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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 1

RIN 0991-AC17

Department of Health and Human Services Good Guidance Practices

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services finalizes its proposed regulations governing the agency's release and maintenance of guidance documents. These regulations will help to ensure that the public receives appropriate notice of new guidance and that the Department's guidance does not impose obligations on regulated parties that are not already reflected in duly enacted statutes or regulations lawfully promulgated under them.

DATES: This final rule is effective [OFR: Insert date 30 days after publication in the Federal Register]

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I. Statutory and Regulatory Background

Subject to certain exceptions, the Administrative Procedure Act (“APA”), 5 U.S.C. 551 *et seq.*, mandates that rules imposing new obligations on regulated parties must go through notice-and-comment rulemaking. *See, e.g., Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979). This is true regardless of whether agencies frame these rules as sub-regulatory guidance. *See, e.g., Iowa League of Cities v. EPA*, 711 F.3d 844, 875 (8th Cir. 2013); *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 385 (D.C. Cir. 2002). The APA’s procedural requirements sound in notions of good governance. *See, e.g., Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 741 (1996). Agencies can generally issue interpretive rules and statements of policy without conducting notice-and-comment rulemaking,¹ although such sub-regulatory guidance lacks the force and effect of law, and cannot bind regulated parties. *See, e.g., Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 99 (1995).

To promote the appropriate issuance and use of guidance documents, and consistent with the requirements of Executive Order 13891, “Promoting the Rule of Law Through Improved Agency Guidance Documents,” 84 FR 55,235 (Oct. 15, 2019), the United States Department of Health and Human Services (“HHS” or “the Department”) proposed regulations that set forth good guidance practices. This good guidance practices rule is one component of the

¹ *But see Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019).

Department's broader regulatory reform initiative.² The final rule is designed to increase accountability, improve the fairness of guidance issued by the Department, guard against unlawful regulation through guidance, and safeguard the important principles underlying the United States administrative law system.

II. Provisions of the Proposed Rule and Analysis of and Response to Public Comments

In the August 20, 2020 **Federal Register** (85 FR 51,396), HHS published a proposed rule titled "Department of Health and Human Services Good Guidance Practices" (hereinafter, "Good Guidance Practices proposed rule"). In response to the publication of that proposed rule, HHS received 88 comments from industry trade organizations, patient advocacy groups, providers, health insurers, manufacturers, a law firm, and members of the public. HHS published a correction to this proposed rule on August 26, 2020 (85 FR 52,515) updating certain proposed effective dates. In the following sections of this final rule, HHS includes a summary of the provisions of the August 20, 2020 proposed rule, the public comments received, HHS's responses to the comments, and any changes made to the regulatory text as a result.

Comment: Several commenters viewed the 30-day comment period (which began on August 17, 2020, the day that the Federal Register publicly displayed the proposed rule) as too short, and they requested a longer comment period.

Response: HHS respectfully disagrees with these commenters and continues to view a 30-day comment period as adequate for this notice of proposed rulemaking. The proposed rule, at only six pages in the Federal Register, is not lengthy. Neither the APA nor any other statute requires a longer comment period for the proposed rule. Instead, the APA merely requires that

² See, e.g., HHS, FY 2020 Annual Performance Plan and Report – Regulatory Reform, <https://www.hhs.gov/about/budget/fy2020/performance/regulatory-reform/index.html>.

“[a]fter notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation.” This standard was met here. Indeed, the fact that the Department received 88 comments from a broad cross-section of interested parties, including many trade organizations representing numerous stakeholders, confirms that the public had ample time to participate in this rulemaking.

A. Scope (§ 1.1)

HHS proposed to add 45 CFR 1.1, stating that the requirements to be established pursuant to the proposed rule would apply to all guidance documents issued by all components of the Department, except for the Food and Drug Administration (“FDA”), which has its own good guidance practices regulations that the Secretary plans to amend to conform those regulations to the requirements of Executive Order 13891. FDA currently operates under a set of good guidance practices regulations, see 21 CFR 10.115, as required by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 371(h), but no other division within HHS operates under a similar set of regulations.

Comment: One commenter urged HHS to amend FDA’s good guidance practices regulations to be consistent with the requirements in the proposed rule.

Response: HHS agrees. The Secretary still plans to amend FDA’s good guidance practices regulations, issued as required by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(h), to conform to the requirements of Executive Order 13891. However, such amendments have not proceeded in parallel with the Department’s broader regulation. Accordingly, in order to avoid significant disparities between the rules around guidance that apply to FDA and the rest of the Department, this final rule clarifies that FDA must comply with all requirements

implemented in this HHS Good Guidance Practices final rule—to the extent not already incorporated in the FDA good guidance practices regulations—until the Secretary issues a final rule amending FDA’s good guidance practices regulations. Primary provisions of this Good Guidance Practices final rule that are not already incorporated into FDA’s good guidance practices include, but are not limited to, the requirement that guidance documents issued after the effective date of this rule include a disclaimer clarifying that the contents do not have the force and effect of law (unless the FDCA or other statute authorizes the issuance of binding guidance), as well as the information fields specified at 45 CFR 1.3(a)(3)(iii); the requirement that all significant guidance documents be issued only following a public notice and comment period (unless an exemption applies); that all guidance documents be included in the HHS guidance repository and if not, they will be considered rescinded; and that all FDA guidance documents shall be subject to the petition process at 45 CFR 1.5.

Comment: One commenter suggested that the final rule exempt Centers for Medicare & Medicaid Services (CMS) guidance documents from being within the rule’s scope, just as HHS had proposed to exempt FDA guidance documents from the scope of the rule.

Response: HHS declines to exempt CMS guidance documents from the scope of the Good Guidance Practices final rule. No division of the Department will be operating in a manner inconsistent with the important protections contained in this final rule. As HHS explained in the proposed rule, FDA has long operated under its own set of good guidance practices regulations, and as this final rule clarifies, FDA will be subject to the requirements of this Good Guidance Practices final rule until the Secretary amends FDA’s own good guidance practices regulations to conform to the requirements of Executive Order 13891.

HHS is finalizing the proposed scope of this rule but clarifying that until the Secretary amends FDA's own good guidance practices regulations, FDA will be subject to the requirements in this Good Guidance Practices final rule. After the Secretary amends FDA's good guidance practices regulations, this rule will, as proposed, apply to all guidance documents issued by HHS except for guidance documents issued by FDA.

B. Definitions (§ 1.2)

1. Guidance Document

HHS proposed that the HHS Good Guidance Practices regulations would apply to all guidance documents and proposed to define the term "guidance document" as any Department statement of general applicability which is intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation. In the proposed rule, HHS explained that the contents of a transmission, rather than its format, dictates whether it would constitute a guidance document; guidance would not need to be in the form of a formal written document to constitute a "guidance document." The hallmark of guidance is that it includes statements of general applicability intended to govern the future behavior of regulated parties. Thus, HHS proposed that agency releases of technical or scientific information by itself would not constitute guidance unless the release also contains a policy on, or related to, technical or scientific information that is intended to affect the future behavior of regulated parties. However, HHS clarified that the Good Guidance Practices regulations would not require HHS to justify the quality of information; regulated parties and other stakeholders should use existing mechanisms to address the quality of information contained in documents issued by HHS.

Materials directed to government employees or agency contractors, rather than regulated parties, would also generally not constitute guidance within the meaning of this proposed rule. Similarly, most agency statements communicating news updates about the agency would not constitute guidance. Agency statements of specific applicability—such as advisory or legal opinions directed to particular parties about circumstance-specific questions; notices regarding particular locations, facilities, or products; and correspondence with individual persons or entities, including congressional correspondence or notices of violation—would also generally not be “guidance.”

HHS proposed that certain categories of documents would be excluded from the term guidance document: rules promulgated pursuant to notice and comment under 5 U.S.C. 553 or similar statutory provisions; rules exempt from rulemaking requirements under 5 U.S.C. 553(a); rules of agency organization, procedure, or practice; decisions of agency adjudications under 5 U.S.C. 554 or similar statutory provisions; internal guidance directed to the Department or other agencies that is not intended to have substantial future effect on the behavior of regulated parties; internal executive branch legal advice or legal opinions addressed to executive branch officials; legal briefs and other court filings; grant solicitations and awards; or contract solicitations and awards.

HHS proposed that whether a document would be exempt as a rule of agency organization, procedure, or practice is a functional test. Documents that are designed to shape the behavior of the Department would be exempt; documents designed to shape the behavior of regulated parties would be considered guidance if they also set forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation.

Pre-enforcement rulings, which are formal written communications applying the law to a specific set of facts (as opposed to making statements of general applicability) would also not constitute guidance documents under the proposed rule. Examples include letter rulings, advisory opinions directed to a specific party, and no-action letters. But material embedded within an advisory opinion or similar letter that otherwise satisfies the definition of “guidance document” would still be guidance for purposes of this rule. If a document addressed to specific individuals nonetheless contains a statement of general applicability setting forth a relevant policy or interpretation that is intended to have future effect by guiding the conduct of other regulated parties, then the document would be a guidance document.

Consistent with its existing responsibilities, HHS proposed that the HHS Office of the General Counsel (“OGC”), after discussing with senior officials within the Department, would make the legal determination of whether a document is excluded from the term “guidance document” and whether a purported guidance document is, in fact, a legislative rule that must go through notice-and-comment rulemaking. OGC would continue to determine whether certain guidance relating to Medicare should nonetheless go through notice-and-comment rulemaking as a result of the Supreme Court’s decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).

HHS received the following comments on the proposed definition of “guidance document.”

Comment: Several commenters thought that the definition of “guidance” as materials “intended to have future effect” was too vague and confusing because it would be difficult to determine the Department’s “intent” in its issuance of a document in order for affected parties to determine whether it is intended to govern the future behavior of regulated parties. Some

commenters also noted that regulated parties may also rely on internal agency documents in guiding their future conduct, and thus these documents should not be exempt from being considered “guidance documents.” A small number of commenters suggested that rather than use the phrase “sets forth a policy,” the definition of guidance document should say “sets forth an expectation.”

Response: The phrase “intended to have future effect” is not a subjective test of an agency official’s thought processes, but rather, is an objective test to be applied when reviewing the face of a guidance document. For example, a document satisfies this standard when it provides information in a manner that can be reasonably interpreted as designed to encourage regulated entities to voluntarily take certain actions. This definition is consistent with the Office of Management and Budget’s (“OMB’s”) longstanding definition of guidance as “an agency statement of general applicability and future effect . . . that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue,” where “future effect” means the “intended . . . impacts due to voluntary compliance with a guidance document.” *See* OMB Bulletin 07-02, “Agency Good Guidance Practices,” 72 FR 3432, 3434–35 (Jan. 25, 2007). HHS has no basis for believing that regulated parties have found this definition confusing in the past and therefore is incorporating a very similar definition in this final rule. It believes that the phrase “sets forth an expectation” is captured by the phrase “intended to have future effect.” HHS agrees with the commenters who noted that internal agency documents can sometimes constitute guidance documents if they are designed to guide the conduct not just of agency officials, but also regulated parties, and it reiterates that whether a document is properly considered a “guidance document” under this rule is a functional test.

