September 16, 2020

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

RE: Comments on RIN 0991–AC17
Department of Health and Human Services Proposed Rule:
Good Guidance Practices

Dear Secretary Azar:

The Consortium for Citizens with Disabilities (CCD) is the largest coalition of national organizations advocating together for federal public policy that ensures the self-determination, independence, empowerment, integration and inclusion of children and adults with disabilities in all aspects of society. We, the co-chairs of the CCD Health and Long Term Services and Supports Task Forces, thank you for the opportunity to comment on the proposed rule.

CCD supports measures that increase transparency, accountability, and foster stakeholder input through the notice and comment process. We also share HHS's concerns about the misuse of guidance documents. However, the proposed rule has significant problems and would not achieve HHS's stated goals. Moreover, HHS fails to explain key provisions adequately, making it impossible for us to provide meaningful comments. We also strongly object to the truncated 30-day comment period, which provides insufficient time to fully consider this complex proposal that has potentially far-reaching consequences. Accordingly, we urge HHS to withdraw this proposed rule.

Background on the Use and Limits on Agency Guidance

Agency guidance is a valuable tool that allows executive branch agencies to help clarify policy issues and explain ambiguities raised by the laws and rules they are tasked with implementing and enforcing. Efforts to clarify the appropriate use and limits of agency guidance are nothing new. For example, in 1997 Congress codified several good guidance practices implemented by the Food and Drug Administration (FDA). In 2007, the Office of Management and Budget (OMB) issued its *Final Bulletin for Agency Good Guidance Practices*.[1]

1 OMB, Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 - 3400 (Jan. 25,

In October 2019, the current administration issued Executive Order 13891, *Promoting the Rule of Law Through Improved Agency Guidance Documents*.[2] Executive Order 13891 seeks to apply notice and comment procedures, which are required for formal rulemaking by the Administrative Procedure Act (APA), to certain guidance documents. It also says "significant guidance" must undergo heightened review procedures required by the Congressional Review Act (CRA) for "major" rules. The Executive Order further directs executive agencies to issue regulations that "develop or set forth processes and procedures for issuing guidance documents" within 300 days. This proposed rule would implement the EO's directives for HHS guidance.

To do so, the proposed rule selectively applies portions of the APA and CRA to guidance documents. Yet neither the APA nor the CRA apply these heightened procedural requirements to "significant guidance" documents. HHS fails to explain the statutory basis authorizing it to apply notice and comment requirements to guidance documents.

The proposed guidance repository would have troubling implications

The proposed rule would create a "guidance repository," a searchable database that would include all current HHS guidance. CMS would need to establish this repository no later than November 16, 2020, according to the tight timeline in the rule. Generally, CCD would support any proposal that increases transparency and accessibility to documents in public programs. However, HHS's proposal contains a highly troubling provision that would automatically rescind any guidance omitted from the repository. Further, HHS has provided no information on the processes or criteria for reviewing and selecting guidance that will appear in the repository on such a short timeline. Further, HHS has not provided a clear opportunity for public input on what guidance should be updated, rescinded, or remain in effect.

The Centers for Medicare and Medicaid Services (CMS) regularly sends out letters to state Medicaid directors explaining in more detail changes in either law or regulation or updates to programs. These letters address the extension of important eligibility rules and demonstration programs such as Congressional reauthorization of the Money Follows the Person program and protections from spousal impoverishment for married individuals eligible for home-and-community based services. Other letters provide important information to Medicare Advantage plans on obligations and best practices for implementing new coverage such as the recent expansion of Medicare coverage of outpatient opioid treatment. Additionally, CMS has used such guidance to remind states of existing authorities and processes for improving care coordination for dually eligible individuals and other populations. We are deeply concerned that

2007), https://www.govinfo.gov/content/pkg/FR-2007-01-25/pdf/E7-1066.pdf.

2 E.O. 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents, 84 Fed. Reg. 55235 - 55238 (Oct. 9, 2019), https://www.federalregister.gov/documents/2019/10/15/2019-22623/promoting-the-rule-of-lawthrough-improved-agency-guidance-documents.

if this proposed rule is finalized, these documents would be rescinded if inadvertently or purposely not included in the repository and these programs and policies left in limbo.

Even if stakeholders petition to reinstate guidance omitted from the repository, such a process would be time consuming, burdensome, and cause uncertainty among the public and regulated entities. Both Marketplace plans and Parts C and D of the Medicare program run on a tight annual cycle built around a fall Open Enrollment Period. CMS makes changes yearly to improve the beneficiary experience, protect against fraud and abuse, improve program performance and address unexpected issues that arose in the prior year. For example, we have seen CMS modify marketing guidance in response to novel forms of abuse. Such changes are routinely subject to public comment, though less formal than envisioned in the proposal. Layering on a protracted process of determining which changes constitute significant guidance (see below) would add delay and uncertainty to the detriment of all stakeholders. Further, the additional proposed process for procedural objections after guidance is issued adds even more to the lack of certainty and finality.

Based on these concerns about potentially losing valuable guidance and creating new administrative burdens to release timely guidance, we oppose these provisions.

The proposed definitions of "guidance" and "significant guidance" are too vague

The proposed rule's definition of what constitutes guidance is vague. HHS states that "content" rather than format dictates whether a document should be considered guidance, and goes on to describe various types of documents, such as videos, letters, and bulletins that could be guidance. To qualify as guidance, a document would need to be a statement of general applicability intended to govern the future behavior of regulated parties, as determined by the Office of the General Counsel (OGC).[3]

While purporting to clarify the definition of guidance for stakeholders and members of the public, the proposed rule actually obfuscates its meaning. It suggests, for example, that guidance may be hidden within nonguidance. HHS does not explain how it will identify and designate incidences of guidance contained within nonguidance. It also does not explain how it will address nonguidance that includes guidance, including "significant guidance," that must undergo notice and comment and be labeled with a disclaimer (discussed below). This provision is confusing and could inhibit other kinds of regulatory activities, such as compliance actions.

