Federation of American Hospitals®

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President & CEO

September 16, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW, Room 713F
Washington, DC 20201

Re: RIN 0991-AC17; Department of Health and Human Services Good Guidance Practices; Proposed Rule

Dear Secretary Azar:

The Federation of American Hospitals (FAH) appreciates the opportunity to submit these comments to the Department of Health and Human Services (HHS or the Department) regarding the *Department of Health and Human Services Good Guidance Practices* (Proposed Rule), published in the *Federal Register* on August 20, 2020 (85 Fed. Reg. 51396).[1] The FAH is the national representative for over 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural America. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH appreciates HHS' regulatory reform efforts to increase accountability, improve fairness of the guidance it issues, guard against unlawful regulation through guidance, and safeguard the principles underlying the administrative law system. We understand that the

[1] A Correction Notice for the Proposed Rule was published in the *Federal Register* on August 26, 2020 (85 Fed. Reg. 52515).

Proposed Rule is meant to support these efforts by providing clarification of the Department's planned process to consolidate and organize the Department's guidance documents[2]. However, the FAH has concerns about the proposed repository as discussed further below, and urges the Department to reconsider the feasibility of implementing the proposal at this time, especially at a time when hospitals' and other stakeholder's key resources are largely focused on the current COVID-19 public health emergency (PHE). If the Department moves forward with the proposal, we urge further clarity regarding implementation of the repository discussed in the Proposed Rule, as well as to ensure that adequate time is devoted to developing and implementing an effective and accurate repository for the guidance.

Timing of the Guidance Repository Implementation

As the Department is well aware, hospitals are facing incredible challenges this year. Our members continue to make great efforts to ensure that they are providing quality care to the patients in their communities throughout the COVID-19 PHE. Whether preparing for a possible surge of COVID-19 patients, caring for COVID-19 patients, or addressing the economic strain of maintaining critical health care services during this pandemic, our members have been impacted significantly by the PHE. During the PHE, it has become clear how important it is for hospitals to have readily accessible guidance from HHS to assist our members in responding to these current challenges. Successful efforts to better streamline accessibility to, and define the impact of, this guidance are necessary and welcome. However, the FAH is concerned that implementation of the Proposed Rule at this time will present additional and significant challenges to hospitals and other stakeholders.

For obvious reasons, all stakeholders rely heavily on guidance from multiple HHS agencies on issues spanning a broad range of topics such as billing practices, licensing requirements, infection control strategies and many others. We understand that the development of the repository is intended to provide positive benefits for providers, suppliers, patients, and the public by creating a centralized access point for this information. However, the FAH is concerned that implementing and populating the repository in the expedited manner described in the Proposed Rule is premature and may add confusion during an already uncertain time.

The FAH asks HHS to consider delaying the implementation of the guidance repository until there is more clarity about how it would work and opportunity for meaningful stakeholder review and comment. This will ensure a more reasonable and appropriate process. It is not entirely clear why it is necessary to have the repository in place as of November 16, 2020. Stakeholders were provided with very little time to consider the Proposed Rule and its impact and to submit responsive and constructive comments. Additionally, the Proposed Rule would have the final rule in place only sixty days following receipt of comments on the Proposed Rule if the repository is made effective in November. It does not seem reasonable that HHS will be able to meaningfully

[2] We note that the Proposed Rule does not apply to the Food and Drug Administration's (FDA) guidance database and that the FDA is separately updating its own good guidance practices to meet the requirements of Executive Order 13891. Our reference to "repository" throughout this letter does not include the FDA's guidance repository.

consider and respond to issues, concerns, and requests for clarity submitted through the comment process. We are concerned that placing all of the applicable guidance into the repository by November 16, 2020 in an accurate, user-friendly, and easy to navigate format may be difficult to accomplish and open to potential unintended errors. The FAH is concerned that inaccuracies and/or omissions from the repository will result in confusion for the industry in an already confusing time. As such, we recommend that HHS delay the implementation date of the rule until greater resources can be dedicated to the design, development, population, organization, improvement, and effective implementation of the guidance repository.

Alternatively, if HHS moves forward with the Proposed Rule, the FAH recommends that HHS develop and implement use of the repository during a six-month transition period. Rather than setting a date absolute where all applicable documents must be in the repository, we urge HHS to consider developing the repository in a manner that allows stakeholders to access it, as well as the current sources of guidance, to ensure that critical guidance is not lost or possibly deemed rescinded if not included in the repository by November 16, 2020. This will enable the Department and stakeholders to test the repository while maintaining existing systems and then to transition once the repository is fully tested and complete.