Comment: Several commenters thought that the definition of “guidance” was too vague and confusing, because categorization of a statement as guidance rests not on the format, but on the content of the communication, such that they believed that “guidance” could be contained “within nonguidance.” These commenters also asserted that the final rule should require OGC to publicly release its analyses of whether a document is a guidance document, “nonguidance document” or “nonguidance” within a guidance document. A few commenters stated that the definition of “guidance” is too vague because the proposed rule did not explain how the term “guidance document” will be defined in the context of Medicaid, CHIP, and other programs administered by CMS.

Response: HHS clarifies that guidance is not embedded in “nonguidance.” Rather, if a document that would generally fall outside of the definition of guidance, *e.g.*, a document of specific applicability, such as an advisory opinion, contains a statement of general applicability setting forth a relevant policy or interpretation that is intended to govern the future behavior of regulated parties—in other words, contains guidance—then the entire document would constitute a guidance document under this rule. As a result, there is no need to designate certain parts of documents as guidance and other parts “nonguidance.” *See also* 85 FR at 51,397 (“If a document addressed to specific individuals nonetheless contains a statement of general applicability setting forth a relevant policy or interpretation that is intended to have future effect by guiding the conduct of other regulated parties, *then the document would be a guidance document.*” (emphasis added)). With respect to the suggestion that HHS OGC publicly post its analysis of whether material constitutes “guidance,” HHS declines to incorporate this requirement. Whether material constitutes “guidance” is a legal question and as such, HHS OGC’s internal analyses of these questions will generally be privileged and confidential.

Furthermore, HHS OGC does not have the resources to prepare formal written analyses of every single document that potentially constitutes guidance. If an interested party has a question about whether a document is properly considered guidance, the interested party could petition the agency under the process set forth in § 1.5, and HHS OGC will work with the relevant operating division to prepare a non-privileged public response.

HHS believes the proposed rule provided sufficient information about how the Department proposed to define the term “guidance document.” It was not feasible for HHS, in the proposed rule preamble, to specifically articulate how the term “guidance document” will be applied in each program implemented by HHS. Further, this proposed term builds on OMB’s longstanding definition of guidance document and OMB’s Final Bulletin on Agency Good Guidance Practices, to which HHS cited in the preamble to the proposed rule. *See* 85 FR at 51,396. This context, in combination with HHS’s own preamble discussion about the term, provided commenters with significant detail about the proposed definition.

Comment: A few commenters asked HHS to clarify the meaning of the term “regulated party” within the definition of “guidance document.” One commenter asked that HHS clarify that “regulated parties” include States or state agencies.

Response: “Regulated party” is a broad term that covers any person or entity that is subject, or potentially subject, to the regulatory authority of any division of HHS. HHS agrees that States and state agencies can be “regulated parties” for purposes of this rule, such as in the context of guidance documents relating to the Medicaid program.

Comment: One commenter asked HHS to limit the definition of “guidance document” to written materials. This commenter also asked HHS to clarify that discussions of technical advisory groups are not “guidance.”

Response: HHS declines to limit the definition of “guidance document” to written materials. As we explained in the proposed rule, citing to OMB’s 2007 “Agency Good Guidance Practices” (72 FR 3432), the definition of “guidance document” encompasses all guidance materials, such as videos, in any format. HHS is reiterating that, consistent with the 2007 OMB Bulletin, the “definition of ‘guidance document’ encompasses all guidance materials, regardless of format.” *Id.* at 3434. Divisions of HHS commonly issue communications with regulated parties through website and blog entries and social media posts. Using such means of communicating with the public can offer benefits to HHS, including more effective outreach to interested parties; however, such electronic communications may often satisfy the definition of “guidance document,” and therefore would be subject to all of the requirements in this final rule, including that they cannot purport to impose binding new obligations on regulated entities. It would be arbitrary, and ultimately undermine the important procedural protections of this rule, if HHS were required to follow certain processes for written materials, but not to follow those same requirements for non-written or non-printed materials, even where they transmitted the same information to regulated parties. However, HHS agrees with the commenter that discussions of technical advisory groups do not constitute guidance because the statements are from members of the public and, thus, are not “agency statements.”

Comment: A few commenters asked HHS to clarify that guidance from HHS to agency contractors is “guidance” under the rule. Another commenter asked HHS to revise the rule to require its contractors to also be obligated to adhere to HHS good guidance practices.

Response: Materials sent from HHS to agency contractors, such as technical directions, are generally not “guidance” under the rule, unless the content is designed to guide the conduct of regulated parties. Documents issued by HHS to agency contractors can be guidance

documents if they include interpretive rules or policies that are of general applicability, particularly if they are also intended to serve a broader audience in addition to contractors, such as CMS Rulings. However, CMS Rulings, like all guidance documents, must still comply with procedural requirements imposed by the APA and Section 1871 of the Social Security Act.

Comment: Several commenters asked HHS to clarify whether particular types of documents are guidance documents, such as Paperwork Reduction Act materials, the Medicaid Managed Care Rate Development Guide, PDP Bid Instructions, guidance documents directed to Medicare Accrediting Organizations, the State Operations Manual, the PACE Manual, the Qualified Health Plan Issuer Application Instructions, the October 31, 2019 memorandum from OMB implementing Executive Order 13891 (“October 31, 2019 OMB Memo”), MLN Matters documents, Frequently Asked Questions (“FAQs”), documents issued by Medicare Administrative Contractors (“MACs”), OIG advisory opinions, and preambles to proposed and final regulations.

Response: This Rule does not affect HHS’s obligations under the Paperwork Reduction Act. The Paperwork Reduction Act requires that when an agency seeks to collect information from ten or more persons, 44 U.S.C. 3501, the agency must, subject to certain exceptions, submit the collection of information to OMB’s Office of Information and Regulatory Affairs (OIRA) for clearance and must publish the proposed information collection in the Federal Register for public comment. 44 U.S.C. 3506, 3507. Whether a document containing a collection of information under the Paperwork Reduction Act is also “guidance” under this Rule, as opposed to a purely factual collection of information, depends on the content of the document. Similarly, we would evaluate Paperwork Reduction Act clearance documents and Federal Register notices based on

their contents to assess whether they constitute guidance, although we do not expect that they would be guidance.

The Medicaid Managed Care Rate Development Guide, PDP Bid Instructions, guidance documents directed at Medicare Accrediting Organizations, the State Operations Manual, the PACE Manual, and the Qualified Health Plan Issuer Application Instructions are all “guidance documents” within the meaning of this rule, because they set forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation, and they are designed to have future effect on the behavior of regulated parties. HHS cannot opine on whether the October 31, 2019 OMB Implementing Memo is “guidance” under the HHS rule. That is because this final rule only applies to statements issued by HHS, and OMB, not HHS, issued that memorandum. MLN Matters documents and HHS-issued FAQs are the type of blog posts and web statements that will generally constitute guidance. Instructions from MACs are not “Department statements” and, thus, are not guidance documents. OIG advisory opinions are generally not considered guidance because they are designed to contain statements of specific, rather than general, applicability. Since the inception of the advisory opinion process, in accordance with Section 1128D(b)(4)(A) of the Social Security Act, OIG has taken the view that all advisory opinions issued under this statute are legally binding on the Department (including the OIG) and the requestor, but only with respect to the specific conduct of the particular requestor, and that no third parties are bound nor may they rely on an advisory opinion. HHS and OIG have concluded that the advisory opinions OIG has issued prior to the issuance of this final rule are not guidance. Preambles to proposed and final regulations are generally considered to be guidance, because they inform the interpretation of the text of a regulation. *See, e.g., Tex.*

Children’s Hosp. v. Azar, 315 F. Supp. 3d 322, 334 (D.D.C. 2018);³ *but see Natural Res. Def. Council v. E.P.A.*, 559 F.3d 561, 564–65 (D.C. Cir. 2009) (“While preamble statements may in some unique cases constitute binding, final agency action susceptible to judicial review, this is not the norm.” (internal citation omitted)). We are finalizing the definition of “guidance document” as proposed.

2. Significant Guidance Document

In the proposed rule, HHS proposed to classify certain guidance documents as “significant guidance documents,” which HHS proposed to define as a guidance document that is likely to lead to an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles of Executive Order 12866, “Regulatory Planning and Review.” In the proposed rule, HHS explained that to calculate whether a guidance document is likely to have an annual effect on the economy of \$100 million or more, HHS would be required to assess the benefits, costs, or transfer impacts imposed by that guidance document; as part of this analysis, any benefit, cost or transfer occurring in any consecutive twelve-month period would be compared against the \$100 million threshold. Future

³ As explained above, HHS is finalizing the proposed definition of “guidance repository,” which permits the primary guidance repository, at www.hhs.gov, to link to subsidiary guidance repositories. HHS will include a link to the Federal Register on the HHS guidance repository. Interpretive rules and policies in preambles to proposed and final HHS rules contained in the Federal Register will be considered guidance included in the guidance repository. HHS will not separately post preambles to the guidance repository.

cost savings would not be used to offset upfront costs. In performing these analyses, HHS further explained in the proposed rule that the Department would recognize that guidance documents are not legally binding and, therefore, not all regulated parties would necessarily conform their behavior to the recommendations set forth in the guidance, and furthermore, that the benefits, costs, and transfers may have been accounted for when HHS issued an underlying regulation, if any.

In the proposed rule, HHS explained that it anticipated that only a subset of guidance documents would satisfy the proposed rule's definition of a significant guidance document. This is because to qualify as guidance, as opposed to a legislative rule, a document must reflect, implement, interpret, or describe a legal obligation imposed by a pre-existing, external source or advise the public prospectively of the manner in which the agency intends to exercise a discretionary power. It is HHS's presumption that a guidance document that HHS deems significant is actually a legislative rule that must go through notice-and-comment rulemaking. HHS shall make all initial decisions as to whether a guidance document is significant, and OMB shall make all final determinations. If a significance determination requires a legal conclusion regarding HHS's governing statutes or regulations, however, OMB cannot reach legal conclusions on behalf of HHS.

HHS received the following comments on the proposed definition of "significant guidance document."

