U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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Decision

Matter of: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention—Applicability of the Congressional Review Act to Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2023

File: B-335316

Date: November 29, 2023

DIGEST

The U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (HHS/CDC) published a document titled *Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2023* (*Schedule*). In the *Schedule*, HHS/CDC summarized recommendations of the Advisory Committee on Immunization Practices (ACIP) that HHS/CDC had previously adopted regarding immunizations for children and adolescents.

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 incorporates the Administrative Procedure Act's (APA) definition of a rule for this purpose with certain exceptions. We conclude that the *Schedule* is not a rule for purposes of CRA because it does not meet the APA definition of a rule.

DECISION

On February 10, 2023, the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (HHS/CDC) published a document titled *Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2023* (*Schedule*), available at https://www.cdc.gov/mmwr/volumes/72/wr/mm7206a1.htm (last visited Nov. 6, 2023). We received a request for a decision as to whether the *Schedule* is a rule for purposes of the Congressional Review Act (CRA). Letter from Senator Tom Cotton

to the Comptroller General (May 16, 2023). As discussed below, we conclude that the *Schedule* is not a rule subject to CRA's submission requirement.

Our practice when rendering decisions is to contact the relevant agencies to 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* https://www.gao.gov/products/gao-06-1064sp. Accordingly, we reached out to HHS/CDC to obtain the agency's legal views. Letter from Assistant General Counsel, GAO, to General Counsel, HHS (May 30, 2023). We received a response from HHS/CDC on July 17, 2023. Letter from General Counsel, HHS, to Assistant General Counsel, GAO (July 17, 2023) (First Response). HHS/CDC provided a supplemental response on August 3, 2023. Letter from General Counsel, HHS, to Assistant General Counsel, GAO (Aug. 3, 3023) (Second Response).

BACKGROUND

ACIP, HHS/CDC, and Recommended Immunization Practices

The Advisory Committee on Immunization Practices (ACIP) provides "advice and guidance to [HHS/CDC] regarding use of vaccines . . ." Charter of the Advisory Committee on Immunization Practices (ACIP Charter), *available at* https://www.cdc.gov/vaccines/acip/committee/charter.html (last visited Nov. 6, 2023).[1] ACIP reviews and makes recommendations with respect to all vaccines licensed for use in the United States. *Id.* When HHS/CDC adopts ACIP's recommendations, it publishes them as official HHS/CDC recommendations in a weekly publication titled *Morbidity and Mortality Weekly Report* (*MMWR*). *Id.*

On an annual basis, HHS/CDC "compiles all current ACIP recommendations for routine use" that HHS/CDC has adopted, and publishes them as "Recommended Immunization Schedules." First Response, at 1. HHS/CDC publishes one schedule for adults, and another for children and adolescents. *Id.*; *see also* CDC Immunization Schedules, *available at* https://www.cdc.gov/vaccines/schedules/index.html (last visited Nov. 6, 2023).

Regardless of whether HHS/CDC adopts ACIP's recommendations, those recommendations do not themselves mandate any action by states or other non-federal entities.[2] First Response, at 1. However, pursuant to the Patient

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[1] ACIP is a federal advisory committee governed by the Federal Advisory Committee Act, 5 U.S.C. Chap. 10. *See* ACIP Charter; *see also* 42 U.S.C. § 217a (providing that the Secretary of HHS may "appoint such advisory councils or committees" as are needed "for the purpose of advising him in connection with any of his functions").

[2] Pursuant to Section 1928 of the Social Security Act, which established the Vaccines for Children (VFC) Program, in order to be a "program-registered provider" that is entitled to receive pediatric vaccines free of charge from a state through

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Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, certain health insurance plans must provide coverage for "immunizations that have in effect a recommendation from the [ACIP] with respect to the individual involved." 42 U.S.C. § 300gg-13(a)(2). PPACA implementing regulations issued by the Centers for Medicare & Medicaid Services (CMS), the Internal Revenue Service (IRS), and the Employee Benefits Security Administration (EBSA), all indicate that for purposes of this provision "a recommendation from the [ACIP] is considered in effect after it has been adopted by [HHS/CDC]," meaning "when it is published in the MMWR." Second Response (quoting 26 C.F.R. § 54.9815-2713(a)(1)(ii), 29 C.F.R. § 2590.715-2713(a)(1)(ii), and 45 C.F.R. § 147.130(a)(1)(ii)).