Guidance Repository Structure

As the repository will be a critical tool for health care providers, it is essential that it is accurate and user friendly as of the day of implementation. We have reviewed the HHS guidance website available at https://www.hhs.gov/guidance/, as well as the current FDA repository. We note that the FDA guidance website appears more robust than the HHS website at this time. The FDA allows the user to both browse guidance documents by topic and search for a specific document using a seemingly practical and comprehensive tool. The search tool has multiple filters that can help narrow the user's search of over 2,600 entries to a manageable list of documents in short order and in an organized manner. Search results can be sorted by document summary, type, issue date, internal agency branch, topic, guidance status, and whether the guidance is open for comment and, if so, the comment closing date for the draft. In contrast, the HHS guidance repository, as it stands today, has more than 22,000 documents, yet allows searches only by keyword, topic, division/office, and language, and providing users with only five sort fields. This raises some concern that the HHS repository may be cumbersome for users and possibly result in improper searches and misleading and/or contradictory guidance.

The FDA repository website also provides ready references regarding the applicability and enforceability of the guidance, procedures to comment on drafts, and the Agency's good guidance practices; none of this information is available currently on the HHS repository website. The date the FDA repository and each of its documents was last updated is clear and current; this is not found on the HHS website. The FDA website provides an example of additional refinements that we believe would be beneficial for HHS to implement. The FAH asks that HHS consider expanding the capabilities of the proposed repository so that it is can be a sophisticated resource that is easily searchable and usable. We believe these additions and improvements to the repository

website may simply require more time to ensure that the result is an efficient, sophisticated, and meaningful tool.

The FAH urges HHS to include in the final rule a defined process of communication between HHS and stakeholders regarding updates and changes to the repository. The rule as proposed lacks any description of the manner in which stakeholders will be notified of important changes to the repository, such as which documents are excluded from the repository at the time of initial implementation and when new documents are added to the repository going forward. Clear and timely communication between the Department and stakeholders are critical to ensuring that the repository performs properly for all involved.

"Guidance" and "Significant Guidance"

The Proposed Rule would apply to guidance documents, including those that are deemed to be "significant" guidance documents. The FAH seeks additional clarification regarding the types of documents that are to be included in each of these categories, as well as processes being developed to identify sources that qualify as "guidance" and those that do not.

We seek to better understand the inclusion of preambles to rules published in the *Federal Register*. The definition of "guidance document" in the Proposed Rule states that "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."[3] The Proposed Rule further elaborates that "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." (Emphasis added.)[4] Preambles to proposed and final rules published in the *Federal Register* are a formal part of notice-and-comment rulemaking.[5] As such, it is unclear whether the disclaimer required by the Proposed Rule to be used on all guidance documents is applicable to preambles, as the disclaimer states that guidance documents "do not have the force and effect of law and are not meant to bind the public in any way . . . ."[6] The FAH is concerned that HHS may assert through this provision the questionable position that if preambles are "guidance documents," the Department has the authority to rescind parts of a preamble even though publication in the *Federal Register* is part of

[3] 85 Fed. Reg. 51396, 51397.

[4] 85 Fed. Reg. 51396.

[5] *See* 1 C.F.R. § 18.12 ("Each agency submitting a proposed or final rule for publication shall prepare a preamble which will inform the reader, who is not an expert in the subject area, of the basis and purpose for the rule or proposal."); *see also* 37 Fed. Reg. 23602, 23602 (final rule establishing revisions to Federal Register "to make the Federal Register a more meaningful and more useful publication" by including, among other improvements, "adequate preambles." In discussing comments received from the federal rule making agencies who questioned whether the proposal to include adequate preambles went "beyond the requirements of the Administrative Procedure Act," the rules states that "the Administrative Committee believes that the proposed requirements are clearly within the spirit of the Federal Register Act (44 U.S.C. 1501-1511) and the Administrative Procedure Act").

[6] 85 Fed. Reg. 51396, 51398.

notice-and-comment rulemaking. Thus, we urge HHS to reconsider its proposal to include preambles in the definition of "guidance documents."

