September 14, 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 National Health Law Program (NHeLP) has worked to improve health care access and quality through education, advocacy and litigation on behalf of low-income and underserved individuals for over 50 years. We appreciate the opportunity to provide comments on the proposed rule establishing regulations governing guidance practices at the Department of Health and Human Services (HHS).[1] Generally, NHeLP supports measures which increase transparency and accountability; and foster stakeholder engagement through public notice and comment. We also share HHS' stated concern with the misuse of guidance documents within the Department.

However, the Proposed Rule on Guidance has significant problems and would not achieve HHS' stated goals. Moreover, HHS fails to adequately explain key provisions, making it impossible for NHeLP and other stakeholders 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 the Proposed Rule on Guidance.

Background on the Use and Limits on Agency Guidance

Administrative agencies regularly rely on the use of guidance documents to help implement and enforce laws and regulations. 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).[2] Among other provisions, the FDA's good guidance rules specify that "employees may depart from the guidance documents only with appropriate justification and supervisory concurrence," and require public notice and comment on guidance topics being considered by the agency.[3]

In 2007, the Office of Management and Budget (OMB) issued its *Final Bulletin for Agency Good Guidance Practices* to address guidance documents that are "poorly designed or improperly implemented," and guidance documents that "may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review."[4] Like the FDA good guidance rules, the OMB Bulletin declared that guidance

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[1] U.S. Dept. of Health and Human Srvs., *Notice of Proposed Rulemaking, Department of Health and Human Services Good Guidance Practices*, RIN 0991–AC17, 85 Fed. Reg. 51396 – 51400 (Aug. 20, 2020), https://www.govinfo.gov/content/pkg/FR-2020-08-20/pdf/2020-18208.pdf; U.S. Dept. of Health and Human Srvs., *Notice of Proposed Rule Correction, Department of Health and Human Services Good Guidance Practices*, RIN 0991–AC17,85 Fed. Reg. 52515 – 52516 (Aug. 26, 2020), https://www.govinfo.gov/content/pkg/FR-2020-08-26/pdf/2020-18744.pdf (hereinafter "Proposed Rule on Guidance).

[2] The FDA underwent an extensive public process to establish good guidance practices, beginning with a solicitation for public comments and formal rulemaking in response to congressional action: FDA, *Notice: Request for Comment*, 61 Fed. Reg. 9181-9185 (Mar. 7, 1996), https://www.govinfo.gov/content/pkg/FR-1996-03-07/html/96-5344.htm; FDA, *Notice: The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents*, 62 Fed. Reg. 8961-8972 (Feb. 27, 1997), https://www.govinfo.gov/content/pkg/FR-1997-02-27/pdf/97-4852.pdf; Food and Drug Administration Modernization Act of 1997, Pub. L. 105–115, 111 Stat. 2368 (Nov. 21, 1997), codified at 21 U.S.C. § 371(h); FDA, *Administrative Practices and Procedures; Good Guidance Practices Proposed Rule*, 65 Fed. Reg. 7321-7330 (Feb. 14, 2000), https://www.govinfo.gov/content/pkg/FR-2000-02-14/pdf/00-3344.pdf; FDA, *Administrative Practices and Procedures; Good Guidance Practices Final Rule*, 65 Fed. Reg. 56468-56480 (Sept. 19, 2000), https://www.govinfo.gov/content/pkg/FR-2000-09-19/pdf/00-23887.pdf, *codified at* 21 C.F.R. § 10.115.

[3] 21 C.F.R. §§ 10.115(d)(3), (f)(5), (g).