The *Schedule*, published on February 10, 2023, is HHS/CDC's most recent annual undertaking to "consolidate and summarize updates to ACIP recommendations [adopted by HHS/CDC] on vaccination of children and adolescents and to assist health care providers in implementing [them]." *Schedule*. As compared with HHS/CDC's 2022 schedule for children and adolescents, the *Schedule* reflected "new or updated ACIP recommendations" with respect to (1) influenza vaccine, (2) pneumococcal conjugate vaccine, (3) measles, mumps, and rubella vaccine (MMR), and (4) COVID-19 vaccine.[3] The *Schedule* did not newly announce or adopt these four recommendations. Rather, HHS/CDC had announced and adopted them in distinct *MMWR* publications earlier in 2022. *See MMWR*, Aug. 26, 2022, *available at* https://www.cdc.gov/mmwr/volumes/71/rr/rr7101a1.htm?s_cid=rr7101a1_w (reflecting new recommendations for influenza vaccine) (last visited Nov. 6, 2023); *MMWR*, Sept. 16, 2022, *available at* https://www.cdc.gov/mmwr/volumes/71/wr/mm7137a3.htm?s_cid=mm7137a3_w (reflecting new recommendations for pneumococcal conjugate vaccine) (last visited Nov. 6, 2023); *MMWR*, Nov. 18, 2022, *available at* https://www.cdc.gov/mmwr/volumes/71/wr/mm7146a1.htm?s_cid=mm7146a1_w (reflecting new recommendations for MMR vaccine) (last visited Nov. 6, 2023); COVID-19 ACIP Recommendations, *available at* https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html (reflecting multiple *MMWR* publications adopting recommendations for pediatric use of COVID-19 in 2022) (last visited Nov. 6, 2023).

HHS/CDC, health care providers must "comply with the schedule, regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines, that is established and periodically reviewed and, as appropriate, revised, by the [ACIP]." 42 U.S.C. § 1396s(c)(2)(B)(i). However, the schedule referenced in this provision is not HHS/CDC's Recommended Immunization Schedule, but a separate list maintained by ACIP. Vaccines for Children Program, *available at* https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html (last visited Nov. 6, 2023).

[3] The *Schedule* also provided "clarification" of other prior recommendations. *See Schedule*.

The Congressional Review Act

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 to the Comptroller General for review before a rule can take effect. 5 U.S.C. § 801(a)(1)(A).[4] The report must contain a copy of the rule, "a concise general statement relating to the rule," and the rule's proposed effective date. *Id*. CRA allows Congress to review and disapprove federal agency rules for a period of 60 days using special procedures. *See* 5 U.S.C. § 802. If a resolution of disapproval is enacted, then the new rule has no force or effect. 5 U.S.C. § 801(b)(1).

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). However, 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. *Id.*

HHS/CDC did not submit a CRA report to Congress or the Comptroller General on the *Schedule*. In its First Response, HHS/CDC stated that the *Schedule* is not a rule because it "merely compiles past agency recommendations without making any new ones." First Response, at 2. In its Second Response, HHS/CDC stated further that the *Schedule* is not a rule by reference to the APA definition that CRA incorporates because it does not "issue new regulations," does not "change regulatory requirements or official policy," and does not "alter how [HHS/CDC] will exercise its discretion" considering that HHS/CDC "has no power to regulate in this area and no enforcement discretion to exercise" but "simply makes recommendations." Second Response, at 2.

For the reasons explained below, we find that the *Schedule* does not meet the definition of a rule and therefore is not subject to CRA.

[4] Alternatively, an agency can find for good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, and the rule will then take effect at a time the agency determines. 5 U.S.C. § 808(2).

DISCUSSION

An agency action is subject to CRA if it meets the APA's definition of a rule and no CRA exception applies. Because we conclude that the *Schedule* does not meet the definition of a rule, we need not address CRA's exceptions.

