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: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services proposes to issue regulations governing the agency's release and maintenance of guidance documents. These regulations would 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: To be assured consideration, comments must be received at one of the addresses provided below, no later than 11:59 p.m. on September 16, 2020.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted electronically at *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Brenna Jenny, Department of Health and Human Services, 200 Independence, Avenue SW, Room 713F, Washington, DC 20201. Email: *Good.Guidance@hhs.gov*. Telephone: (202) 690–7741.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Before or after the close of the comment period, the Department of Health and Human Services will post all timely submitted comments on *http://www.regulations.gov*. Follow the search instructions on that website to view public comments.

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. *E.P.A.,* 711 F.3d 844, 875 (8th Cir. 2013); *Gen. Elec. Co.* v. *E.P.A.,* 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, 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).

II. Summary of Proposed Good Guidance Practices Regulations

To promote the appropriate issuance and use of guidance documents, and consistent with the requirements of Executive Order 13891 of October 9, 2019, ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' 84 FR 55235 (Oct. 15, 2019), the United States Department of Health and Human Services (''HHS'' or ''the Department'') is proposing to issue regulations that set forth good guidance practices that would apply to all divisions of HHS other than the Food and Drug Administration (''FDA''). 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, 21 U.S.C. 371(h), but no other division within HHS operates under a similar set of regulations. FDA will also be proposing amendments to its good guidance practices regulations, which would revise the requirements at 21 CFR 10.115 to incorporate the directives of Executive Order 13891. The requirements in this HHS proposed rule, if finalized, would be promulgated at 45 CFR part 1, which is currently unassigned.

This proposed good guidance practices rule is one component of the Department's broader regulatory reform initiative. The proposed 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.

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

A. Scope (§ 1.1)

HHS proposes that the requirements to be established pursuant to this proposed rule would apply to all guidance documents issued by all components of the Department, except for FDA, which has its own good guidance practices regulations that it is in the process of amending to conform, as appropriate, to the requirements of Executive Order 13891.

B. Definitions (§ 1.2)

Guidance Document

This proposed rule, if finalized, would apply to guidance documents (including those deemed ''significant'') issued by the Department, other than guidance documents issued by FDA. HHS proposes to define ''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. 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'' under this proposed rule. Rather, guidance may come in a variety of forms, including, but not limited to, letters, memoranda, circulars, bulletins, advisories, and preambles and may include video, audio, and Web-based formats. *See* OMB Bulletin 07–02, ''Agency Good Guidance Practices,'' 72 FR 3432, 3434 (January 25, 2007). The hallmark of guidance is that it includes statements of general applicability intended to govern the future behavior of regulated parties. Thus, agency releases of technical or scientific information would not constitute guidance unless also accompanied by a policy on or related to that technical or scientific information that is intended to affect the future behavior of regulated parties. This proposed rule 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 at government employees or agency contractors, rather than regulated parties would also 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 not be ''guidance.''

Certain categories of documents would be excluded from the term guidance document under the proposed rule: 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.

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, 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, 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 the contents of 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). Such guidance documents would still need to meet all applicable requirements in this part.

Significant Guidance Document

HHS proposes to define ''significant guidance document''; additional procedural requirements, as set forth below, would apply to a significant guidance document. HHS proposes to define the term 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.'' 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 cost savings would not be used to offset upfront costs. In performing these analyses, HHS 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.

HHS operates from the principle that actions imposing significant benefits, costs, or transfer impacts on regulated parties must comply with heightened procedural requirements. However, it anticipates that only a subset of guidance documents would satisfy this 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, OMB cannot reach legal conclusions on behalf of HHS.

Issued

HHS proposes to define ''issued'' to mean distribution of information to the public that HHS initiated or sponsored. But 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 under this proposed rule.

Guidance Repository

HHS proposes to define ''guidance repository'' to mean an online electronic database containing or linking to guidance documents. It further proposes that the Department's primary guidance repository can link to subsidiary guidance repositories.

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

The proposed rule reiterates the application of existing legal principles to HHS's guidance: 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.

The proposed rule would also create a process for issuing guidance that formalizes guardrails designed to ensure

that guidance documents are appropriately issued and used. If the proposed rule is finalized, following the effective date, 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.'' 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.

HHS proposes to require that each guidance document issued by it or any component after the effective date of this rule, if finalized, 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 the implementation date of this rule, HHS would not retrospectively revise those guidance documents to include the information listed in this paragraph. 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 is proposing to apply additional procedures to significant guidance documents. Under the proposed rule, HHS would submit all significant guidance documents to the Office of Information and Regulatory Affairs (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 also proposes that, prior to issuing any significant guidance document, HHS must also 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., City of Portland, Oregon* v. *E.P.A.,* 507 F.3d 706, 715 (DC Cir. 2007).

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.