[4] OMB, *Final Bulletin for Agency Good Guidance Practices*, 72 Fed. Reg. 3432 - 3400 (Jan. 25, 2007), https://www.govinfo.gov/content/pkg/FR-2007-01-25/pdf/E7-1066.pdf (hereinafter "OMB Bulletin").

represents an "agency's current thinking" but is not legally binding, and that agency employees should not depart from agency guidance "without appropriate justification and supervisory concurrence."[5] The OMB Bulletin called upon federal agencies to establish written procedures for "significant guidance" including an opportunity to comment and public access to guidance documents.[6]

In April 2019, the OMB issued a memo to federal agencies saying that "The [Congressional Review Act] CRA applies to more than just notice and comment rules; it also encompasses a wide range of other regulatory actions, including, inter alia, guidance documents, general statements of policy, and interpretive rules."[7] The OMB Memo instructs agencies to follow procedures under the CRA and Executive Order 12866 for significant regulatory actions, including guidance documents.[8]

Then, in October 2019, the current administration issued Executive Order 13891, *Promoting the Rule of Law Through Improved Agency Guidance Documents*.[9] Executive Order 13891seeks to apply notice and comment procedures, which are required for formal rulemaking by the Administrative Procedure Act (APA), to certain guidance documents.[10] It also says "significant guidance" must undergo heightened review procedures required by the Congressional Review Act (CRA) for "major" rules.[11] As explained below, neither the APA nor the CRA apply these heightened procedural requirements to "significant guidance" documents. 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.[12]

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[5] 72 Fed. Reg. 3436, 3437.
[6] 72 Fed. Reg. 3434.
[7] Russell T. Vought, Acting Director, OMB, *Guidance on Compliance with the Congressional Review Act* (April 11, 2019), at 3, https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-14.pdf (hereinafter "OMB Memo").
[8] *Id*. at 4. *See also* EO 12866, § 3(f), 58 Fed. Reg. 51735 (Oct. 4, 1993).
[9] 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-law-through-improved-agency-guidance-documents.
[10] *Id*. at 55237.
[11] *Id*.
[12] *Id*.

On August 28, the Department of Labor (DoL) published its own "good guidance" rule, which largely resembles the HHS Proposed Rule on Guidance.[13] The DoL finalized its rule without notice and comment or any public input, declaring that good guidance practices "are purely internal matters of agency management."[14]

The APA expressly exempts guidance from notice and comment requirements

The APA establishes the processes for executive branch agencies to promulgate both formal and informal rules. The APA defines the term "rule" expansively as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency."[15] The APA expressly exempts general statements of policy from notice and comment requirements.[16]

Rules issued pursuant to the APA's notice and comment procedures are referred to as legislative rules and carry the "force and effect of law."[17] While administrative guidance can serve as a valuable tool for executive branch agencies, it does not carry the same legal weight as a legislative rule.[18]

Nothing in the CRA requires guidance to undergo notice and comment

Enacted in 1996 to give Congress more oversight of agency rulemaking, the CRA requires federal agencies to report to Congress any major rules it intends to promulgate. The CRA defines a major rule as "any rule that the Office of Information and Regulatory Affairs [OIRA] of the Office of Management and Budget [OMB] finds has resulted in or is likely to result in—

A. an annual effect on the economy of $100,000,000 or more;
B. a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

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[13] Dept. of Labor, Promoting Regulatory Openness Through Good Guidance (PRO Good Guidance), 85 Fed. Reg. 53163 – 53173 (Aug. 28, 2020), https://www.govinfo.gov/content/pkg/FR-2020-08-28/pdf/2020-18500.pdf.
[14] 85 Fed. Reg. 53170.
[15] 5 U.S.C. § 551(4).
[16] 5 U.S.C. § 553(b)(3)(A).
[17] 5 U.S.C. § 553. *See* Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 96 (2015) *citing* Chrysler Corp. v. Brown, 441 U.S. 281, 302-303 (1979) (noting that "legislative [**1201] rules" are issued through notice and comment rulemaking, see §§ 553(b),(c), and have the "force and effect of law").
[18] See Ronald M. Levin, *Rulemaking and the Guidance Exemption* 70 Admin. L. Rev. 263, 266 (noting that" legislative rules have the force of law and guidance does not.").

C. significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets." [19]

A series of Executive Orders require agencies to provide the public and OMB a thorough analysis of the costs and benefits of all significant regulatory actions.[20] OIRA remains the final arbiter of whether a rule meets this definition.[21] However, the CRA does not require significant regulatory actions to undergo notice and comment.

