November 16, 2021

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

RE: Comments on RIN 0991–AC20
Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures

Dear Secretary Becerra:

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 Repeal of the Rules on Guidance, Enforcement, and Adjudication Procedures at the Department of Health and Human Services (HHS).[1]

The Proposed Rule repeals the so-called Good Guidance Practices (GGP) Rule, which HHS finalized in late 2020.[2] As we discussed in our September 14, 2020 comments to that proposed rule, instead of promoting good guidance practices, the GGP Rule imposes burdensome standards and procedures related to guidance documents that interfere with the HHS's ability to respond efficiently to public health matters. The rule harms not only HHS programs, but also the people who rely on those programs.[3]

NHeLP supports the proposal to repeal the GGP Rule. We also support the repeal of the Civil Enforcement "rule," which the previous administration promulgated without public notice and the opportunity to comment.

Background on the use and limits on agency guidance

Administrative agencies regularly rely on 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).[4] 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.[5]

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

---

[1] U.S. Dept. of Health and Human Servs., *Notice of Proposed Rulemaking, Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures*, RIN 0991–AC20, 86 Fed. Reg. 58042 – 58053 (Oct. 20, 2021), https://www.govinfo.gov/content/pkg/FR-2021-10-20/pdf/2021-22503.pdf.

[2] U.S. Dep't of Health and Human Servs., *Department of Health and Human Services Good Guidance Practices*, 85 Fed. Reg. 78770 (Dec. 7, 2020), https://www.federalregister.gov/documents/2020/12/07/2020-26832/department-of-health-and-human-services-good-guidance-practices.

[3] Ltr. From Wayne Turner, Senior Attorney., Nat'l Health L. Program, to Alex Azar II, Sec'y, U.S. Dep't Health & Hum. Servs., *NHeLP Comments on HHS Proposed Rule on Guidance* (Sept. 14, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0008-0007.

[4] 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.

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

careful consideration accorded under the procedures for regulatory development and review."[6] Like the FDA good guidance rules, the OMB Bulletin declared that guidance 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."[7] 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.[8]

In October 2019, the previous administration issued Executive Order 13891, *Promoting the Rule of Law Through Improved Agency Guidance Documents*.[9] Executive Order 13891 sought 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 said "significant guidance" must undergo heightened review procedures required by the Congressional Review Act (CRA) for "major" rules.[11] The Executive Order further directed executive agencies to issue regulations that "develop or set forth processes and procedures for issuing guidance documents" within 300 days.[12]

The Biden-Harris Administration, recognizing the need for all available tools to address ongoing crises, including COVID-19 and economic distress, repealed Executive Order 13891 in January 2021.[13] As the Administration explained in Executive Order 13992, *Revocation of Certain Executive Orders Concerning Federal Regulation*, "to tackle these challenges effectively, executive departments must be equipped with the flexibility to use robust regulatory action to address national priorities."[14]

We agree.

---

[6] 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").
[7] 72 Fed. Reg. 3436, 3437.
[8] 72 Fed. Reg. 3434.
[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.*
[13] E.O. 13992 Revocation of Certain Executive Orders Concerning Federal Regulation (Jan. 25, 2021), https://www.federalregister.gov/documents/2021/01/25/2021-01767/revocation-of-certain-executive-orders-concerning-federal-regulation.
[14] *Id.*

The GGP Rule is contrary to the Administrative Procedure Act, which 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
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]

---

[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 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.").
[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.*

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 GGP Rule makes no mention of these requirements and fails to provide for congressional review of "significant guidance."

The GGP Rule fails to explain why HHS selectively applies some portions, but not others, of the APA and CRA to guidance documents. (By contrast, the FDA good guidance regulations, in effect for twenty years, are expressly authorized by Congress.)[26]

NHeLP and other commenters raised these concerns regarding the legal authority and implications of the GGP Rule.[27] However, HHS finalized the GGP Rule without addressing those concerns.

---

[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 Bulletin, note 6 *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).
[26] See Food and Drug Administration Modernization Act of 1997, note 4, *supra*.
[27] See NHeLP Comments, note 3 *supra*. *See also* Consortium of Citizens with Disabilities, *Comments on RIN 0991–AC17 Department of Health and Human Services Proposed Rule: Good*

The GGP Rule creates burdensome and confusing processes that delay or prevent the issuance of important guidance.

We agree that the GGP Rule creates processes that are cumbersome, confusing, and do not allow individual agencies the flexibility they need to respond to matters in a timely fashion. Particularly problematic is the GGP Rule's requirement to subject "significant guidance" to notice and comment rulemaking procedures.

