



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: Proposed rule; correction

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: August 18, 2020.

FOR FURTHER INFORMATION CONTACT: Brenna Jenny, Department of Health and Human Services, 200 Independence Avenue, S.W., Room 713F, Washington, D.C. 20201. Email: Good.Guidance@hhs.gov. Telephone: (202) 690-7741.

SUPPLEMENTARY INFORMATION:

I. Summary of Errors

In FR Doc. 2020-18208, the notice of proposed rulemaking entitled "Department of Health and Human Services Good Guidance Practices" (hereinafter referred to as the Good Guidance Practices Rule) there was an error in the proposed date by which 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 Good Guidance Practices Rule used the proposed date of November 2, 2020, but the correct date is November 16, 2020. Similarly, in several places the Good Guidance Practices Rule referred to a time period after “the effective date of the final regulation” or a date “60 days after [the] effective date of the final rule”; these references throughout should be replaced with the correct proposed date of November 16, 2020.

We are correcting our previous statement in the August 17, 2020 notice of proposed rulemaking accordingly.

Therefore, FR Proposed Rule Doc. 2020-18208, published August 20, 2020, beginning on page 51396, is corrected as follows:

II. Correction of Errors in the Preamble

1. On page 51398, in the first column, the second sentence is corrected to read as follows:

“If the proposed rule is finalized, following 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.” “

2. On page 51398, in the first column, the first sentence of the second paragraph sentence is corrected to read as follows:

“HHS proposes to require that each guidance document issued by it or any component after November 16, 2020, 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.”

3. On page 51398, in the third column, the third sentence of the second paragraph sentence is corrected to read as follows:

“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.”

4. On page 51398, in the third column, the first sentence of the third paragraph sentence is corrected to read as follows:

“Under this proposal, 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.”

5. On page 51398, in the third column, the fourth paragraph is corrected to read as follows:

“If the Department would desire 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.”

6. On page 51398, in the third column, the first sentence of the fifth paragraph is corrected to read as follows:

“If this proposed rule is finalized, guidance documents issued after November 16, 2020 would be required to comply with all applicable requirements in § 1.3.”

7. On pages 51398-51399, in the third column, the last sentence in the fifth paragraph is corrected to read as follows:

“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.”

III. Correction of Errors in Proposed Regulation Text

On page 51401, in the first column, added § 1.4 is corrected to read as follows:

§ 1.4 Guidance repository.

(a) *Existing guidance.* By November 16, 2020, 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 16, 2020, 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 November 16, 2020.

(b) *Guidance issued after November 16, 2020.* (1) For all guidance documents issued after November 16, 2020, 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 November 16, 2020, the Department shall post proposed new significant guidance to the guidance repository as part of the notice-and-comment process.

(ii) 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.

Dated: August 21, 2020

Wilma M. Robinson,

Deputy Executive Secretary to the

Department,

Department of Health and Human Services.

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