The CRA allows Congress to review a wide-range of regulatory actions, including certain guidance documents that have not gone through notice and comment.[22] The CRA requires that before rules subject to the CRA can take effect, the promulgating agency must send a report on the rule to each house of Congress and to the Government Accountability Office ("GAO").[23] The report must contain a copy of the rule, a "concise general statement" relating to the rule including whether it is a major rule, and the rule's proposed effective date.[24] The agency must also simultaneously submit to the GAO a copy of the cost-benefit analysis of the rule, if any, and a statement concerning the agency's actions under a variety of potentially applicable procedural rulemaking requirements.[25] However, the Proposed Rule on Guidance makes no mention of these requirements and fails to provide for congressional review of "significant guidance."

The Proposed Rule on Guidance selectively applies portions of the APA and CRA to guidance documents. However, HHS fails to explain the statutory basis authorizing it to apply notice and comment requirements to guidance documents. (We note that the Proposed Rule on Guidance expressly requires guidance documents to explain and cite to

[19] 5 U.S.C. § 804(2). Note that this "term does not include any rule promulgated under the Telecommunications Act of 1996 and the amendments made by that Act" *Id.*
[20] E.O. 12866 (Sept. 30, 1993), https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf; E.O. 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executiveorder-13563-improving-regulation-and-regulatory-review (specifically requiring agencies to "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible").
[21] 5 U.S.C. § 804(2).
[22] See OMB Memo, note 7 *supra*, citing 5 U.S.C. § 551(4). *See also* Valerie C. Brannon & Maeve P. Carey, Congressional Research Service, *The Congressional Review Act: Determining Which "Rules" Must Be Submitted to Congress* (March 6, 2019), https://fas.org/sgp/crs/misc/R45248.pdf (noting that "115th Congress used the CRA to pass, for the first time, a resolution of disapproval overturning an agency guidance document that had not been promulgated through notice-and-comment procedures.").
[23] 5 U.S.C. § 801(a).
[24] 5 U.S.C. § 801(a)(1)(A).
[25] 5 U.S.C. § 801(a)(1)(B).

the statutory basis under which they are promulgated).[26] By contrast, the FDA good guidance regulations, in effect for twenty years, are expressly authorized by Congress.[27] If the administration wants to curb administrative excesses that exceed statutory authority, it could start by withdrawing these so-called good guidance rules.

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

The definition of what constitutes guidance for the purposes of this rule is vague. HHS states that the "content," rather than format, dictates whether a document would be considered guidance, and goes on to describe various types of documents, such as videos, letters, bulletins that could be guidance.[28] 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).[29] Rules, advisory opinions, court filings, compliance actions, certain "internal guidance," and other types of documents are not guidance documents for purposed of the proposed rule.[30] However, HHS muddies its definition of guidance documents by stating that material contained within nonguidance could be guidance:

> [M]aterial 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.[31]

While purporting to provide clarity on guidance for stakeholders and members of the public, the proposed rule actually obfuscates, suggesting that guidance may actually 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.

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[26] 85 Fed. Reg. 51400, requiring guidance documents to cite to "to the statutory provision(s) and/or regulation(s) (in Code of Federal Regulations format) that the guidance document is interpreting or applying;" to be codified at 45 C.F.R. § 1.3(a)(3)(iii)(A).
[27] See Food and Drug Administration Modernization Act of 1997, note 2, *supra*.
[28] 85 Fed. Reg. 51396.
[29] 85 Fed. Reg. 51396, 51400, to be codified at 45 C.F.R. §1.2.
[30] *Id*.
[31] 85 Fed. Reg. 51397 (emphasis added).

Moreover, it is difficult to infer an agency's intent when it issues a document upon which affected parties may rely. For example, the Center for Consumer Information and Insurance Oversight (CCIIO) developed a series of templates and other resources for issuers seeking certification of Qualified Health Plans (QHPs).[32] Ostensibly, these resources are intended to serve as internal documents, developed for CCIIO personnel to evaluate plans for compliance with Essential Health Benefits (EHB), nondiscrimination, and other requirements. However, issuers rely on these documents when developing plan benefit design. It is not clear whether CCIIO templates would constitute guidance, nonguidance, or nonguidance that actually contains guidance under the Proposed Rule on Guidance.