Comment: Several commenters thought that the definition of "significant guidance" was confusing and unclear because it does not provide a clear explanation for how costs related to significant guidance would be calculated and provided no discussion of standards, methodologies, or other criteria to determine whether guidance is "significant." One commenter

specifically suggested that the test for inconsistencies with the planned actions of other agencies and the novel legal issues test be eliminated from the definition of “significant guidance,” because these tests would impose a burdensome cross-agency review of all sub-regulatory guidance. Other commenters supported the proposed definition of “significant guidance.”

Response: HHS appreciates the comments. The definition of “significant guidance” is modeled after the major-rule test from the Congressional Review Act. See 5 U.S.C. 804(2). For example, to determine whether guidance is significant because it will likely result in an annual effect on the economy of \$100 million or more, HHS will use the well-established test for making that same determination under the Congressional Review Act, as noted in the proposed rule. The other criteria for determining whether guidance is significant are also specified in the proposed rule, and some of these criteria also have some overlap with the Congressional Review Act’s definition of major rule. Specifically, guidance is significant if it adversely affects in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; creates a serious inconsistency or otherwise interferes with an action taken or planned by another agency; materially alters the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or raises novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles of Executive Order 12866, “Regulatory Planning and Review.” HHS believes the Department has discretion in assessing these factors and that these types of assessments are well within the Department’s expertise to make. HHS respectfully disagrees that the criteria relating to novel legal issues or the planned actions of other agencies would require a cross-agency review of all sub-regulatory guidance. OMB—which has an excellent overview of guidance and regulatory issues across all

agencies—will make all final decisions on the significant guidance determination and will help identify guidance documents that could trigger this criterion. If an interested party believes that the Department has incorrectly categorized a guidance document as non-significant, the interested party may utilize the petition process set forth at § 1.5.

Comment: Several commenters asserted that the proposed definitions of “guidance document” and “significant guidance” provided insufficient information to allow for effective comment.

Response: HHS respectfully disagrees with these comments. HHS received a diverse set of comments on various aspects of the proposed definitions of “guidance document” and “significant guidance document,” as summarized above and below, which confirms that the Department provided the public with sufficient information about its proposals to permit comment on the proposed definitions. *See Nuvio Corp. v. FCC*, 473 F.3d 302, 310 (D.C. Cir. 2006) (citing comments received as evidence that notice of proposed rulemaking “gave interested parties a reasonable opportunity . . . to present relevant information on the central issues”); *see also, e.g., Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004); *Appalachian Power Co. v. EPA*, 135 F.3d 791, 816 (D.C. Cir. 1998) (per curiam); *Stringfellow Mem’l Hosp. v. Azar*, 317 F. Supp. 3d 168, 187 (D.D.C. 2018).

Comment: One commenter suggested that HHS expand the definition of “significant guidance” to include any guidance that sets forth an initial interpretation of a statutory or regulatory requirement or changes such an interpretation. Another commenter suggested that HHS expand the definition of “significant guidance” to include any guidance that requires states to revise their statutes or regulations.

Response: HHS appreciates the first commenter’s suggestion. However, HHS believes this would significantly expand the set of documents categorized as “significant guidance” and may prove unworkable. HHS will consider potentially expanding the category of significant documents in the future, as the Department gains more experience implementing this final rule. HHS also declines to include within “significant guidance” any instructions that require states to revise their statutes or regulations. Guidance documents cannot impose new binding obligations on any entity. As a result, if a document purported newly to require states to revise a statute or regulation, such a purported instruction could not, by definition, be guidance. Guidance documents may, however, restate and discuss binding statutory or regulatory requirements, but should, when doing so, provide the citation for the applicable statutory or regulatory requirement.

Comment: Several commenters concluded that any document categorized as “significant” is in fact a legislative rule that must go through the APA notice-and-comment rulemaking process. Another commenter expressed concern that significant guidance will be viewed as permissibly being able to impose binding new obligations on regulated parties.

Response: HHS appreciates the commenters’ concerns. As explained in the preamble to the proposed rule, HHS expects significant guidance documents to be relatively few, because as these commenters note, many issuances satisfying one of the significant guidance document criteria may also impose binding new obligations and as such, are legislative rules that must go through the APA’s notice-and-comment rulemaking process. Interested parties who believe that HHS has incorrectly classified a legislative rule as a significant guidance document may utilize the petition process set forth in § 1.5.

HHS disagrees that significant guidance documents will be viewed as authorized to impose binding new obligations on regulated parties. These guidance documents, like all other guidance documents, will be posted to the HHS guidance repository, which will carry a disclaimer reiterating that all documents contained therein do not impose any new binding obligations unless authorized by law to do so. In addition, any significant guidance documents issued after this rule is finalized will generally include on their face the disclaimer set forth at § 1.3, which reiterates that such documents “do not have the force and effect of law and are not meant to bind the public in any way.”

HHS finalizes the definition of “significant guidance” as proposed.

3. Issued

In the proposed rule, HHS defined “issued” to mean a distribution of information to the public that HHS initiated or sponsored. However, HHS clarified that if a document directed solely to Department employees must be made publicly available under law or agency disclosure policies, for example posted on an agency website as the result of multiple requests under the Freedom of Information Act, the document would not be considered to be issued.

HHS received one comment on the definition of “issued”:

Comment: A commenter expressed concern that the proposed definition of “issued” excluded documents directed solely to government employees or agency contractors, explaining that CMS and others have attempted to use instructions to contractors to impose binding requirements on Medicare Advantage plans through audit and other enforcement activities.

Response: As HHS explained in the proposed rule, whether something is a guidance document is a functional test. Documents ostensibly directed at government employees or agency contractors but that are designed to, or are used to, shape the behavior of regulated parties

will be considered guidance if they also set forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation.

HHS is finalizing the definition of “issued” as proposed.

4. Guidance Repository

HHS proposed to define “guidance repository” to mean an online electronic database containing or linking to guidance documents, and proposed that the Department’s primary guidance repository could link to subsidiary guidance repositories.

Comment: One commenter asked HHS to clarify that the online electronic database would be publicly available and free to access.

Response: HHS clarifies that by “online,” the final rule refers to a publicly available internet portal that is not behind a paywall.

Comment: A few commenters commended FDA’s pre-existing guidance website for its functionality and utility and expressed a desire for the HHS guidance repository to become more user-friendly.

Response: HHS is glad that regulated parties have found FDA’s guidance website to be useful. We note that FDA’s guidance website has been operational for far longer than the HHS guidance repository, and HHS will consider incorporating additional functionality elements in the future, as the Department gains more experience with administering the guidance repository.

HHS finalizes the definition of “guidance repository” as proposed.

C. Requirements for Department Issuance and Use of Guidance Documents (§ 1.3)

In the proposed rule, HHS proposed that, unless otherwise authorized by statute, HHS may not issue any guidance document that establishes legal obligations not reflected in duly enacted statutes or regulations lawfully promulgated under them, and may not use any guidance

document for purposes of requiring persons or entities outside HHS to take any action or to refrain from taking any action beyond what is already required by the terms of an applicable statute or regulation. HHS explained that this is an existing legal obligation but that the Department proposed to codify this requirement in order to ensure consistent compliance with these important legal principles.

HHS also proposed a process for issuing guidance that would formalize guardrails designed to ensure that guidance documents are appropriately issued and used. HHS proposed that after November 16, 2020, each guidance document issued by HHS, or any of its components, would be required specifically to state that it is a “guidance” document and use the following language, unless the guidance is authorized by law to be binding: “The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.” HHS proposed that no guidance document issued by HHS would be able to direct parties outside the federal government to take or refrain from taking action, except when restating—with citations to statutes, regulations, or binding judicial precedent—mandates contained in a statute or regulation.

In the proposed rule, HHS also proposed to require that each guidance document issued by HHS or any component of HHS after November 16, 2020, must also include the following information: (1) the activities to which, and the persons to whom, the guidance applies; (2) the date HHS issued the guidance document; (3) a unique agency identifier; (4) a statement indicating whether the guidance document replaces or revises a previously issued guidance document and, if so, identifying the guidance document that it replaces or revises; (5) a citation

to the statutory provision(s) and/or regulation(s) (in Code of Federal Regulations format) that the guidance document is interpreting or applying; and (6) a short summary of the subject matter covered in the guidance document. For guidance documents issued before November 16, 2020, HHS proposed that the Department would not retrospectively revise those guidance documents to include the information listed in this paragraph. HHS further clarified that any guidance document issued in conjunction with one or more other agencies would nonetheless be required to comply with all requirements that would be applicable if the guidance document were issued solely by HHS.

HHS proposed to apply additional procedures to significant guidance documents. HHS would submit all significant guidance documents to OIRA for review under Executive Order 12866 prior to issuance. Significant guidance documents would be required to comply with applicable requirements for significant regulatory actions, as set forth in executive orders, except that only economically significant guidance documents would require a separate Regulatory Impact Analysis. The Secretary, on a non-delegable basis, would have to approve any significant guidance document before the Department issues it. HHS specifically requested comments as to whether the Secretary should instead have the limited authority to delegate approval of guidance documents to the Deputy Secretary, and whether the Secretary should be required to approve certain non-significant guidance documents prior to publication.

HHS proposed that, prior to issuing any significant guidance document, HHS must offer a public notice and comment period of at least 30 days. HHS would be required to publish a public notice in both the Federal Register and the guidance repository. This notice would list the end of the comment period, provide information about where the public may access a copy of the proposed significant guidance document, and include how written comments may be submitted

on the proposed significant guidance document and an internet website where those comments may be reviewed by the public. When issuing the significant guidance document, HHS would be required to review all comments received and publish an easily accessible public response to major concerns raised. *Cf., e.g., New Lifecare Hosps. of Chester Cty. LLC v. Azar*, 417 F. Supp. 3d 31, 43–44 (D.D.C. 2019) (discussing APA standard for agency responses to public comments during notice-and-comment rulemaking).

Under the proposed rule, HHS could elect not to conduct a comment period if it were to find that notice and public comment are impracticable, unnecessary, or contrary to the public interest. The Secretary, as the individual approving the significant guidance document, would be required to make this finding, and the significant guidance document would have to incorporate the finding and a brief statement of reasons in support of such finding. In addition, a significant guidance document could be exempted from any other requirement otherwise applicable to significant guidance documents if the Secretary of HHS and the Administrator of OIRA were to agree that exigency, safety, health, or other compelling cause warrants the exemption.

HHS also proposed that it would seek from OIRA, as appropriate, categorical determinations that classes of guidance presumptively do not qualify as significant. Any guidance satisfying such a categorical exemption presumptively need not comply with the requirements of § 1.3(b) but would need to comply with all other requirements applicable to guidance documents. OIRA may request to review guidance documents within a categorical exemption and may nonetheless conclude that a guidance document that is presumptively not significant is in fact significant.

