidance is a rule for purposes of CRA. Treasury deferred to HHS’s response. HHS responded by letter dated March 22, 2019, stating that the 2018 Guidance is not a rule under CRA because it is not binding and if it were rescinded, it would not alter or affect the rights and obligations of any state or other stakeholder under PPACA. HHS also noted that it informally notified member offices, the Senate Health, Education, Labor, and Pensions and Senate Finance Committees, and the House Ways and Means and Education and Labor Committees of the 2018 Guidance. See HHS Letter at 1.

HHS provided a similar response when we requested its views on its Information Memorandum concerning the TANF program. See B-323772, at 5. As we noted in our 2012 opinion, the definition of rule is expansive and specifically includes documents that implement or interpret law or policy, whether or not the agency characterizes the

⁶ Section 1115 also authorizes the Secretary to waive compliance with certain other requirements of the Social Security Act not related to TANF.

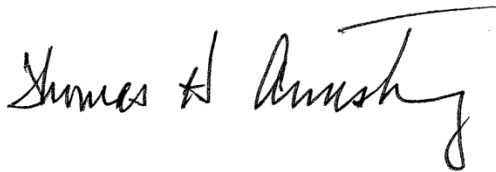
document as non-binding. *Id.* (citing B-281575, January 20, 1999). Finally, as we have stated previously, informal notification does not meet the reporting requirements of CRA. 5 U.S.C. § 801(a)(1); B-323772, at 5.

CONCLUSION

The 2018 Guidance sets forth what a state needs to provide to demonstrate that its proposal meets the four criteria for a waiver under section 1332 of PPACA and how the proposals will be evaluated. The 2018 Guidance meets the APA definition of a rule and does not fall under an exception as provided in CRA. Accordingly, given our conclusions above, and in accordance with the provisions of 5 U.S.C. § 801(a)(1), the 2018 Guidance is subject to the requirement that it be submitted to both Houses of Congress and the Comptroller General before it can take effect.

If you have any questions about this opinion, please contact Shirley A. Jones, Managing Associate General Counsel, at (202) 512-8156 or Janet Temko-Blinder, Assistant General Counsel, at (202) 512-7104.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Thomas H. Armstrong". The signature is written in a cursive style with a long horizontal line above the name.

Thomas H. Armstrong
General Counsel