There is much guidance in health care that flows from agencies within HHS via sub regulatory guidance. The FAH has identified certain sources of information for which we request that HHS provide additional direction regarding whether they will be included among the guidance documents in the repository. For example, *MLN Matters* articles contain extremely important explanations of Medicare policies concerning coverage, billing, and payment rules for specific providers types in an easily understood format.[7] The *MLN Matters* articles often serve as providers' and suppliers' first notice of interim updates to policies and procedures that will later be incorporated into the Medicare Claims Processing Manual, the Medicare Benefit Policy Manual, and other official agency administration and informational documents.[8] A decision not to include these articles in the guidance repository would leave hospitals without timely updates regarding CMS' newest expectations and delay their ability to comply. We ask that HHS continue to develop and issue the *MLN Matters* articles and to identify them as relevant guidance appropriate for inclusion in the repository.

HHS has proposed additional procedures related to significant guidance documents. One such addition is the provision of a comment period of at least 30 days for "significant guidance" documents prior to issuing such a document. The FAH agrees that a comment period is appropriate but suggests that the period be at least 60 days to allow meaningful review and comment.

The Proposed Rule would define a significant guidance document as one 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." Therefore, by definition, a significant guidance document is likely to raise important and complex issues on which the public should have an adequate time to comment. Both the commenters and HHS will benefit from comments that are thoughtful and well-developed. By way of comparison, proposed rules issued by HHS components, such as CMS, rarely have a comment period of less than 60 days, and sometimes have a period of 90 days or more.

Also, the rulemaking provisions of section 1871(b)(1) of the Social Security Act (the Act) generally mandates a comment period of at least 60 days for any rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a

[7] Centers for Medicare & Medicaid Services, *MLN Matters Articles* (last modified Aug. 13, 2020), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles.
[8] *See* Centers for Medicare & Medicaid Services, *Internet-Only Manuals* (last modified Apr. 5, 2012). https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.

substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare. Given the Proposed Rule's statement that HHS presumes that a guidance document it deems significant is actually a legislative rule that must go through notice-and-comment rulemaking, and given the Supreme Court's holding in *Allina* that the notice and comment provisions in section 1871 of the Act apply to more than just legislative rules, it would seem to be in HHS's interest to provide for a comment period of at least 60 days for significant guidance documents affecting Medicare, lest they be successfully challenged as violating the rulemaking procedures of the Act.

Likewise, given the likelihood that a significant guidance document will be deemed to be a legislative rule, HHS should require that any significant guidance document carry a delayed effective date of at least 30 days, in accordance with section 1871(e) of the Act with respect to Medicare rules, and 5 U.S.C. § 553(d) with respect to rules issued under the requirements of the Administrative Procedure Act (unless an exception is met as provided for in such statutes).

Petition for Review of Guidance

Finally, the Proposed Rule provides a mechanism for any interested party to petition HHS to withdraw or modify any particular guidance document. HHS would be required to respond to all petitions within 90 business days of the date the petition was received, with the time tolled if HHS were to request additional information from the person who submitted the petition or to consult with other stakeholders. The FAH respectfully submits that this timeline for response is too protracted to be effective. The contested guidance could easily become effective during the review process, leaving stakeholders in administrative limbo regarding the proper implementation of their programs and initiatives. There does not appear to be any consequence as a result of HHS' failure to meet the 90-business day deadline. This could potentially lead to a timeline that is already too long becoming extended indefinitely if HHS fails to meet the deadline and stakeholders being left without recourse if this occurs. Additionally, the FAH is concerned that HHS may mistakenly interpret unchallenged guidance to mean that the guidance is clear and certain to stakeholders, increasing the possibility of expensive and interminable administrative and legal challenges if a question later arises.

While HHS proposes to respond to petitions for review within 90 business days, there is concern regarding the ability of the Department to meet this deadline. We believe that, given the nature of the guidance documents to be included in the repository, there will likely be a large number of stakeholders seeking modifications or withdrawals of guidance following the implementation of the guidance repository in November. We question whether HHS has the resources to respond to such an influx of requests. The potential volume of requests lends additional support to our request above that full implementation should occur during a transition period to allow HHS to respond to such requests and to update the repository accordingly. While there is likely to be a large number of requests initially, it is unclear if there is a limitation as to when such a petition for review can be submitted. With such a large volume of documents

populating the website, the potential for error is high – either by omission or inclusion – and such errors may not be identified for months or years. Thus, the FAH respectfully requests that HHS make it clear that petitions for review may be submitted at any time an issue arises to ensure that the guidance repository is accurate and reliable.

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The FAH appreciates the opportunity to comment on this Proposed Rule. We look forward to continued partnership with HHS to modernize the presentation and clarify the impact of the Department's guidance documents in a way that ensures accessibility, clarity, and accuracy. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,