HHS received the following comments on the proposed process for issuing guidance documents:

Comment: Several commenters stated that the APA exempts guidance documents from the notice-and-comment requirements of 5 U.S.C. 553, and that the Congressional Review Act, 5 U.S.C. Sections 801–808, also does not require guidance to go through notice and comment procedures. They assert that HHS fails to explain the statutory basis authorizing it to apply notice and comment requirements to guidance documents.

Response: The APA requires that agencies must publish notice of a proposed rulemaking and give the public the opportunity to participate, usually by submitting comments, prior to issuing the rule. *See* 5 U.S.C. 553(b). Subsection 553(b) exempts interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice from the notice and comment requirement, unless otherwise required by statute. However, it does not prohibit agencies from using additional procedures for rules that would otherwise be exempt from notice and comment procedures. The Supreme Court has recognized that the APA provides a statutory floor, not a ceiling, on the administrative procedures an agency may choose to adopt when promulgating legislative rules or issuing guidance. *See Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978) (“Agencies are free to grant additional procedural rights in the exercise of their discretion . . .”).

HHS has previously adopted procedures above the APA floor. In 1971, then-Health Education and Welfare Secretary Richardson announced that, despite the exemption in the APA, the department would no longer consider matters relating to public property, loans, grants, benefits, and contracts exempt from notice and comment rulemaking (36 FR 2532 (Feb. 5, 1971)), and the courts have enforced the requirement that these programs use notice and comment rulemaking ever since. *See, e.g., Humana of S.C. v. Califano*, 590 F.2d 1070, 1084 (D.C. Cir. 1978) (discussing waiver of benefit exemption and application of mandatory rulemaking procedures). *See generally*

Service v. Dulles, 354 U.S. 363, 388 (1957) (where agency had adopted regulations governing decision committed to the Secretary’s discretion by statute, failure to apply agency regulations was illegal).

Similarly, nothing in the Congressional Review Act precludes the adoption of additional procedures for guidance documents, nor does using these procedures affect whether any particular guidance is also a rule subject to the Congressional Review Act.

The requirements within this final rule are well within the authority provided by the APA and the Congressional Review Act. HHS does not need additional statutory authority to provide notice and solicit public comments on significant guidance documents, or to apply any of the other procedures implemented by this final rule.

Comment: Several commenters noted that the Congressional Review Act requires agencies to submit certain guidance documents to Congress, even if they are exempt from notice and comment rulemaking. The commenters expressed concern that the proposed rule did not mention these requirements and did not explicitly discuss congressional review of significant guidance.

Response: The Congressional Review Act requires agencies to give Congress notice whenever they issue rules, 5 U.S.C. 801(a)(1)(A), which the Congressional Review Act defines to include interpretive rules and policy statements if they are “designed to implement, interpret, or prescribe law or policy,” 5 U.S.C. 551, as incorporated by 5 U.S.C. 804(3). The Congressional Review Act authorizes OIRA to make a determination whether a rule is a “major rule” under the Congressional Review Act. 5 U.S.C. 804(2). For rules determined by OIRA to be “major rules,” agencies must generally provide advance notice to Congress. 5 U.S.C. 801(a)(3). Section 1.2 of this final rule incorporates and extends the major rule test from the

Congressional Review Act in the definition of “significant guidance.” Section 1.3(b)(2)(i) of the final rule requires the Department to submit significant guidance to OIRA for review. To the extent that a guidance document is also a “rule” subject to the Congressional Review Act, this final rule does not purport to change or modify the Congressional Review Act’s requirements for Congressional notification.

Comment: Several commenters pointed to what they perceived to be important questions left open by the proposed rule, such as whether HHS has an obligation to consider and respond to comments and how stakeholder input would be considered or integrated into proposed significant guidance.

Response: As HHS explained in the preamble to the final rule, HHS does have an obligation to consider all comments and to respond not to each individual comment, but rather to all major concerns raised. *See* 85 FR at 51,398 (“HHS would be required to review all comments received and publish an easily accessible public response to major concerns raised.”). This is a familiar standard for the Department and commenters. *Cf. Env’tl. Def. Fund v. E.P.A.*, 922 F.3d 446, 458 (D.C. Cir. 2019) (describing obligation under the APA to respond to major substantive comments during notice-and-comment rulemaking). Accordingly, HHS clarifies that the Department will consider comments timely submitted during a comment period and, as appropriate, modify a significant guidance document based upon stakeholder feedback in a manner similar to the process the Department uses for reviewing and incorporating feedback during the APA notice-and-comment rulemaking process.

Comment: Several commenters asked whether significant guidance issued through a notice-and-comment process could be rescinded without notice and comment.

Response: HHS will not use a notice-and-comment process for rescinding significant guidance documents. As the proposed rule explained, significant guidance documents are a subset of guidance documents, and the Department can rescind a guidance document by not posting it, or not maintaining its posting, on the HHS guidance repository. With the limited exception of certain Medicare guidance for which notice-and-comment rulemaking is required under Section 1871 of the Social Security Act, the Department is under no obligation to rescind significant guidance documents through a notice-and-comment process simply because the Department elected to apply such a process to the issuance of the significant guidance document. *See Vermont Yankee*, 435 U.S. at 524, 543–44; *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 101 (2015). HHS notes that if, after the effective date of this final rule, rescinded guidance is replaced by a new guidance document, the replacement guidance must contain a reference to the rescinded guidance, and, if significant, the replacement guidance would itself be subject to notice and comment.

Comment: A few commenters expressed concern that the proposed notice-and-comment process for significant guidance documents would be too cumbersome, and it would inhibit the Department’s ability to timely issue significant guidance documents, particularly in circumstances such as during public health emergencies. Other commenters expressed strong support for the proposed notice-and-comment process, indicating that they welcomed the opportunity to participate in the development of significant guidance documents. Some of these commenters suggested that the Department should offer a longer comment period, such as 60 days instead of 30 days, in order to ensure robust public participation. Other commenters expressed support for the proposed exceptions to the notice-and-comment process, under which HHS could elect not to conduct a comment period if it were to find that notice and public

comment are impracticable, unnecessary, or contrary to the public interest. Some of these commenters asked HHS to provide specific examples of when the Secretary might invoke this exceptions process. A couple of commenters recommended that HHS implement a process for soliciting public feedback about whether a guidance document is significant.

Response: HHS appreciates the comments and agrees that the benefits of receiving stakeholder input on significant guidance documents generally outweigh any administrative costs or incremental delays. A 30-day comment period generally strikes the right balance between competing needs, namely, the Department's interest in promptly issuing significant guidance and the public's interest in having sufficient time to offer thorough feedback. Nonetheless, HHS also agrees with the commenters who voiced support for the exceptions process. HHS plans to use this exceptions process when needed, as the Department acknowledges that certain circumstances, such as public health emergencies, may make it appropriate to invoke this exceptions process.

HHS does not plan to solicit public feedback as to whether a guidance document is significant. First, this would further lengthen the process of issuing a significant guidance document, which may make it more difficult for the Department to timely issue relevant guidance. HHS also believes that the criteria for a guidance document being "significant" require an assessment of factors that lie within the unique expertise of the Department and OMB. And finally, as indicated in the preamble to the proposed rule, OMB will make all final determinations as to whether a guidance document is significant. If HHS concludes in the future that public feedback on any question relating to significant guidance would be helpful, HHS may issue a Request for Information.

Comment: A couple commenters suggested specific documents that HHS should work with OMB to categorize as presumptively exempt from being considered significant guidance, and furthermore, that HHS provide a notice and comment process for categories of documents that are being contemplated for exemption.

Response: HHS will consider seeking public feedback through a future request for information as to categories of documents that should qualify for an exemption. OMB will make final determinations as to the categories of documents that are considered presumptively exempt.

Comment: Several commenters claimed that the proposed rule failed to address joint guidance issued by multiple agencies. Other commenters asked HHS to carefully coordinate with other agencies when jointly issuing guidance, in order to avoid legal and operational challenges for regulated parties.

Response: HHS respectfully disagrees that the proposed rule did not address guidance jointly issued by multiple agencies. In the preamble to the proposed rule, HHS stated, “Any guidance issued in conjunction with one or more other agencies would nonetheless be required to comply with all requirements that would be applicable if the guidance document were issued solely by HHS.” 85 FR at 51,398. HHS agrees that coordination with other agencies when jointly issuing guidance will be important. HHS has significant experience, in particular working with the Department of Labor, the Department of Agriculture, and the Department of the Treasury, on jointly issued guidance. HHS will continue to work closely with other agencies when issuing guidance to minimize any procedural complications that could affect regulated parties.

Comment: Several commenters criticized the disclaimer HHS proposed to apply to all guidance documents issued after the final rule. These commenters stated that the disclaimer’s

statement that each guidance document “has no legal effect” has the potential to be confusing to regulated entities and members of the public. This is because, for example, regulated entities may believe they can ignore HHS guidance documents and substitute their own interpretations of regulations in place of the Department’s interpretations. One commenter stated that the disclaimer is confusing because it is not clear whether regulated parties will need to conduct their own legal analysis to determine whether a guidance document is “authorized by law.” A few commenters asked whether significant guidance documents must include the disclaimer, and how HHS plans to incorporate the disclaimer into non-written guidance materials such as video clips or make them searchable. Other commenters expressed strong support for the disclaimer requirement. Two commenters, while expressing support for the disclaimer, suggested that HHS should modify the proposed text, because they believe that the second sentence of the proposed disclaimer appears to suggest that guidance documents are binding because they purport to provide clarity regarding existing requirements under the law.

Response: The proposed disclaimer is correct as a matter of law and is unlikely to be confusing. As a result of the notice, the public and regulated entities will have greater clarity about the role and implications of guidance documents when they are informed through the disclaimer that guidance documents cannot impose binding legal obligations above and beyond such legal obligations that are imposed by statute or regulation. Because the APA forbids agencies from imposing binding obligations on regulated parties through sub-regulatory guidance, unless authorized by law, regulated parties have always been free to choose not to adhere to interpretive rules set forth in guidance documents. However, they do so at their own risk, because guidance documents often provide important insight into how HHS interprets, and applies, its statutes and regulations. Regulated parties that take actions inconsistent with HHS’s

interpretive statements in guidance documents may be violating underlying statutory or regulatory obligations. HHS clarifies that regulated parties do not need to undertake their own legal analyses to determine whether any provision of law authorizes binding guidance documents: If a provision of law does authorize HHS to issue binding guidance documents, then the guidance document will not include the disclaimer stating that it lacks the force and effect of law. See § 1.3(a)(3)(i) of the final rule, stating that guidance documents must include the specified disclaimer, “unless the guidance is authorized by law to be binding.”