Adopting language from Executive Order 13891, the Proposed Rule on Guidance also establishes a definition of "significant guidance," subject to heightened procedural requirements.[33] Specifically, HHS would conduct an analysis and would submit guidance designated "significant" to OMB's OIRA for review.[34] Further, the Proposed Rule on Guidance would require any guidance determined to be significant to go through a notice and comment process that lasts at least 30 days.[35]

However, neither the Proposed Rule on Guidance nor Executive Order 13891 provide a clear explanation for how costs related to significant guidance would be calculated, with 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.

Moreover, although the Proposed Rule on Guidance claims to bring transparency and accountability to guidance documents and "significant guidance" documents, it fails to require the HHS OGC to publicly post its analyses of putative rules, guidance documents, nonguidance documents, and nonguidance documents that include guidance. HHS OGC will undertake important review processes, and make consequential determinations regarding the nature of agency action and procedural requirements, hidden from public view, contrary to the stated goals of Proposed Rule on Guidance.

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

[32] See CCIIO, Qualified Health Plan Certification, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp (last visited Sept. 3, 2020).
[33] 85 Fed. Reg. 51397.
[34] 85 Fed. Reg. 51397, 51400, to be codified at 45 C.F.R. § 1.3(b)(2)(i).
[35] 85 Fed. Reg. 51397, 51400, to be codified at 45 C.F.R. § 1.3(b)(2)(ii).

and a rule. HHS suggests that such guidance, unlike rules, would not have the force of law. Further questions remain: 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.

HHS insists that only a handful of guidance documents would meet the definition of significant guidance, "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."[36] Instead the Proposed Rule on Guidance asserts that 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."[37]

This provision in the Proposed Rule on Guidance is, like others, ambiguous. It implies that almost any guidance document that HHS would deem as significant would, instead of guidance, be a legislative rule that required to go through the full process of notice and comment rulemaking. This statement does not offer any clear procedures to distinguish how HHS will, in fact, determine whether significant guidance is actually guidance, or whether it should be deemed a legislative rule according to the APA. It also seems to indicate that a large scope of documents previously issued by the Department might instead be 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 fails to list any examples of such guidance that would now be deemed a legislative rule.

Ultimately, the legal effect of notice and comment for guidance documents, and what degree of deference they should be afforded, is a matter for courts to decide. The Proposed Rule on Guidance, instead of providing clarity, fails to address these key questions, is likely to conflict with judicial administration of the APA, and should be withdrawn.

Requiring disclaimers on guidance documents will create confusion and administrative burden

The Proposed Rule on Guidance would require guidance documents to include a disclaimer stating, in part: "The contents of this document do not have the force and effect

[36] 85 Fed. Reg. 51397.
[37] *Id*.

of law and are not meant to bind the public in any way."[38] It is unclear whether this provision also applies to "significant guidance." The Proposed Rule on Guidance 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.[39]

Additionally, the Proposed Rule on Guidance fails to explain how it will insert the disclaimer notice in nonguidance documents that HHS has determined actually include guidance. For example, if HHS were engaged in a compliance or enforcement action, and its directive to a regulated entity included material considered "guidance," would the disclaimer apply to the whole document, or just that portion determined to be "guidance?" It seems enforcement actions would be seriously undermined if they included at the onset the statement "the contents of this document do not have the force and effect of law."

Confusion over the disclaimer would not be limited to enforcement actions. The very point of guidance is to add clarity. As the OMB Bulletin acknowledged, "[guidance can] increase efficiency, and enhance fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties."[40] HHS fails to address the confusion created in providing the public clear notice on what is permissible, while simultaneously declaring that the notice has no legal effect.

In short, adding a disclaimer to guidance documents, and nonguidance documents that include guidance, creates a burdensome and complicated process that will create confusion, with little benefit.