Applying APA's definition of a rule, the *Schedule* meets some but not all of the required elements. The *Schedule* is an agency statement because it is an official HHS/CDC document published on the agency's website. *Schedule*; *cf.* B-334005, Jan. 18, 2023. Additionally, the *Schedule* has future effect because it reiterates recommendations meant "to assist health care providers" on a prospective basis, presumably until HHS/CDC issues a superseding Recommended Immunization Schedule in 2024. B-316048, Apr. 17, 2008 (distinguishing agency statements that present considerations for the future from those limited to the evaluation of past or present conduct).[5] However, the *Schedule* does not meet the third element of the APA's definition of a rule because it was not designed to implement, interpret, or prescribe law or policy, nor was it meant to describe the organization, procedure, or practice requirements of an agency.

An agency action implements, interprets, or prescribes law or policy when it "issues new regulations, changes regulatory requirements or official policy, or alters how the agency will exercise its discretion, among other things." *See* B-334005, Jan. 18, 2023. GAO elaborated on this principle in B-334005, which concerned a system of records notice (SORN) published by the District of Columbia Court Services and Offender Supervision Agency, Pretrial Services Agency (PSA). *Id*. PSA had published this SORN to provide notice that it needed to create a system of records to facilitate storage, dissemination, and disposal of new information covered by the Privacy Act of 1974, 5 U.S.C. § 552a—namely, information about federal employees' requests for religious accommodation in response to Executive Order 14043, which required those employees' vaccination against COVID-19. *Id*. Under these circumstances, GAO found the SORN was not a rule. *Id*. As we explained, "the SORN was issued after the policy decision [to require vaccination] had been made by the President." *Id*. It "addressed a necessary statutory step implicated by th[at] prior policy decision" but did not, itself, implement, interpret, or prescribe policy. *Id*. Put differently, the SORN "left the world as [PSA] found it prior to [its] issuance." *Id*.

GAO reached a similar conclusion in B-330288, which concerned a memorandum

[5] HHS/CDC states that the *Schedule* lacks future effect because it does not add to prior HHS/CDC recommendations. First Response, at 2. However, the *Schedule's* purpose is not to present an evaluation of those prior recommendations or to provide for their final disposition in some respect, either of which may have suggested a lack of future effect. B-316048, Apr. 17, 2008. Rather, the *Schedule's* purpose is to present HHS/CDC's prior recommendations "in a user-friendly graphical format" for health care providers' ease of use going forward. *Id*. For that reason, the document

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from the Secretary of Commerce to the Under Secretary of Economic Affairs. B-330288, Feb. 7, 2019. As we explained in that case, the memorandum was not a rule because its only purpose was to explain the Secretary's rationale for a previous decision to include a question on the census. *Id*. "By making the memorandum public," moreover, "the agency was not engaging in any rulemaking" but simply "informing the public about both agency activities and the policy views that underlie those activities." *Id*. (noting the "responsibility" and "inherent authority" of agencies to inform the public about agency activities and their policy rationale).

Agency actions that meet the third element of APA's rule definition are readily distinguishable from the SORN in B-334005 and the memorandum in B-330288. For example, in B-238859, we found that the Forest Service engaged in rulemaking by amending the Tongass Land and Resource Management Plan. B-238859, Oct. 23, 2017. As we explained, "the purpose of this amendment" was to "implement" statutory responsibilities under the National Forest Management Act of 1976, which the amendment accomplished through policy changes such as the establishment of new criteria for the sale of timber to non-agency parties. *Id*. In B-329129, likewise, we found that a bulletin issued by the Consumer Financial Protection Bureau (CFPB) implemented policy, and thus met the third element of APA's rule definition, by specifying actions that lenders should take to ensure compliance with CFPB-enforced laws and regulations. B-329129, Dec. 5, 2017. *See also* B-287557, May 14, 2001 (finding that Record of Decision issued by Department of the Interior was a rule because it changed agency policy on how it would protect a river going forward).