HHS does not believe that the second sentence in the proposed disclaimer text (“This document is intended only to provide clarity to the public regarding existing requirements under the law.”) suggests that guidance documents are binding. The first sentence clearly states that the contents of the document “do not have the force and effect of law.” Thus, the “existing requirements under the law” must arise from other sources that do have the force and effect of law, namely, validly enacted statutes and regulations.

HHS clarifies that significant guidance documents must include the proposed disclaimer. All guidance documents issued after the final rule’s effective date must include the disclaimer, and significant guidance documents are a subset of guidance documents. HHS will also include this disclaimer on non-written forms of guidance documents, such as videos. HHS will do so in a format appropriate to the medium, for example, in a guidance video, HHS might include an audio voiceover or a textual statement. If an operating division issues a non-written guidance document, the operating division is also responsible for creating a searchable transcript of that non-written guidance document and uploading it to the guidance repository.

Comment: A couple of commenters expressed the concern that this Good Guidance Practices rule will inhibit informal agency communications with regulated parties, such as CMS stakeholder engagement calls.

Response: HHS does not intend for this rule to adversely impact informal agency communications with regulated parties. Many of these communications do not constitute guidance, because they involve the application of laws to a regulated party's specific factual circumstances. However, where an HHS operating division provides information that satisfies the definition of "guidance document," HHS expects that information also to be posted to the guidance repository. This will ultimately inure to the benefit of regulated parties, because a broader set of entities will now have access to the guidance.

Comment: One commenter opposed the proposed additional rules relating to the issuance and use of guidance documents, explaining that it had not seen a pattern of overreach by HHS, through its guidance documents, that would justify the additional proposed rules.

Response: The rule is not being promulgated as a remedy for overreach. HHS believes that the Good Guidance Practices rule will improve its guidance practices and help to ensure that it acts in a fair, transparent, and lawful manner.

Comment: Commenters generally expressed support for the inclusion of the proposed six categories of information on all guidance documents issued after the final rule. Some commenters suggested that HHS should include these six information categories on all guidance documents, even those issued before the implementation date of the final rule. Some commenters also suggested that HHS also add to the required categories of information the effective date of the guidance document, and furthermore, that HHS make guidance documents effective only after a reasonable implementation period.

Response: HHS appreciates the commenters' support. Unfortunately, HHS does not currently have the resources to add the six categories of information to all of the thousands of guidance documents in the guidance repository that were issued before the effective date of this final rule. Accordingly, HHS finalizes its proposal to only apply this requirement prospectively, to guidance documents issued after the effective date of this final rule.

HHS also finalizes the set of six categories of information, without adding any additional information fields, such as the guidance document's effective date. Generally, a guidance document will be effective as of the date it is issued, which is one of the six information categories that must be included in all guidance documents issued after this final rule's effective date. If a guidance document has a different effective date, HHS expects the issuing operating division will make that clear in the guidance document. HHS always strives to issue guidance documents in a timely manner, so that regulated parties can take HHS's views into account, but it believes that imposing a particular delay in effective date for guidance documents is outside the scope of the proposed rule. Nonetheless, HHS does not believe that issuing such a requirement in future rulemaking is necessary, given that guidance documents cannot impose binding new obligations.

Comment: A few commenters expressed concern as to the statement in the proposed disclaimer that guidance documents "are not meant to bind the public in any way, unless specifically incorporated into a contract." A couple of these commenters explained that many federal healthcare programs involve mandatory contracts with CMS, and CMS often includes in these contracts a general covenant to abide by all sub-regulatory guidance that CMS has issued in the past or may issue in the future. Another commenter requested that HHS modify this portion of the disclaimer to clarify that it only applies to a legally enforceable contract, rather

than an opt-in agreement that simply memorializes a party's decision to participate in a certain program and abide by the program's laws and regulations.

Response: HHS agrees that so-called "catchall" clauses that generically purport to bind the signatory to all guidance ever issued by the Department do not fall within this exception, because the guidance materials are not "specifically" incorporated into the contract. If the government intends for a guidance document incorporated into a contract by reference to have independent legal basis, the government must make that intention clear through unambiguous language. For example, if a contract states that Medicare Advantage organizations must operate "in compliance with the requirements of this contract and applicable Federal statutes, regulations, and policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual, etc.)," the signatory must comply with CMS call letters and the Medicare Managed Care Manual, because these sub-regulatory materials are specifically referenced in the contract. However, the contract does not make compliance with any other sub-regulatory guidance issued by HHS legally binding. This narrow exception applies to the same extent to contracts categorized as opt-in agreements. HHS also clarifies that grants are analogous to contracts for purposes of this rule and the Department can accordingly also render guidance documents binding on grantees by specifically incorporating them into the grant agreement.

Comment: Several commenters asked HHS to clarify the intersection between the Good Guidance Practices rule and the Department's obligations under Social Security Act Section 1871, as interpreted by the Supreme Court in *Allina Health Services*. One commenter suggested that the Department amend proposed § 1.3(a)(1) expressly to acknowledge the Supreme Court's decision in *Allina Health Services*. This commenter also noted that Section 1871 of the Social Security Act further imposes requirements on HHS that the Department is currently not

satisfying, namely, to “publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which—(A) are promulgated to carry out this subchapter, but (B) are not published pursuant to subsection (a)(1) and have not been previously published in a list under this subsection.” *See* 42 U.S.C. 1395hh(c)(1) (Section 1871(c)(1) of the Social Security Act).

Response: In the preamble to the proposed rule, HHS noted that “OGC would continue to determine whether the contents of certain guidance relating to Medicare” must go through notice-and-comment as a result of the Supreme Court’s decision in *Allina Health Services*, but that “[s]uch guidance documents would still need to meet all applicable requirements” of the Good Guidance Practices rule. 85 FR at 51,397. HHS clarifies that some substantive legal standards otherwise qualifying as “guidance documents” under this rule may also be subject to notice-and-comment obligations imposed by Section 1871. If so, the substantive legal standards must comply both with the obligations imposed by Section 1871 and the requirements in this final rule. Thus, for example, following publication in proposed and final rules, consistent with Section 1871, HHS would post the guidance document to the guidance repository.

HHS believes § 1.3(a)(1) accurately describes its obligations under Section 1871 and the APA as proposed, and declines to amend it. Section 1.3(a)(1) states, “Under the Administrative Procedure Act, the Department may not issue any guidance document that establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute.” Even if an interpretive rule qualifies as a substantive legal standard that is subject to notice-and-comment obligations under Section 1871, as an interpretive rule, it cannot “establish[] a legal obligation.” Nothing in this Good Guidance Practices rule purports to

override or alter the statutory obligations imposed on HHS with respect to the Medicare program under Section 1871.

HHS acknowledges that it has not been fully complying with the requirements of Social Security Act Section 1871(c)(1) and commits to moving into full compliance with this requirement.

Comment: A few commenters expressed support for the proposal that only the Secretary (on a non-delegable basis) can approve significant guidance documents. HHS did not receive any comments as to whether the Secretary should be required to approve certain non-significant guidance documents prior to publication.

Response: We appreciate the commenters' support and agree that the Secretary should be required to approve, on a non-delegable basis, all significant guidance documents. The Department has also concluded that the Secretary should approve certain guidance documents that have the potential to materially impact the Department's work, even though their consequences external to the Department do not cause them to be considered "significant." Accordingly, the Secretary must also approve, on a non-delegable basis, all non-significant guidance documents that he determines will either 1) implicate, including potentially impede, any policy matter of priority to the Secretary, or 2) where one operating division's proposed non-significant guidance document may create a serious inconsistency, or otherwise interfere, with an action taken or planned by another operating division or the Office of the Secretary.

HHS finalizes the process for issuing guidance documents, including significant guidance documents, as proposed, except to specify that the effective date of the rule will be 30 days after publication of this final rule. HHS is also defining two types of non-significant guidance documents that the Secretary must review on a non-delegable basis.

D. Guidance Repository (§ 1.4)

In the proposed rule, HHS proposed to make its guidance documents available to the public through the Internet, by establishing a guidance repository on the HHS website at www.hhs.gov/guidance. HHS proposed that by November 16, 2020, the Department would be required to have posted to the guidance repository all guidance documents in effect that were issued by any component of the Department, and that the guidance repository must be fully text searchable.

HHS proposed that any webpage in the guidance repository that contains guidance documents would clearly indicate that any guidance document previously issued by the Department would no longer be in effect and would be considered rescinded if it is not included in the guidance repository by November 16, 2020. All webpages in the guidance repository containing guidance documents would also state that the guidance documents contained therein “lack the force and effect of law, except as authorized by law or as specifically incorporated into a contract” and “the Department may not cite, use, or rely on any guidance that is not posted on the guidance repository, except to establish historical facts.” HHS proposed that if the Department would like to reinstate a rescinded guidance document not posted to the guidance repository by November 16, 2020, the Department would be able to do so only by following all requirements applicable to newly issued guidance documents.

HHS proposed that guidance documents issued after November 16, 2020 would be required to comply with all applicable requirements in § 1.3, *Requirements for Department Issuance and Use of Guidance Documents*. HHS would be required to post a new or amended guidance document to the guidance repository within three business days of the date on which that guidance document was issued. For significant guidance documents issued after November

16, 2020, HHS would be required to post proposed versions of significant guidance documents to the guidance repository as part of the notice-and-comment process. The Department shall clearly indicate the end of each significant guidance document's comment period and the mechanisms by which members of the public may submit comments on the proposed significant guidance document. The Department would also be required to post online all HHS responses to major concerns raised in public comments.

HHS received the following comments relating to the proposed guidance repository:

Comment: Some commenters strongly supported the creation of the guidance repository and the enhanced transparency, accountability, and fairness that they believe would come with the requirement that HHS post all operative guidance materials to the guidance repository. Some of these commenters pointed out that, under the Department's existing processes, it is often not apparent when HHS issues guidance documents, and it is challenging to stay abreast of the Department's constantly evolving guidance documents.

However, other commenters criticized the proposed requirement that any guidance document not posted to the guidance repository by November 16, 2020, would be considered rescinded, and that HHS could not cite, use, or rely on such guidance documents except to establish historical facts. These commenters argued that the proposed process for rescinding guidance documents decreased agency transparency as compared to the status quo, rather than increasing it. Some commenters also expressed concern that HHS did not have sufficient time to come into compliance with the rule and transfer to the guidance repository all guidance documents that the Department intends to keep in effect, and that HHS should delay the effective date of the final rule. Due to the concern that HHS may accidentally rescind guidance documents by unintentionally omitting them from the guidance repository, several commenters

recommended that HHS create a grace period during which time regulated parties could provide inadvertently omitted guidance documents to HHS for posting, without those guidance documents being considered rescinded. A couple commenters suggested that HHS should give a 30-day grace period for any guidance document that is rescinded, before it is treated as being rescinded. Some commenters further stated that it would be confusing to the public and regulated entities if a guidance document appears on an HHS website but is not included in the repository. Other commenters asked HHS to clarify what regulated entities should do if they are unsure as to whether a guidance document is still valid. A few commenters recommended that HHS create a guidance repository housing all rescinded guidance documents, and that where a guidance document replaces another guidance document, the new guidance document should link to the old guidance document being replaced.