The proposed guidance repository would have troubling implications

The Proposed Rule on Guidance would establish a guidance "repository" by November 16, 2020 – a searchable database of current guidance documents.[41] Generally, NHeLP would support any proposal that increased transparency in public programs. However, HHS' proposal includes a highly troubling provision - guidance omitted from the repository would be automatically rescinded.[42]

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[38] 85 Fed. Reg. 51398, 51400, to be codified as 45 C.F.R. § 1.3(a)(3)(i).
[39] 85 Fed. Reg. 51396.
[40] 72 Fed. Reg. 3432.
[41] 85 Fed. Reg. 52515. HHS posted a version of the guidance portal at https://www.hhs.gov/guidance/.
[42] 85 Fed. Reg. 51398, 51401, to be codified as 45 C.F.R. § 1.4.

HHS has repeatedly sought and been granted extensions by OMB in reviewing documents and identifying those to be included in the repository.[43] However, HHS provides no indication of the process and criteria for reviewing and identifying guidance to be included in the repository. Moreover, neither the Proposed Rule on Guidance nor other HHS notices provide the opportunity and means for the public to weigh in on what guidance should be updated, rescinded, or remain in effect.

Members of the public will likely be confused if a guidance document appears on a HHS website, but is not included in the repository. It would not be apparent that such guidance is considered rescinded under this rule. 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. We therefore oppose these provisions.

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

The Proposed Rule on Guidance fails to address instances whereby multiple federal agencies issue joint guidance. For example, one of the key components of the Affordable Care Act (ACA) that has made it so popular is the requirement that certain health plans provide preventive services without cost sharing.[44] To implement this and other ACA provisions, HHS issued joint guidance with the Departments Treasury and Labor. Joint guidance clarified insurers' obligation to cover the entire costs of preventive screening colonoscopies without charge to the patient, including anesthesia, bowel preparation medication, and polyp removal incidental to a screening.[45]

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[43] Memorandum from Ann. C. Agnew, Executive Secretary, Dept. of Health and Human Servs., to Pay Ray, Administrator, OIRA, *RE: Executive Order 13891 Extension Request* (Feb. 27, 2020), https://www.hhs.gov/sites/default/files/eo-13891-extension-request-2-27-20r.pdf; Dept. of Health and Human Servs., *Promoting the Rule of Law Through Improved Agency Guidance Documents Notice*, 85 Fed. Reg. 39919 (Jul. 2, 2020), https://www.govinfo.gov/content/pkg/FR-2020-07-02/pdf/2020-14433.pdf; Dept. of Health and Human Servs, *Promoting the Rule of Law Through Improved Agency Guidance Documents Notice*, 85 Fed. Reg. 55306 (Sept. 4, 2020), https://www.govinfo.gov/content/pkg/FR-2020-09-04/pdf/2020-19568.pdf.

[44] 42 U.S.C. § 300gg–13; 29 C.F.R. §§ 2590.715-2713; 45 CFR § 147.130.

[45] Dept. of Health and Human Srvs., Dept. of Labor, Dept. of Treasury, *FAQS about Affordable Care Act Implementation (PART XII)*(Feb. 20, 2013), https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf; Dept. of Health and Human Srvs., Dept. of Labor, Dept. of Treasury, *FAQS about Affordable Care Act Implementation (PART XXVI)* (May 11, 2015), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf; Dept. of Health and Human Srvs., Dept. of Labor, Dept. of Treasury, *FAQS About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation* (April 20,

Consider this scenario: HHS omits from its repository the guidance instructing plans to include anesthesia for preventive screening colonoscopies, but DoL continues to post such guidance pursuant to its rule (to be codified at 29 C.F.R. § 89.5). How would health plans know which, if any, guidance applies? Health care consumers undergoing a colonoscopy should have clear information on whether anesthesia is included without cost sharing, or if they may be required to pay out of pocket, or undergo the colonoscopy without anesthesia. The early implementation of the ACA demonstrates how different federal departments and agencies can coordinate their efforts in effectively issuing joint guidance. The current administration should follow that example as it considers so-called good guidance practices.

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

NHeLP shares the concern that agencies within the Department have misused guidance documents. However, there is no indication that the Proposed Rule on Guidance would effectively eliminate this malpractice. HHS has failed to reign in rogue agency administrators who exceed statutory bounds by issuing unlawful guidance.