Subjecting significant guidance to notice and comment rulemaking creates legal ambiguity

As NHeLP emphasized in its comments on the GGP Rule, the APA expressly exempts guidance from notice and comment requirements.[28] Further, nothing in the CRA requires guidance to undergo notice and comment. Yet, by requiring certain "significant guidance" to undergo a formal notice and comment process, HHS created a new, legally ambiguous category somewhere between guidance and a rule. However, HHS ignored these concerns in the final GGP Rule.[29] Additionally, the final GGP Rule left many questions unanswered such as: what obligation does HHS to consider and respond to comments; how would stakeholder input be considered or integrated into proposed guidance; could guidance promulgated through notice and comment be rescinded without notice and comment? The final rule does not answer these questions, despite commenters raising these and other concerns.[30]

Guidance Practices (Sept. 16, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0008-0055; Georgetown Center for Children and Families, *Attention: RIN 0991-AC 17 Department of Health and Human Services Good Guidance Practices* (Sept. 16, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0008-0072; Planned Parenthood Federation of America, *Comments on RIN 0091-AC17 Department of Health and Human Services Proposed Rule: Good Guidance Practices* (Sept. 16, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0008-0087.

[28] See NHeLP Comments, note 3 *supra*.

[29] *See* Sec. II (B) (2) in the Preamble, 85 Fed. Reg. 78774 – 78775.

[30] See NHeLP Comments, note 3 *supra*. *See also* Consortium of Citizens with Disabilities, *Comments on RIN 0991–AC17 Department of Health and Human Services Proposed Rule: Good Guidance Practices* (Sept. 16, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0008-0055; Georgetown Center for Children and Families, *Attention: RIN 0991-AC 17 Department of Health and Human Services Good Guidance Practices* (Sept. 16, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0008-0072; Planned Parenthood Federation of America, *Comments on RIN 0091-AC17 Department of Health and Human Services Proposed Rule: Good Guidance Practices* (Sept. 16, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0008-0087.

The GGP Rule 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."[31] HHS's "clarification" resolves nothing. 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 notice and comment rulemaking. HHS does not offer any clear standards or procedures to distinguish how HHS will determine whether significant guidance is actually guidance, or whether it should be deemed a legislative rule. HHS also suggests that a large scope of guidance documents previously issued by the HHS might instead be subject to notice and comment rulemaking. However, the GGP Rule fails to list any examples of such guidance that would now be deemed a legislative rule.

As we noted in our comments on the proposed GGP 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.[32] The GGP Rule, instead of providing clarity, fails to address these key questions, and is likely to conflict with judicial administration of the APA.

Subjecting significant guidance to notice and comment rulemaking is cumbersome and creates administrative burden

In the proposed repeal rule, HHS notes that subjecting 'significant guidance' to notice and comment procedures is burdensome, draining both time and resources from the Department.[33] We agree. In particular, the process requires submitting potential guidance to OIRA in the OMB for a full review, subjecting potential guidance to a full notice and comment period, and requiring the agency to review and respond to public comments.

As HHS notes, guidance plays an important role for agencies, allowing them to "quickly and responsively communicate its . . . non-binding current thinking regarding legal interpretations, recommendations, and policies."[34] Guidance allows HHS the flexibility and freedom to respond, in a timely manner, to quickly-evolving situations, and has been especially critical during the COVID-19 pandemic. As HHS notes, the Department already has a wide-range of tools to solicit input and feedback on guidance when necessary. Further, this cumbersome, uniform process fails to account for the unique processes, procedures, and operations of the many diverse agencies under HHS's umbrella.

---

[31] *Id*.
[32] NHeLP Comments, note 3 *supra.* See also *Fact Sheet: Deference to the Federal Medicaid Agency's Rules and Guidelines,* note 52*, infra.*
[33] 86 Fed. Reg. 58046.
[34] *Id*.

The COVID-19 pandemic has created unprecedented challenges, especially for programs and agencies within HHS. Federal policy needs to able to react quickly to the rapidly changing pandemic. For example, the Centers for Medicare & Medicaid Services (CMS) issued, and has repeatedly updated, guidance on vaccine coverage and administration in health care safety net programs including Medicaid, the Children's Health Insurance Program, and Basic Health Plans.[35] The scope and impact of the vaccine guidance arguably could be considered "significant guidance." If CMS had subjected the guidance and updates to public notice and comment, it would have significantly delayed its release and implementation.

Similarly, the HHS Office for Civil Rights (OCR) has issued and updated important guidance addressing COVID-19. For example, OCR issued needed guidance in July 2021 to issues concerning "long-haul" COVID survivors who may experience discrimination by providers.[36] The urgency of responding to the deadly COVID-19 pandemic, as well as other challenges, make complicated procedures for guidance documents untenable.

We agree with HHS's revised thinking described in the proposed rule that the exceptions process provided under 45 C.F.R. § 1.3(b)(2)(ii) is inadequate and still places significant burden on HHS to include "findings" as to why significant guidance qualifies for an exception to notice and comment rulemaking.[37]

Moreover, since the onset of the COVID-19 pandemic, Congress has enacted four major pieces of legislation to respond to the emergency.[38] With these, and the landmark Build Back Better plan current pending before Congress, HHS and other executive agencies need maximum flexibility to quickly implement these laws and bring desperately needed relief.