Also under the proposed rule, HHS 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 seeks comments on the proposed process for issuing guidance documents, as well as the proposed additional requirements for issuing significant guidance documents, including, for example, whether under this proposed rule the Secretary should have the limited authority to delegate approval of guidance documents to the Deputy Secretary; whether the Secretary should be required to approve guidance documents that fall into a broader or narrower category than significant guidance documents prior to publication; and the process for soliciting and responding to public comments.

D. Guidance Repository (§ 1.4)

HHS proposes to make its guidance documents available to the public through the internet. The Department would establish a guidance repository on its website at *www.hhs.gov/guidance*. By November 2, 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. The guidance repository would be required to be fully text searchable.

Under this proposal, any web page 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 2, 2020. All web pages 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.''

If the Department would desire to reinstate a rescinded guidance document not posted to the guidance repository by November 2, 2020, the Department would be able to do so only by following all requirements applicable to newly issued guidance documents.

If this proposed rule is finalized, guidance documents issued after the effective date of the final regulation would be required to comply with all applicable requirements in section 1.3. 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 the effective date of the final regulation, 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 public comments.

HHS seeks comments on all proposed aspects of the guidance repository.

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

Regulated parties should have an opportunity for administrative and judicial review of whether a guidance document inappropriately creates new obligations or is being used by HHS to create new obligations. Under the proposed rule, 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 this proposed rule.

As part of this petition process proposed under this proposed rule, 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.[2]

Petitions under this proposed section would be addressed to HHS in writing. 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.

To facilitate transparency and avoid duplication of work, under the proposed rule, 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, it would be able to aggregate those petitions and respond to them in a single response, so long as all petitions were responded to within the appropriate time period. Under the proposed rule, HHS would 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). OGC and the departmental division that authored the challenged guidance would be responsible for responding to all petitions received on the guidance document.

HHS seeks comments on the proposed procedure to allow interested parties to petition the Department.

III. Rulemaking Analyses and Notices

A. Executive Orders 12866 and 13563

Executive Orders 12866 and 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. As such, the Department does not anticipate that this rulemaking will impose measurable costs on regulated parties. This proposed rule describes proposed agency processes for issuing guidance and responding to petitions regarding guidance that allegedly is inappropriate or is being used inappropriately. The Department proposes to adopt these procedures as part of its regulatory reform initiative. Implementation of this proposed rule would 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. The Department expects benefits to accrue as a result of the streamlined and clarified process of issuing guidance documents, in addition to positive consequences flowing from improved agency decision making. If this proposed rule is finalized, the Department anticipates that the public, and, in particular, regulated parties, would benefit from greater efficiencies and more transparency in how the Department operates and regulates.

B. Executive Order 13771

This proposed rule is expected to be neither a regulatory nor a deregulatory action under E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' because this rule is estimated to impose no more than *de minimis* costs on regulated entities.

C. Regulatory Flexibility Act

The Department has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq*. The RFA requires an agency to describe the impact of a proposed rulemaking on small entities by providing an initial regulatory flexibility analysis, unless the agency determines that the proposed rule will not have a significant impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a) and 605(b). The Department considers a proposed or final rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue on at least five percent of small entities. The Department anticipates that, if finalized, this proposed rule would 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 proposed rule would not have a significant impact on the operations of a substantial number of small entities.

D. Executive Order 13132 (Federalism)

Executive Order 13132 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 proposed rule would not impose such costs or have any federalism implications.

[2] 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.

E. Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3506; 5 CFR part 1320, appendix A.1), the Department has reviewed this proposed rule and has determined that it proposes no 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 proposes to amend 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, except the Food and Drug Administration, for which all requirements at 21 U.S.C. 371(h) and 21 CFR 10.115 shall continue to apply.

§ 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.

(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 [*date 60 days after effective date of the final rule*] 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 November 2, 2020, the guidance document shall be considered rescinded.

(3) Any web page 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 [effective date of the final rule].

(b) *Guidance issued after [effective date of the final rule].* (1) For all guidance documents issued after [effective date of the final rule], 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 [effective date of the final rule], 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 will publish all responses to petitions under this section to a designated web page on its guidance repository.

Dated: August 14, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–18208 Filed 8–17–20; 4:15 pm]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MB Docket Nos. 19–193, 17–105; Report No. 3154; FRS 16953]

Petitions for Reconsideration of Action in Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petitions for Reconsideration.

SUMMARY: Petitions for Reconsideration have been filed in the Commission's proceeding by Foundation for a Beautiful Life; and by Todd Urick and Paul Bame (previously commenting under ''LPFM/NCE Community-Radio Engineer Advocates'' or ''LPFM Advocates''), along with Peter Gray (KFZR–LP), Makeda Dread Cheatom (KVIB–LP), Brad Johnson (KGIG–LP), David Stepanyuk (KIEV–LP), and Andy Hansen-Smith (KCFZ–LP).

DATES: Oppositions to the Petition must be filed on or before September 4, 2020. Replies to an opposition must be filed on or before September 14, 2020.

ADDRESSES: Federal Communications Commission, 445 12th Street SW,