In the most recent and egregious example, the Centers for Medicare & Medicaid Services (CMS) issued guidance that would radically alter the Medicaid financing structure.[46] Although Congress has considered, and repeatedly rejected legislative proposals to impose block grants and per capita caps on the Medicaid Program, CMS has sought to make this legislative change through guidance.[47]

2016), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf.

[46] 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").

[47] See, *e.g.*, Omnibus Reconciliation Act of 1981, S. 1337, 97th Cong. (1981), https://www.congress.gov/bill/97th-congress/senate-bill/1377 (setting an upper limit on federal contributions to state Medicaid expenditures); Medicare Preservation Act of 1995, H.R. 2425, 104th Cong. (1995), https://www.congress.gov/bill/104th-congress/house-bill/2425?q=%7B%22search%22%3A%5B%22H.R.+2425%22%5D%7D&r=1&s=1 (establishing a Medicaid block grant called "Medigrant"); Budget of the United States Government, Fiscal Year 2004, https://georgewbush-whitehouse.archives.gov/news/usbudget/budget-fy2004/ (would give the states the option of accepting federal block grant funding); American Health Care Act of 2017, H.R. 1628, 115th Cong. (2017) (would cap the total amount of federal funding that states receive); Graham-Cassidy Amendment, S. Amdt. 1030, 115th Cong. (2017)(would place an upper limit on federal financing on Medicaid on a per-capita basis).

CMS initially followed procedures under the OMB Memo and submitted the Block Grant Guidance to OIRA for review on June 4, 2019.[48] Dozens of interested parties and stakeholder organizations conducted meetings with OMB officials to express concerns and opposition to the Block Grant Guidance.[49] However, after many months and without explanation, CMS withdrew the guidance from OIRA.[50] According to *Inside Health Policy*, approximately 6% of proposals reviewed by OMB are withdrawn by the originating agency, which "generally means there were serious defects with the proposal that could not be fixed during the review process."[51] CMS then released the Block Grant Guidance in January 2020, just months after withdrawing it from OIRA.[52] CMS Administrator Verma insisted the guidance was approved by OMB, and "didn't immediately respond to questions as to why this approval was not listed on OMB's website."[53] To date, neither CMS, HHS OGC, nor OMB have provided further information that the Block Grant Guidance completed the review and approval process.

The Block Grant Guidance debacle shows how agencies can push through guidance that contravenes not only the statutory limits established by Congress, but also the review procedures described in the 2019 OMB Memo. 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. HHS should reign in the excesses of its personnel instead of promulgating new regulatory requirements that it will not follow.

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 on Guidance would fail to achieve these goals. Instead, it would add confusion, obfuscation, and administrative burden. Moreover, HHS seems intent on

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[48] See OMB Memo, note 7, *supra*; OIRA, https://www.reginfo.gov/public/do/eoDetails?rrid=129184 (last visited Sept. 6, 2020).
[49] See OIRA, EO 12866 Meetings Search Results, https://www.reginfo.gov/public/do/eom12866SearchResults?pubId=&rin=0938-ZB55&viewRule=true (last visited Sept. 8, 2020).
[50] James Romoser, *Medicaid Stakeholders Perplexed By Withdrawal Of Block Grant Proposal*, INSIDE HEALTH POLICY (Nov. 18, 2019).
[51] *Id*.
[52] CMS Press Release, *Trump Administration Announces Transformative Medicaid Healthy Adult Opportunity* (Jan. 30, 2020), https://www.cms.gov/newsroom/press-releases/trump-administration-announces-transformative-medicaid-healthy-adult-opportunity.
[53] Chelsea Cirruzzo, *CMS Allows States To Use Block Grants For Parts Of Medicaid Programs*, INSIDE HEALTH POLICY (Jan. 30, 2020).

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. If HHS is serious about transparency, accountability, and public input, it should withdraw this ill-considered proposed rule.

Finally, we have included citations to research and other materials, including direct links to those materials. We request that the full text of material cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If HHS is not planning to consider these citations part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies into the record.

Please feel free to contact me at (202) 289-7661 or turner@healthlaw.org if you have questions.

Yours truly,

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