---

[35] CMS, *Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program* (May 5, 2021), https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf.
[36] HHS Office for Civil Rights, *Guidance on "Long COVID" as a Disability Under the ADA, Section 504, and Section 1557* (July 26, 2021), https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/guidance-long-covid-disability/index.html.
[37] 86 Fed. Reg. 58047.
[38] Families First Coronavirus Response Act, Pub. L. No. 116-117 (2021), https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf; Coronavirus Aid, Relief, and Economic Security Act (CARES), Pub. Law. No. 116-136 (2020), https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf; Consolidated Appropriations Act, 2021, Public Law No: 116-260 (2021), https://www.congress.gov/bill/116th-congress/house-bill/133/text; American Rescue Plan of 2021, Public Law No: 117-2 (2021), https://www.congress.gov/117/plaws/publ2/PLAW-117publ2.pdf.

Given this, we fully support HHS's proposal to repeal the GGP Rule. HHS should maintain a flexible approach that allows for timely guidance that is consistent with the APA, which exempts nonbinding guidance from notice and comment review.

The GGP Rule creates vague standards that impede the issuance and implementation of important guidance

The GGP rule creates vague standards for distinguishing guidance, nonguidance, and significant guidance. It also imposes a blanket disclaimer requirement for guidance documents that is confusing to members of the public and regulated entities.

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

The GGP Rule definition of what constitutes guidance is vague. HHS states that the "content," rather than format, dictates whether a document would be considered guidance, and then describes various types of documents – such as videos, letters, and bulletins – that could be guidance.[39] 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).[40] 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.[41] 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.[42]

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

---

[39] 85 Fed. Reg. 78785, codified at 45 C.F.R. §1.2; *see also* Sec. II (B)(1) of the Preamble, 85 Fed. Reg. 78773.
[40] 85 Fed. Reg. 78785, codified at 45 C.F.R. §1.2.
[41] *Id*.
[42] *See* Sec.II (B)(1) of the Preamble, 85 Fed. Reg. 78772 (emphasis added).

certification of Qualified Health Plans (QHPs).[43] 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 significant guidance.

Adopting language from Executive Order 13891, the GGP Rule also establishes a definition of "significant guidance," subject to heightened procedural requirements.[44] Specifically, HHS would conduct an analysis and would submit guidance designated "significant" to OMB's OIRA for review.[45] Further, the GGP Rule requires any guidance determined to be significant to go through a notice and comment process that lasts at least 30 days.[46]

Moreover, although the GGP Rule 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 significant 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 GGP Rule.

Requiring disclaimers on guidance documents creates confusion with no benefit

The GGP Rule requires guidance documents to include a disclaimer stating, in part: "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."[47] The GGP 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.[48]

HHS agencies vary widely on whether and how to display the disclaimer. For example, a recent Frequently Asked Questions (FAQ) from CCIIO has the disclaimer emblazoned across the top of the document;[49] whereas CCIIO's 2022 Letter to Issuers released a few

[43] See CCIIO, Qualified Health Plan Certification, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp (last visited Nov. 12, 2021).
[44] 45 C.F.R. § 1.3(b).
[45] 45 C.F.R. § 1.3(b)(2)(i).
[46] 45 C.F.R. § 1.3(b)(2)(ii).
[47] 45 C.F.R. § 1.3(a)(3)(i).
[48] *See* Sec.II (B)(1) of the Preamble, 85 Fed. Reg 78772 (emphasis added).
[49] CCIIO, *Annual Income Threshold Adjustment FAQ* (Oct. 22, 2021), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Income-Threshold-FAQ.pdf.

months earlier adds the disclaimer as an inconspicuous footnote.[50] (Note, the annual Letter to Issuers undergoes notice and public comment, describes obligations for covered entities, and would likely be considered a rule under the APA, not guidance, notwithstanding the disclaimer).

The GGP Rule's disclaimer requirement creates confusion for covered entities in clearly understanding their obligations under the law. 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."[51] HHS fails to address the confusion created in clarifying obligations, while simultaneously declaring that the notice has no legal effect.

Moreover, the GGP Rule fails to explain why a disclaimer is needed; or what problem a disclaimer is trying to solve. Ultimately, courts decide the degree of deference to afford agency action, including guidance documents.[52]

In short, adding a disclaimer to guidance documents results in a complex process that creates confusion, with no benefit.