Here, by reference to the above cases, the *Schedule* does not implement, interpret, or prescribe law or policy. The *Schedule*, like the PSA SORN, "left the world as [it] found it." B-334005, Jan. 18,2023. While the *Schedule* included additional recommendations, as compared with the prior year's Recommended Immunization Schedule, none of these recommendations were truly new—HHS/CDC had announced and adopted each of them in prior publications over the preceding calendar year. *See supra*, pp. 3–4. The purpose of the *Schedule* was just to "consolidate and summarize" those prior recommendations to "assist health care providers." *Schedule*. In that respect, the *Schedule* closely resembles the memorandum from B-330288, which "inform[ed] the public" about a prior decision by the Secretary of Commerce. B-330288, Feb. 7, 2019. HHS/CDC, like other agencies, has inherent authority to inform the public of its decisions, and its efforts to do so are not automatically rulemaking. *Id.* Unlike the agency documents from B-238859 and B-329129, the *Schedule* does not establish new criteria for agency action or change any existing criteria.

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is oriented toward the future rather than to the past or to a discrete present scenario. *See Schedule*, at 2 (directing health care providers to reference ACIP's website for "further guidance" and indicating that HHS/CDC "will post revised versions" of the *Schedule* if it discovers "errors or omissions").

Although PPACA requires that certain health insurance plans provide coverage for "immunizations that have in effect a recommendation from the [ACIP] with respect to the individual involved", HHS/CDC does not have authority or responsibility to enforce this requirement. 42 U.S.C. § 300gg-13(a)(2); Second Response, at 3–4. That authority and responsibility falls to the Centers for Medicare & Medicaid Services (CMS), the Internal Revenue Service (IRS), and the Employee Benefits Security Administration (EBSA). Second Response, at 3. CMS, IRS, and EBSA have vested HHS/CDC's adoption actions with some measure of importance by indicating, in their respective implementing regulations, that "a recommendation from the [ACIP] is considered in effect after it has been adopted by [HHS/CDC]," meaning "when it is published in the MMWR." Second Response, at 3 (quoting 26 C.F.R. § 54.9815-2713(a)(1)(ii), 29 C.F.R. § 2590.715-2713(a)(1)(ii), and 45 C.F.R. § 147.130(a)(1)(ii)). However, importantly, HHS/CDC has no control over these regulations, and they only make the timing of HHS/CDC's adoption actions significant for *other* agencies' enforcement purposes.

The *Schedule* also does not meet the third element of the APA's rule definition because it does not "describe the organization, procedure, or practice requirements of an agency." GAO has explained that rules falling into this category are those which "discuss the internal operations of [an] agency." B-334005, Jan. 18, 2023. In B-329926, for example, we found that the Social Security Administration's (SSA) Hearings, Appeals, and Litigation Law Manual (HALLEX) discussed the internal operations of SSA by outlining procedures for SSA employees to follow in "processing and adjudicating" benefits claims. B-329926, Sept. 10, 2018. In B-334005, by contrast, we found that the PSA SORN did not describe agency organization, procedure, or practice requirements, but merely "describe[d] [a] system of records the agency [was] establishing as required by the Privacy Act." B-334005, Jan. 18, 2023. In reaching this conclusion, we emphasized that the SORN, unlike the HALLEX in B-329926, "was not a matter of agency discretion" and "d[id] not govern" agency practice going forward. *Id.*

Here, as in B-334005, the *Schedule* does not discuss the internal operations of an agency, does not inform the agency's exercise of discretion, and does not govern agency procedures or practice. As explained above, it merely consolidates and describes vaccine-use recommendations that HHS/CDC previously adopted.

CONCLUSION

HHS/CDC published the *Schedule* to consolidate and summarize ACIP recommendations that HHS/CDC had previously adopted regarding immunizations for children and adolescents. The *Schedule* did not present new information or guidance and its purpose was to assist health care providers rather than to organize or inform agency action. The *Schedule* therefore was not designed to implement, interpret, or prescribe law or policy, nor did it describe HHS/CDC's organization, procedure, or practice requirements. As such, the *Schedule* is not a rule for

purposes of CRA and, thus, is not subject to the requirement that it be submitted to Congress and the Comptroller General before it may take effect.

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