

Department of Health and Human Services

Request for Information on Guidance Documents

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

ACTION: Request for information.

DATES: To be assured consideration, comments must be received by October 12, 2020.

ADDRESSES: Comments should be submitted electronically to GuidanceRFI@hhs.gov. Commenters are encouraged to provide the name of their organization and a contact person, mailing address, email address, and phone number. However, this information is not required as a condition of HHS's full consideration of your comment. Commenters are encouraged to submit their comments in PDF format.

BACKGROUND: On August 20, 2020, HHS published a Notice of Proposed Rulemaking that proposes to issue regulations governing the agency's release and maintenance of guidance documents. See 85 FR 51396 (hereinafter, "Proposed Good Guidance Practices Regulations"). These regulations should, if finalized, 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. This Request for Information ("RFI") solicits comments relating to the Department's current compliance with Executive Order 13891, and in particular, seeks specific feedback about potential opportunities to improve and ensure the Department's compliance with, and best practices relating to, the legal obligations governing the appropriate issuance of guidance.

REQUEST FOR INFORMATION: Various statutory obligations govern the Department's issuance and use of guidance documents. Principally—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). Other relevant statutory provisions include the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Public Law 106-554) and Social Security Act section 1871 (*see Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019)). The Department's Proposed Good Guidance Practices Regulations reiterate the application of these existing legal principles to HHS's guidance documents and confirm HHS's commitment to upholding these obligations. As HHS works to implement Executive Order 13891, HHS broadly seeks input from regulated parties and other interested parties about specific guidance documents that should, in light of their content, current use, and agency practice, be issued through notice-and-comment rulemaking. For any such guidance document that is identified by a commenter, please provide a link to the guidance document as posted on the HHS Guidance Portal (available at hhs.gov/guidance), or if the guidance document is not currently posted on the HHS Guidance Portal, please provide another internet link to the guidance document. If the guidance document is not currently available online, please append a copy of the guidance document to the

comments you submit. For each identified guidance document, commenters may, but are not required to, briefly explain the reason or reasons for their concern or suggestion relating to the issuance or use of the guidance document.

SPECIAL NOTE TO RESPONDENTS: This is a request for information only. We welcome your input as to which existing HHS guidance documents should be issued through notice-and-comment rulemaking. HHS would like to request that submissions be limited to ten pages or less (excluding any copies of guidance documents provided) to ensure that comments can be reviewed timely and thoroughly.

This RFI is issued solely for information and planning purposes; it does not constitute a request for proposal, applications, proposal abstracts, or quotations. This RFI does not commit the Government to contract for any supplies or services or make a grant award. Further, HHS is not seeking proposals through this RFI and will not accept unsolicited proposals. Respondents are advised that the Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, should one be conducted. HHS does not anticipate additional notifications regarding the RFI; however, potential respondents should continue to monitor HHS announcements for additional information pertaining to this RFI.

Please note that HHS will not respond to questions about the policy issues raised in this RFI. HHS may or may not choose to contact individual commenters. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which payment would be required or sought. All submissions become Government property and will not be returned. HHS may publicly post the comments received, or a summary thereof.

COLLECTION OF INFORMATION REQUIREMENTS: This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. However, this document does contain a general solicitation of comments in the form of a request for information. In accordance with implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR § 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the Federal Register or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 USC § 3501 *et seq.*).