Response: HHS believes that the requirement that any guidance document be posted to the guidance repository or otherwise be considered rescinded will improve upon existing levels of transparency and ultimately will decrease confusion. Currently, it is difficult for regulated parties definitively to ascertain what set of guidance documents HHS views as operative and what guidance documents they are expected to consider. This uncertainty carries its own confusion and causes a lack of transparency. The guidance repository will allow regulated parties to identify the complete set of guidance materials potentially applicable to their conduct. Nor does the fact that HHS can rescind a guidance document by not posting it to the guidance repository diminish existing levels of transparency. With the limited exception of certain Medicare guidance for which notice-and-comment rulemaking is required under Section 1871 of the Social Security Act, and thus a notice-and-comment process is required to rescind them, HHS is free to elect to stop relying on or using a guidance document, including without soliciting

public feedback. But currently, the public has no way to know that HHS has decided to withdraw a guidance document, unless HHS chooses to make a specific announcement. Operating divisions remain free to announce when they are rescinding or replacing a guidance document, and we encourage operating divisions to do so. But regardless of whether they do, under the new process, the public will also be able to know that HHS has rescinded a guidance document, because the guidance document will not appear in, or will cease to appear in, the guidance repository.

Posting a comprehensive list of all guidance documents HHS is rescinding and providing a justification for each guidance document the Department is rescinding would impose a significant burden on HHS, for the simple fact that the Department currently lacks a comprehensive list of all guidance documents it has issued. Prior to the issuance of Executive Order 13891, few agencies were required to house all of their guidance documents in a single location. This regulation and Executive Order 13891 are intended to address a symptom of the current problem—the Department issues guidance documents in various media without ever transparently aggregating those materials. HHS has undertaken significant efforts to locate all of its guidance documents and include them in the repository, to help remedy the difficulties previously faced by regulated parties who were unable to ascertain all potentially applicable guidance materials. The rule provides additional clarity over the status quo, because where a guidance document issued after the effective date of this final rule replaces an existing document, the guidance document must indicate that it “replaces or revises a previously issued guidance document” and “identify the guidance document that it replaces or revises.” 45 CFR 1.3(a)(3)(iii)(D).

Following the issuance of Executive Order 13891, HHS has been working to implement the guidance repository before it issued the August 20, 2020 Notice of Proposed Rulemaking, and HHS does not believe that an additional delay in the effective date, beyond the 30 days incorporated into this final rule, is warranted.⁴ The Department acknowledges that it may erroneously rescind a guidance document because it has failed to identify and upload the guidance document to the guidance repository by the effective date of this rule. However, both HHS and regulated parties effectively have a 30-day grace period before any guidance documents become rescinded as a result of HHS erroneously omitting them from the guidance repository. This is because this final rule will go into effect 30 days after publication. HHS encourages regulated parties to review the guidance documents posted on the guidance repository and notify HHS of guidance documents that may have been inadvertently omitted. Please email the Department at good.guidance@hhs.gov or contact the issuing component of HHS. To the extent a guidance document appears on an HHS website but is not contained in the guidance repository, this should not be confusing: under this final rule, the guidance document is considered rescinded. However, this inconsistency may be a sign that HHS inadvertently failed to upload that guidance document to the guidance repository, and, as discussed in further detail below, HHS can remedy this mistake by issuing the guidance consistent with the procedures in this rule.

Comment: Several commenters also stated that HHS should provide the public with an opportunity to weigh in on what guidance documents should be rescinded. These commenters generally recommended that HHS publish the criteria it will apply when deciding to rescind

⁴ OMB has been involved with this implementation process and approved extensions to provide HHS with additional time to come into compliance with the requirements of Executive Order 13891. *See* 85 FR 55,306 (Sept. 4, 2020); 85 FR 39,919 (July 2, 2020); 85 FR 15,482 (Mar. 18, 2020).

guidance documents. Some commenters also requested that HHS post a justification for every guidance document that the Department rescinds.

Response: HHS currently has discretion to rescind a guidance document without soliciting public feedback and, indeed, without even providing notice to regulated parties. The proposed rule was not intended to alter the Department’s existing authority to rescind guidance documents without engaging in a public comment process, although, as described above, the proposed rule would ensure that regulated parties, by searching the guidance repository, can identify when guidance documents are or are not considered operative. HHS currently lacks the resources to draft publicly issued justifications for every guidance document that the Department rescinds. And, as previously explained, HHS cannot compile a list of guidance documents that potentially may be rescinded, or a justification for why they are being rescinded. HHS will post all guidance documents that it intends to continue to use to the guidance repository, and it will not so post guidance documents that are outdated, or that HHS otherwise no longer intends to use.

Comment: A few commenters asked HHS to provide notification, for those who choose to opt into receiving such notifications, of when the Department posts new guidance documents to the guidance repository and when HHS rescinds a guidance document.

Response: HHS currently lacks the resources to implement this process. It will consider adding this requested functionality in the future. However, the guidance repository allows users to sort by “Issue Date,” *i.e.*, the date on which the guidance document was issued. This will allow users to review the subset of most recently issued guidance documents.

Comment: A couple of commenters suggested that HHS maintain a repository of rescinded guidance documents, and that where a guidance document replaces another guidance document, the new guidance document should link to the replaced guidance document.

Response: HHS currently lacks the resources to implement either suggestion. In particular and as discussed above, the Department currently lacks a comprehensive list of all guidance documents it has issued. HHS will consider a future guidance repository of guidance documents rescinded after the effective date of the final rule. Regardless, for these guidance documents, regulated parties will be able to ascertain if a rescinded guidance is replaced by a new guidance document, because the replacement guidance will be required to contain a reference to the rescinded guidance.

Comment: A few commenters asked HHS to clarify the effect of HHS rescinding a guidance document. One commenter asked HHS to clarify that if a guidance document's rescission has substantive effect, that the effect will be prospective only. One commenter suggested that HHS incorporate a "hold harmless" provision in the final rule, which would guarantee regulated entities that they would not be penalized if they rely on a guidance document that has been rescinded due to not being included in the guidance repository.

Response: If HHS rescinds a guidance document, the Department may not cite, use, or rely on that guidance document, except to establish historical facts. Guidance documents reflect the Department's interpretations and policies during the time period that they are in effect. Because guidance documents cannot impose binding legal obligations on regulated entities independent of obligations imposed by duly enacted statutes or regulations, the consequences of rescinding a guidance document should generally be minimal. *See Mortgage Bankers*, 575 U.S. at 103 (explaining that interpretive rules cannot change the regulation or statute they interpret).

Because guidance documents generally cannot impose any new binding obligations, there rarely should be circumstances where entities adopt practices consistent with a guidance document that is subsequently rescinded and, as a result, are in noncompliance with the law and subject to penalty. Accordingly, HHS sees no need for inclusion of a “hold harmless” clause in the final rule.

Comment: A couple commenters stated that the process for reinstating rescinded guidance is vague, impractical, time consuming, creates uncertainty, and will inhibit access to guidance documents. Other commenters claimed that rescinding guidance would create confusion, because it could be interpreted by some as a reversion to a different policy than the one explained in the rescinded guidance.

Response: HHS respectfully disagrees with these commenters. As explained in the proposed rule, to reinstate a rescinded guidance document, HHS will merely need to use the same process that it will use for all guidance documents newly issued after the effective date of this final rule. That process, for all but the generally small number of significant guidance documents, merely requires HHS to include a disclaimer and six information fields in the guidance document, and to ensure that the content adheres to pre-existing legal obligations under the APA. This process is not overly burdensome for the Department, and if an operating division wants to re-issue guidance, it can, and will, readily do so. HHS believes that some of the commenters’ concerns stem from misunderstandings about guidance documents. Guidance documents cannot alter legal obligations, and therefore whether a guidance document is rescinded should not create any confusion about a regulated party’s legal obligations—they remain the same. If a regulated party is confused about whether an operating division is altering

its interpretation of a statute or regulation, the regulated party should reach out to the relevant operating division to ask for clarification.

Comment: A few commenters suggested that HHS continue to post guidance materials to operating division-specific websites, in addition to posting those same materials to the guidance repository. A couple commenters further suggested that guidance materials on operating division websites link to the guidance document in the guidance repository.

Response: HHS currently lacks the resources to provide the requested cross-linking between guidance documents on operating division websites and on the guidance repository. However, HHS will continue to post guidance documents on operating division websites, in parallel with posting those materials to the guidance repository. In general, the posting of guidance documents to the guidance repository is not intended to, and will not, alter or otherwise disrupt the posting of guidance documents to operating division websites.

HHS finalizes the requirements relating to the guidance repository as proposed, except to specify that the effective date of the rule will be 30 days after publication of this final rule.

E. Procedure to Petition for Review of Guidance (§ 1.5)

In the proposed rule, HHS proposed that any interested party would be able to petition HHS to withdraw or modify any particular guidance document. Such petitions would include requests to determine whether

- A guidance document, no matter how styled, imposes binding obligations on parties beyond what is required by the terms of applicable statutes and/or regulations.

- An HHS component is using a guidance document to create additional legal obligations beyond what is required by the terms of applicable statutes and/or regulations.
- HHS is improperly exempting a guidance document from the procedures set forth in the proposed rule.

As part of this petition process, HHS proposed that the interested party would be able to ask HHS to remedy the deficiency relating to the use or contents of the guidance document by modifying or withdrawing the guidance document.⁵ HHS notes that the remedy for a successful petition commonly may be modification or withdrawal of a guidance document, and HHS is not waiving the presentment and exhaustion requirements for claims arising under the Medicare statute, including claims for payment and coverage. Any such claim that an interested party asserts is related to the guidance document that is the subject of a petition under this section must still move through the existing administrative process for that claim, including exhaustion.

HHS proposed that petitions must be addressed to HHS in writing, and the guidance repository would include clear instructions to members of the public regarding how to petition for review of guidance, including how such petitions can be submitted, and an HHS office responsible for coordinating such requests.