The guidance repository is problematic and creates confusion

The GGP Rule established a guidance "repository"– a searchable database of current HHS guidance documents.[53] Generally, NHeLP supports the use of a searchable repository that would make it easy to locate guidance documents and increase public transparency. However, GGP Rule includes a highly troubling provision - guidance omitted from the repository is considered automatically rescinded.[54]

---

[50] CCIIO, *2022 Final Letter to Issuers in the Federally-facilitated Exchange* (May 6, 2021), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2022-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces.pdf.
[51] 72 Fed. Reg. 3432.
[52] See Jane Perkins and Sarah Somers, Nat'l Health L. Program, Training & Advocacy Support Center, *Fact Sheet: Deference to the Federal Medicaid Agency's Rules and Guidelines* (Jan. 2015), https://www.tascnow.com/wp-content/uploads/2019/03/FS_-_Deference_to_federal_Medicaid_Agency_guidance_Jan_2015_update_NHeLP_FINAL.pdf. See also Sarah Somers, Nat'l Health L. Program, A Medicaid Advocate's Guide to Deference (July 23, 2013), https://healthlaw.org/resource/a-medicaid-advocates-guide-to-deference/.
[53] 45 C.F.R. § 1.4. *See also* https://www.hhs.gov/guidance/.
[54] 45 C.F.R. § 1.4(a)(3)(ii).

HHS never provided a clear process or criteria for reviewing and identifying guidance to be included in the repository. Additionally, HHS did not provide a meaningful opportunity or time for the public to weigh in on what guidance should be updated, rescinded, or remain in effect. [55]

Further, this process creates ambiguity for stakeholders searching for information. Members of the public can be easily confused when 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. 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.

The GGP Rule also fails to address instances whereby multiple federal agencies issue joint guidance. For example, one of the key components of the ACA that has made it so popular is the requirement that certain health plans provide preventive services without cost sharing.[56] To implement this and other ACA provisions, HHS issued joint guidance with the Department of the Treasury and the Department of Labor (DoL). 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.[57]

The DoL and CCIIO continue to post FAQs on preventive services, however, these guidance documents from 2013, 2015, and 2016 do not appear in the HHS repository.[58] Health plans and 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

---

[55] See Ltr. From Wayne Turner, Senior Attorney., Nat'l Health L. Program, to Alex Azar II, Sec'y, U.S. Dep't Health & Hum. Servs., *RE: Request for Information on Guidance Documents* (Oct. 13, 2020), https://healthlaw.org/resource/nhelp-response-to-hhs-request-for-information-on-guidance-documents/.

[56] 42 U.S.C. § 300gg–13; 29 C.F.R. §§ 2590.715-2713; 45 CFR § 147.130.

[57] 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, 2016), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf.

[58] Search conducted on Nov. 14, 2021. See https://search.usa.gov/search?affiliate=guidance-portal&page=2&query=FAQS+about+Affordable+Care+Act+Implementation+&sort_by.

pocket, or undergo the colonoscopy without anesthesia. Having guidance documents posted on HHS and DOL websites, but not findable in the HHS repository, creates confusion for consumers and regulated entities whether the guidance remains in effect or has been rescinded.

HHS should repeal the GGP Rule in full. We do, however, support HHS's stated efforts to maintain an up-to-date, user-friendly guidance portal to help improve public transparency. We encourage HHS to maintain flexibility so that agency documents can be easily found on agency websites. Additionally, we encourage HHS to continue improving technology and best practices to make the repository easily searchable and user friendly.

The Civil Enforcement Rule creates unnecessary barriers to agency enforcement and should be repealed

We agree with HHS's analysis that Civil Enforcement Rule creates unnecessary barriers to agency action and enforcement, undercuts current agency procedures, and diverts critical resources that are desperately needed elsewhere. The Civil Enforcement Rule sets up a lengthy set of procedural requirements that hamper agency enforcement actions. As HHS notes, delaying or impeding civil enforcement actions could "not only leave more bad actors in the market, but could embolden them, ultimately undermining the public interest."[59] As HHS notes in the proposed rule, while there is an exception for actions involving the "health, safety, or a similar emergency" that exception does not extend to important issues like fraudulent billing. HHS also notes that the various agencies under the Department's umbrella have well-developed procedures and plans that are well-tailored to specific types of proceedings.[60] The Civil Enforcement Rule has the potential to undermine such procedures and create confusion among agency staff.

We agree that the Civil Enforcement Rule undermines current, well-developed agency procedures, and diverts agency resources that are critically needed elsewhere, particularly in the middle of a public health emergency. Additionally, the Civil Enforcement Rule imposes a set of rigid requirements that could create roadblocks to agency enforcement that would undermine the public interest. Given this, we agree the rule should be repealed.

Conclusion

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

[59] 86 Fed. Reg. 58051.
[60] *Id.*

fails to achieve these goals. Instead, it adds confusion, obfuscation, and administrative burden. HHS should repeal the GGP Rule and Civil Enforcement Rule in full.

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 APA. 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,

Wayne Turner
Senior Attorney