Adopting language from Executive Order 13891, the proposed rule also establishes a definition of "significant guidance," subject to heightened procedural requirements. Specifically, HHS would conduct an analysis and would submit guidance designated "significant" to OMB's OIRA for review. Further, the proposed rule would require any guidance determined to be significant to go through a notice and comment process that lasts at least 30 days.

3 85 Fed. Reg. 51396, 51400, to be codified at 45 C.F.R. §1.2.

However, neither the proposed rule nor Executive Order 13891 provides a clear explanation for how costs related to significant guidance would be calculated. They include no discussion of standards, methodologies, or other criteria for determining whether guidance is "significant." We are therefore unable to provide further comments on this provision, but note that it is confusing and unclear.

Despite its stated goal of transparency, the proposed rule also fails to require the HHS OGC to post its analyses publicly. HHS OGC will undertake important review processes, and make consequential determinations regarding the nature of agency action and procedural requirements, hidden from public view.

Subjecting "significant guidance" to formal rulemaking procedures creates legal uncertainty and ambiguity

By requiring certain "significant guidance" to undergo a formal notice and comment process, HHS is creating a new, legally ambiguous category somewhere between guidance and a rule. HHS suggests that significant guidance would, like rules, have to go through a notice and comment process, but implies that unlike rules, such significant guidance would not carry the force of law. Further questions remain unaddressed: How would the notice and comment process for significant guidance differ from that of formal rulemaking? What obligation does HHS to consider and respond to comments, and how would stakeholder input be considered or integrated into proposed guidance? HHS does not say. Could guidance promulgated through notice and comment be rescinded without notice and comment? Again, HHS does not say.

This also seems to indicate that a large scope of documents previously issued by the Department should have been subject to the more laborious process of notice and comment rulemaking and would, at the end of this process, carry the "force and effect of law." The proposed rule would not necessarily require these previously issued documents to now undergo notice and comment, but as noted above, any guidance that is not initially included in the proposed guidance repository would be rescinded. Such guidance would have to go through full notice and comment to get reinstated. Future revisions to existing significant guidance might also require this process. Thus, in addition to creating more ambiguity, the significant guidance category could create substantial administrative burdens that hamstring HHS from issuing clarifying interpretations and other guidance going forward.

Requiring disclaimers on guidance documents will create confusion and administrative burden

The proposed rule would require guidance documents to include a disclaimer noting that the contents of these documents "do not have the force and effect of law and are not meant to bind the public in any way."[4] It is unclear whether this provision also applies to "significant guidance."

4 85 Fed. Reg. 51398, 51400, to be codified as 45 C.F.R. § 1.3(a)(3)(i).

The proposed rule does not explain how, or in what form, it will add such a disclaimer to videos, audio and other non-written material, which HHS acknowledges could serve as guidance documents.[5] Additionally, the proposed rule fails to explain how or whether it will insert the disclaimer notice in nonguidance documents that HHS has determined actually include guidance.

HHS' proposed rule fails to address joint guidance issued by multiple agencies

The proposed rule fails to address instances whereby multiple federal agencies issue joint guidance. What happens if joint guidance is not included in HHS' repository but remains valid for another agency? For example, HHS and the DOE have issued joint guidance on privacy and student education and health records based on HIPAA and FERPA. What would happen if this guidance was not included in HHS's repository and was rescinded, but was still in effect through the Department of Education?

HHS failed to reign in the misuse of guidance documents under existing authorities

CCD shares HHS's concern that agencies within the Department have, at times, misused guidance documents. However, there is no indication that the proposed rule would effectively eliminate this malpractice.

In a recent and egregious example, the Centers for Medicare & Medicaid Services (CMS) issued guidance that would radically alter the Medicaid financing structure.[6] After Congress has considered, and repeatedly rejected, legislative proposals to impose block grants and per capita caps on the Medicaid Program, the administration sought to make this policy change through CMS guidance. CMS initially followed procedures under the OMB Memo and submitted its Block Grant Guidance to OIRA for review. Dozens of interested parties requested meetings with OMB officials to express concerns and opposition. After many months and without explanation, CMS withdrew the guidance from OIRA. CMS then released the Block Grant Guidance in January 2020. To date, neither CMS, HHS OGC, nor OMB have provided further information that the Block Grant Guidance completed the review and approval process.

If agency heads can abandon OMB review procedures without explanation, it is unlikely that adding more procedures for guidance review would be faithfully implemented, or better address the problem agencies' misusing guidance documents.

Conclusion

Transparency, accountability, and public input are important goals in the implementation of laws and policies, especially those affecting health and well-being. However, HHS' proposed rule

5 85 Fed. Reg. 51396.
6 CMS, Dear State Medicaid Director (Jan. 20, 2020) (SMD # 20-001), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf (hereinafter "Block Grant Guidance").

would fail to achieve these goals. Instead, it would add confusion, obfuscation, and administrative burden. Moreover, HHS seems intent on implementing the provisions of this rule, and its arbitrary "repository" by the November 16, 2020 deadline, without regard to the many flaws of this proposal and public comment submitted herein. This ill-conceived process could result in the loss of critically important guidance documents that help protect and implement the rights of people with disabilities and could seriously hinder efforts to create new guidance and clarifying documents in the future. If HHS is serious about transparency, accountability, and public input, it should withdraw this ill-considered proposed rule.

Please contact David Machledt with any questions or comments (machledt@healthlaw.org).

Respectfully Submitted,

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