HHS proposed that, in order to facilitate transparency and avoid duplication of work, HHS would publish all responses to petitions for guidance review in a designated section of its online guidance repository. If HHS were to receive multiple similar petitions within a short time period, HHS proposed that the Department could aggregate those petitions and respond to them in a single response, so long as all petitions were responded to within the appropriate time

⁵ However, an interested party could not use this process to seek changes based on the quality of the information contained in a document; there are other processes to address the quality of information contained in HHS issuances.

period. It further proposed that HHS must respond to all petitions within 90 business days of the date on which the petition was received. The time period to respond would be suspended if HHS were to need to request additional information from the person who submitted the petition or to consult with other stakeholders. Under the proposed rule, HHS's response to any such petition would be considered final agency action reviewable in court, because it would mark the consummation of HHS's decision-making process and legal consequences flow from the response to the petition. *See, e.g., Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1022 (D.C. Cir. 2000) (defining reviewable agency action).

HHS received the following comments relating to the proposed petition process.

Comment: Several commenters supported the proposed petition process. Other commenters were concerned that the petition process might delay the issuance of guidance documents or that the petition process would be too burdensome on the Department. A couple of commenters stated that the petition process would create uncertainty and confusion, because regulated parties would feel as though they cannot rely on guidance that could be rescinded at any time, and furthermore, the ability of "any interested party" to use the proposed petition process would give almost anyone the opportunity to undermine guidance documents. A few commenters suggested that the petition process should only apply to guidance documents issued after the effective date of the final rule; others conversely asked HHS to clarify that the petition process does apply to guidance documents issued before the effective date of the final rule. One commenter asked HHS to clarify that petitions can be filed whenever an interested party identifies a perceived issue with a guidance document.

Response: HHS appreciates the commenters' support and agrees in particular with the commenter who characterized the petition process as "key to policing compliance with the

principles” set forth in this Good Guidance Practices rule. HHS does not believe that the proposed petition process would delay or otherwise impact the issuance of guidance documents. This is because the petition process is only available to challenge guidance documents that have already been issued, and guidance documents will remain in effect throughout the petition process, unless and until HHS issues a petition response concluding that a guidance document should be modified or rescinded. HHS believes that the 90-business-day period in which to respond to petitions provides sufficient time to accommodate petition responses alongside the work of issuing new guidance documents, without unduly straining HHS resources and delaying the issuance of new guidance documents.

HHS agrees that the term “interested party” is broad, and extends to more than merely regulated parties, however, HHS does not think that the petition process will undermine the utility of the Department’s guidance documents: HHS can currently rescind guidance documents at any time; therefore, it does not believe that the petition process would undermine the extent to which regulated parties feel comfortable looking to guidance documents for HHS’s current views on the subjects covered by such documents.

HHS clarifies that the petition process can be applied to any HHS guidance document, regardless of when HHS issued that guidance document, so long as the guidance document is in effect at the time the petition is filed. HHS also clarifies that interested parties can file a petition at any time. In other words, regulated parties are under no obligation to file a petition within a certain time period.

Comment: One commenter asked HHS to clarify the standard that HHS will use to grant a petition. This commenter also suggested that HHS clarify that the final rule requires the Department to clearly grant or deny the requested remedy and include a rationale for the

decision. One commenter asked HHS to clarify that the petition process can be used to challenge a guidance document that HHS initially treated as non-significant and assert that it should actually be categorized as significant.

Response: Under § 1.5(a)(1)-(3), as finalized in this rulemaking, interested parties can petition HHS and assert one of three bases for the petition:

- The substance of an HHS guidance document is unlawful, *i.e.*, the guidance document purports to impose binding new obligations on regulated parties.
- While the substance of an HHS guidance document may be lawful, a division of HHS is using or interpreting the guidance document unlawfully, *i.e.*, to impose binding new obligations on regulated parties.
- HHS is improperly exempting a guidance document from the requirements in the Good Guidance Practices rule.

HHS clarifies that § 1.5(a)(3) allows interested parties to challenge a guidance document that HHS initially treated as non-significant, thereby improperly exempting that guidance document from this rule's requirements for significant guidance documents.

HHS will respond to a petition, generally by agreeing either to modify or withdraw the challenged guidance document or documents, modify its application or treatment of the challenged guidance document or documents, or declining to take any action. If HHS agrees with the petitioner that a guidance document is substantively unlawful, is being used unlawfully, or is being improperly exempted from the requirements of this rule, then HHS will take actions that bring the Department's conduct, and the guidance documents, into compliance with all legal obligations, including this Good Guidance Practices regulation. HHS agrees that the proposed § 1.5(e) is insufficiently clear about what is required in HHS's response to a petition.

Accordingly, in finalizing § 1.5(e), HHS modifies the text to clarify that the Department's petition response must state whether the Department agrees or disagrees with the petition; the Department's rationale for such position; and if the Department agrees that the petitioner has identified an unlawful action, that the Department must remedy the unlawful action.

Comment: A few commenters asked HHS to give regulated parties an opportunity to respond to or comment on petitions.

Response: In order to streamline the petition process and ensure a prompt response within the 90-business-day time limit, HHS will not accept comments on petitions from third parties.

Comment: Some commenters asked HHS to clarify that guidance documents would remain in effect during the petition process, while other commenters suggested that HHS clarify that guidance documents will be held in abeyance, and viewed as not in effect, pending the Department's response to a petition.

Response: The initiation of a petition regarding a particular guidance document or documents will have no immediate impact on those guidance documents. Instead, only if HHS agrees with the petitioner that the guidance document(s) at issue in the petition are unlawful will HHS modify or rescind the guidance document(s). Temporarily withdrawing, or holding in abeyance, guidance documents every time they are the subject of a petition would be extraordinarily disruptive to regulated parties and the Department.

Comment: Several commenters suggested that HHS shorten the time period to respond to a petition to less than 90 business days. A couple of commenters suggested a longer time period in which to respond. Several commenters suggested that HHS place a time limit on the extent to which the Department can suspend this 90-day clock when consulting with stakeholders. A

couple of commenters asked HHS to implement consequences for failing to follow the procedures in this rule, including the petition response time.

Response: HHS finalizes the 90-business-day time period. This strikes the right balance between ensuring that HHS has sufficient time to thoughtfully respond to petitions and seeking to issue petition responses relatively promptly. HHS does not limit the time period during which the Department can suspend the 90-day clock when consulting with stakeholders or incorporating any specific penalty for non-compliance with the procedures in this rule. However, HHS believes that in these circumstances, regulated parties could have a cause of action under the APA for delayed or withheld agency action.

Comment: One commenter stated that this Good Guidance Practices rule is unnecessary, because regulated parties today can file APA challenges if an agency purports to impose binding obligations through guidance.

Response: HHS agrees that regulated parties currently may have a cause of action under the APA if the Department were to purport to impose binding obligations through guidance documents, unless authorized by law. This Good Guidance Practices rule seeks to enhance the Department's practices with respect to guidance, including by creating a central guidance repository that will allow regulated parties to search for potentially relevant guidance documents.

Comment: One commenter asked that HHS publish not just its responses to petitions, but also the petitions themselves.

Response: HHS will publish in the guidance repository petition requests alongside petition responses.

Comment: A few commenters asked HHS to clarify that the petition process does not affect the availability of other legal causes of action, including those under the APA, and in

particular, that filing a petition with HHS is not a threshold requirement for a judicial challenge relating to a guidance document.

Response: HHS agrees that the petition process does not create an administrative exhaustion requirement or affect the availability of other legal causes of action. In some circumstances, Article III jurisdiction may exist to challenge a guidance document or use of a guidance document, even without a prior petition. The petition process is available for those who would like to engage administratively with the Department, and may provide an avenue to resolve issues without the need for litigation.

Comment: One commenter asked HHS to accept petitions alleging that the Department of Justice or a qui tam relator has used a guidance document inappropriately.

Response: HHS declines to incorporate this proposal; HHS will only accept petitions relating to its own conduct. HHS acknowledges that some actors outside of HHS, such as qui tam relators, could use a guidance document inappropriately, in a manner that attempts to impose binding new obligations on regulated parties. However, HHS lacks the authority to grant a remedy with respect to the conduct of the Department of Justice or qui tam relators. HHS suggests that in these circumstances, regulated parties file a petition with HHS seeking clarification as to the appropriate scope of the guidance document at issue. HHS also notes that such use of guidance documents by the Department of Justice is inconsistent with the January 25, 2018 Memorandum from then-Associate Attorney General Rachel Brand, “Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases,” and should be brought to the attention of Department of Justice leadership.

Comment: One commenter suggested that when HHS aggregates similar petitions filed within a “short” time of one another, HHS should define “short” as 14 calendar days and should require a reasoned response to every substantive issue raised by each of the aggregated petitions.

Response: HHS respectfully declines to adopt a rigid time period for when HHS can aggregate responses to similar petitions filed within a short time period. However, each response to a petition must satisfy the 90-business-day time limit (subject to any permissible tolling); this requirement will serve as a natural time limit on the extent to which HHS can aggregate petition responses.

Comment: One commenter suggested that HHS incorporate an express judicial reviewability clause in the final rule’s regulation text.

Response: The regulation text governs HHS’s own actions. HHS cannot directly confer Article III jurisdiction through statements in regulation text. Accordingly, HHS does not agree that adding such a clause in the final rule’s regulation text would alter the rule.

HHS finalizes the petition process in § 1.5 as proposed, with clarifying edits to § 1.5(e).

III. Required Rulemaking Analyses

A. Executive Orders 12866 and 13563: Regulatory Planning and Review Analysis

HHS examined the effects of this rule as required by E.O. 12866, “Regulatory Planning and Review,” 58 FR 51,735 (Oct. 4, 1993), E.O. 13563, “Improving Regulation and Regulatory Review,” 76 FR 3821, (Jan. 21, 2011), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Order 12866, “Regulatory Planning and Review,” and Executive Order 13563, “Improving Regulation and Regulatory Review,” direct agencies to assess all costs and benefits

of available regulatory alternatives and, if the regulation is necessary, to select regulatory approaches that maximize net benefits. A Regulatory Impact Analysis must be prepared for major rules with economically significant effects. The Department has determined that this rulemaking is not a significant regulatory action under these Executive Orders. In addition, the Department does not anticipate that this rulemaking will impose measurable costs on regulated parties. This final rule describes agency processes for issuing guidance and responding to petitions regarding guidance that allegedly is inappropriate or is being used inappropriately. Implementation of this final rule will require HHS expenditures to create and maintain the guidance repository, along with employing a new process for the review of significant guidance documents and for the review of guidance documents which are the subject of a petition for review. For 2020, HHS expended approximately \$2.4 million to develop the guidance repository. HHS expected annual costs for 2021 and 2022 to be about \$1 million. However, the Department expects benefits to accrue as a result of the streamlined and clarified process for issuing guidance documents. The Department anticipates that the public, and, in particular, regulated parties, will benefit from greater efficiencies and more transparency in how the Department operates and regulates. The Office of Management and Budget (OMB) has reviewed this rule.

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs has determined that this final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

Section 202(a) of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532(a), requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any federal mandate that may result

in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.” In 2019, that threshold was \$154 million. HHS does not expect this rule to exceed the threshold.

B. Executive Order 13771

This final rule is neither a regulatory nor a deregulatory action under Executive Order 13771, “Reducing Regulation and Controlling Regulatory Costs,” 82 FR 9339 (Feb. 3, 2017), because this rule is estimated to impose no more than *de minimis* costs on regulated entities.

C. Regulatory Flexibility Act and Executive Order 13272

The Department has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.* The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996 (Pub. L. 104-121), which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. The Department considers a rule to have a significant impact on a substantial number of small entities if the rule has at least a three percent impact on revenue on at least five percent of small entities. The Department anticipates that this final rule will allow small entities to operate more efficiently, by increasing the transparency of government regulation. As a result, the Department has determined, and the Secretary certifies, that this final rule does not have a significant impact on a substantial number of small entities.

D. Executive Order 13132 (Federalism)

Executive Order 13132, “Federalism,” 64 FR 43,255 (Aug. 10, 1999), establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct

requirement costs on State and local governments or has federalism implications. The Department has determined that this final rule does not impose such costs or have any federalism implications.

E. Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Department has reviewed this final rule and has determined that it does not create new collections of information.

List of Subjects in 45 CFR Part 1

Guidance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR, subtitle A, subchapter A, by adding part 1 to read as follows:

PART 1—GOOD GUIDANCE PRACTICES

Sec.

1.1 Scope.

1.2 Definitions.

1.3 Requirements for Department issuance and use of guidance documents.

1.4 Guidance repository.

1.5 Procedure to petition for review of guidance.

Authority: 42 U.S.C. 1302; 5 U.S.C. 301, 551 *et seq.*

§ 1.1 Scope.

This part shall apply to guidance documents issued by all components of the Department, until the Secretary amends the Food and Drug Administration's good guidance regulations at 21 CFR 10.115 to bring them into conformance with the requirements of this part, at which point, such amended regulations shall apply to the Food and Drug Administration's issuance and use of guidance documents.

§ 1.2 Definitions.

The following definitions apply to this part. Different definitions may be found in Federal statutes or regulations that apply more specifically to particular programs or activities.

Guidance document means any Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation. The term "guidance document" does not include rules promulgated pursuant to notice and comment under 5 U.S.C. 553, or similar statutory provisions; rules exempt from rulemaking requirements under 5 U.S.C. 553(a); rules of agency organization, procedure, or practice; decisions of agency adjudications under 5 U.S.C. 554, or similar statutory provisions; internal guidance directed to the Department or other agencies that is not intended to have substantial future effect on the behavior of regulated parties; internal executive branch legal advice or legal opinions addressed to executive branch officials; legal briefs and other court filings; grant solicitations and awards; or contract solicitations and awards. Pre-enforcement rulings, *i.e.*, communications with a person that interpret or apply the law to a specific set of facts, such as letter rulings, advisory opinions, no-action letters, and notices of noncompliance, do not constitute guidance documents. If, however, the Department issues such a document that on its

face is directed to a particular party, but the content of the document is designed to guide the conduct of other regulated parties, such a document would qualify as guidance.

Guidance repository means an online database containing or linking to guidance documents.

Issued means the Department initiated or sponsored distribution of information to the public. “Issued” does not include distribution intended to be limited to government employees or agency contractors, or distribution required under law or agency disclosure policies.

Significant guidance document means a guidance document that may reasonably be anticipated to lead to an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles of Executive Order 12866. The term “significant guidance document” does not include the categories of documents exempted in writing by the Office of Management and Budget’s (“OMB”) Office of Information and Regulatory Affairs (“OIRA”).

§ 1.3 Requirements for Department issuance and use of guidance documents.

(a) *Guidance documents.*

- (1) Under the Administrative Procedure Act, the Department may not issue any guidance document that establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute.

- (2) The Department may not use any guidance document for purposes of requiring a person or entity outside the Department to take any action, or refrain from taking any action, beyond what is required by the terms of an applicable statute or regulation.
- (3) Each guidance document issued by the Department must:
 - (i) Identify itself as “guidance” (by using the term “guidance”) and include the following language, unless the guidance is authorized by law to be binding: “The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.”;
 - (ii) Not direct parties outside the Federal Government to take or refrain from taking action, except when restating—with citations to statutes, regulations, or binding judicial precedent—clear mandates contained in a statute or regulation; and
 - (iii) Include the following information:
 - (A) The activities to which and the persons to whom the document applies;
 - (B) The date of issuance;
 - (C) Unique agency identifier;
 - (D) Whether the guidance document replaces or revises a previously issued guidance document and, if so, identify the guidance document that it replaces or revises;
 - (E) Citation to the statutory provision(s) and/or regulation(s) (in Code of Federal Regulations format) that the guidance document is interpreting or applying;and

- (F) A short summary of the subject matter covered in the guidance document.
- (4) The Secretary must approve, on a non-delegable basis, all non-significant guidance documents that the Secretary determines will either
- (i) Implicate, including potentially impede, any policy matter of priority to the Secretary, or
 - (ii) Potentially create a serious inconsistency, or otherwise interfere, with an action taken or planned by another operating division or the Office of the Secretary.
- (b) *Significant guidance documents.*
- (1) Before the Department issues any significant guidance document, it must be approved, on a non-delegable basis, by the Secretary.
 - (2) Before issuing any significant guidance document, the Department must:
 - (i) Submit the significant guidance document to OIRA for review under Executive Order 12866 prior to issuance.
 - (ii) Provide at least a 30-day public notice and comment period on the proposed significant guidance document, unless the Department for good cause finds (and incorporates such finding and a brief statement of reasons therefor into the guidance document) that notice and public comment are impracticable, unnecessary, or contrary to the public interest. If no such good cause exists, the public notice (which must be published in the Federal Register and posted in the guidance repository) shall include all of the following information:
 - (A) Information as to where the public may access a copy of the proposed significant guidance document;

- (B) Information as to where written comments may be sent, and an internet website where those comments may be reviewed by the public; and
 - (C) The time period during which comments will be accepted.
- (iii) Publish a public response to the major concerns raised during the comment period.
- (3) Significant guidance documents must comply with applicable requirements for significant regulatory actions, as set forth in Executive Orders, except that only economically significant guidance documents require a separate Regulatory Impact Analysis.
- (4) A significant guidance document may be exempted from any requirement otherwise applicable to significant guidance documents if the Secretary and the Administrator of OIRA agree that exigency, safety, health, or other compelling cause warrants the exemption. The Secretary must make this finding, and the significant guidance document must incorporate the finding and a brief statement of reasons in support.
- (5) The Department shall seek from OIRA, as appropriate, categorical determinations that classes of guidance presumptively do not qualify as significant. Any guidance satisfying such a categorical exemption presumptively need not comply with the requirements of this paragraph (b) but must comply with all other requirements applicable to guidance documents. OIRA may determine that a particular guidance document within a categorical exemption is nonetheless significant.

§ 1.4 Guidance repository.

- (a) *Existing guidance.* By [**OFR insert date 30 days after publication in the Federal Register**], the Department shall maintain a guidance repository on its website at www.hhs.gov/guidance.
- (1) The guidance repository shall be fully text searchable and contain or link to all guidance documents in effect that have been issued by any component of the Department.
 - (2) If the Department does not include a guidance document in the guidance repository by [**OFR insert date 30 days after publication in the Federal Register**], the guidance document shall be considered rescinded.
 - (3) Any webpage in the guidance repository that contains or links to guidance documents must state:
 - (i) That the guidance documents contained therein:
 - (A) “Lack the force and effect of law, except as authorized by law or as specifically incorporated into a contract.”; and
 - (B) “The Department may not cite, use, or rely on any guidance that is not posted on the guidance repository, except to establish historical facts.”
 - (ii) That any guidance document previously issued by the Department is no longer in effect, and will be considered rescinded, if it is not included in the guidance repository.
 - (4) If the Department wishes to reinstate a rescinded guidance document, the Department may do so only by complying with all of the requirements applicable to guidance documents issued after [**OFR insert date 30 days after publication in the Federal Register**].

(b) *Guidance issued after* [**OFR insert date 30 days after publication in the Federal Register**]

(1) For all guidance documents issued after [**OFR insert date 30 days after publication in the Federal Register**], the Department must post each guidance document to the Department's guidance repository within three business days of the date on which that guidance document was issued.

(2) For significant guidance documents issued after [**OFR insert date 30 days after publication in the Federal Register**], the Department shall post proposed new significant guidance to the guidance repository as part of the notice-and-comment process.

(i) The posting shall clearly indicate the end of each significant guidance document's comment period and provide a means for members of the public to submit comments.

(ii) The Department shall also post online all responses to major public comments.

§ 1.5 Procedure to petition for review of guidance.

(a) Any interested party may petition the Department to withdraw or modify any particular guidance document. Such petitions may include requests to determine whether:

(1) A guidance document, no matter how styled, imposes binding obligations on parties beyond what is required by the terms of applicable statutes and/or regulations;

(2) A component of the Department is using a guidance document to create additional legal obligations beyond what is required by the terms of applicable statutes and/or regulations; or

- (3) The Department is improperly exempting a guidance document from the requirements set forth in this part.
- (b) As part of a petition under this section, an interested party may ask that the Department modify or withdraw any guidance document in effect at the time of the petition.
- (c) Petitions under this section must be addressed to the Department in writing. The Department's guidance repository must include clear instructions to members of the public regarding how to petition for review of guidance, including how such petition can be submitted, and an office at the Department responsible for coordinating such requests.
- (d) The Department must respond to all petitions no later than 90 business days after receipt of the petition. The applicable time period for responding is suspended from the time the Department:
- (1) Requests additional information from the requestor, until the Department receives the additional information; or
 - (2) Notifies the requestor of the need to consult with other stakeholders, including but not limited to the Department of Justice or the Department's Office of Inspector General, until the Department completes consultation with other stakeholders.
- (e) The Department's written response to petitions must state whether the Department agrees or disagrees with the petition and the Department's rationale. The Department must remedy the substance or use of any guidance documents that it determines in a petition response to be inconsistent with this part or otherwise unlawful. The Department will post all responses to petitions under this section to a designated webpage on its guidance repository.

Dated:

Alex M. Azar II,

Secretary,

Department of Health and Human Services.