

November 19, 2021

VIA ELECTRONIC SUBMISSION

Department of Health & Human Services

Re: Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures, 86 Fed. Reg. 58,042 (proposed October 20, 2021)

Docket ID: HHS-OS-2020-0008; HHS-OS-2021-0001

The Institute for Policy Integrity (Policy Integrity) at New York University School of Law¹ respectfully submits the following comments to the Department of Health and Human Services (HHS or the Department) regarding its Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures (Proposed Repeal).² The Proposed Repeal would rescind two prior HHS rules: (1) the Department of Health and Human Services Good Guidance Practices (GGP Rule)³ and (2) the Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions (Enforcement Rule).⁴ Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

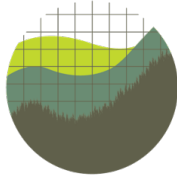
These comments focus specifically on the repeal of the GGP Rule. The GGP Rule's four main provisions are: (1) a requirement that each HHS guidance documents contain a statement on its nonbinding nature; (2) heightened procedures for "significant guidance" documents, including a period of notice and comment; (3) creation of a repository for all guidance along with a provision stating that guidance documents not in the repository are not effective and will be considered rescinded; and (4) procedures for the public to petition the Department to withdraw or modify any particular guidance document.

¹ This document does not purport to present New York University School of Law's views, if any.

² Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures, 86 Fed. Reg. 58,042 (proposed Oct. 20, 2021) [hereinafter Proposed Repeal].

³ Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 78,770 (Dec. 7, 2020) [hereinafter GGP Rule].

⁴ Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions, 86 Fed. Reg. 3010 (Jan. 14, 2021) [hereinafter Enforcement Rule].



We make the following observations and recommendations:

- The GGP Rule is arbitrary and capricious, and HHS is justified in repealing it. In promulgating the rule, the Department:
 - Ignored the rule’s costs, in the form of forgone health benefits, costs to regulated entities, and increased monitoring burdens on the public; and
 - Failed to justify its benefits beyond insufficient conclusory statements contradicted by the facts.
- HHS should strengthen its case for the Proposed Repeal by:
 - Taking note of the Proposed Repeal’s aggregate costs and benefits in a designated additional section of the preamble;
 - Incorporating further information that clarifies the scope of the Proposed Repeal’s costs and benefits when possible; and
 - Incorporating public comments on the GGP Rule into the record for the Proposed Repeal if they inform its decisionmaking on the Proposed Repeal.

I. The GGP Rule Is Arbitrary and Capricious, and HHS Is Justified in Repealing It

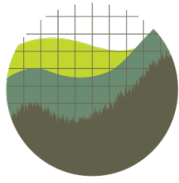
HHS should finalize its repeal of the GGP Rule because the GGP Rule is arbitrary and capricious. Under the Administrative Procedure Act (APA), an agency issuing a rule “must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.”⁵ In issuing the GGP Rule, the Department did neither.

First, HHS ignored the rule’s costs in the form of forgone health benefits, costs to regulated entities, and monitoring burdens on the public. Second, HHS failed to provide any explanation, let alone a satisfactory one, for how the GGP Rule would produce its purported benefits of increased efficiency and transparency. These omissions rendered the GGP Rule arbitrary and capricious and HHS is accordingly justified in repealing the rule.

A. The GGP Rule Ignored the Rule’s Costs, in the Form of Forgone Health Benefits, Costs to Regulated Entities, and Increased Monitoring Burdens on the Public

When promulgating the GGP Rule, HHS ignored the forgone public health benefits, costs to regulated entities, and monitoring burdens that were likely to result from the rule. Instead, the Department acknowledged only the government expenditures required “to create and maintain the guidance repository, along with employing a new process for the review of significant

⁵ *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).



guidance documents and for the review of guidance documents which are the subject of a petition for review.”⁶ Because the GGP Rule’s forgone public health benefits, costs to regulated entities, and monitoring burdens costs were each “an important aspect of the problem,” the Department rendered the GGP Rule arbitrary and capricious by failing to consider them.⁷

While the GGP Rule’s direct costs fall only on HHS (because it is the Department that must comply with changed rules around issuing and withdrawing guidance documents), any delays in the issuance of guidance or automatic rescissions of guidance that result from HHS’s compliance with the GGP Rule will have negative consequences for other entities. HHS’s failure to consider such indirect costs when issuing the GGP Rule was arbitrary and capricious. As the Supreme Court explained in *Michigan v. EPA*, “[a]gencies have long treated cost as a centrally relevant factor when deciding whether to regulate,” and costs “include[] more than the expense of complying with regulations”; instead, “any disadvantage could be termed a cost.”⁸ Accordingly, federal courts have repeatedly struck down rules that, like the GGP Rule, fail to consider potentially significant indirect costs.⁹

Foregone Benefits to Public Health:

As HHS itself now acknowledges, the heavy administrative burdens of the GGP Rule could, by delaying issuance of essential guidance, “have substantial negative consequences for the public.”¹⁰ Commenters on the GGP Rule provided examples of guidance issued during the COVID-19 emergency that saved lives due to its quick release.¹¹ Even in the absence of a public health emergency, uncertainty from delays in issuing guidance would hinder programs providing hundreds of billions of dollars in healthcare to more than 80 million individuals in Medicaid and

⁶ GGP Rule, 85 Fed. Reg. at 78,784.

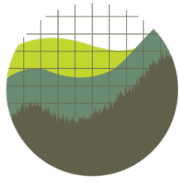
⁷ *State Farm*, 463 U.S. at 42.

⁸ *Michigan v. EPA*, 135 S. Ct. 2699, 2707–08 (2015); see also *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732–33 (D.C. Cir. 2016) (Kavanaugh, J., dissenting) (“As a general rule, the costs of an agency’s action are a relevant factor that the agency must consider before deciding whether to act.”).

⁹ See, e.g., *Competitive Enter. Inst. v. Nat’l Highway Traffic Safety Admin.*, 956 F.2d 321, 326–27 (D.C. Cir. 1992) (remanding fuel-efficiency rule due to agency’s failure to consider indirect safety costs); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (striking down rule for failure to consider indirect safety effects of substituting asbestos-free car brakes). In addition to violating the APA, ignoring indirect costs is inconsistent with OMB guidance on regulatory cost-benefit analysis. See OFF. OF MGMT. & BUDGET, EXEC. OFF. OF THE PRESIDENT, CIRCULAR A-4: REGULATORY ANALYSIS 3 (2003) (instructing agencies to “identify the expected undesirable side-effects . . . of the proposed regulatory action” and add them to the direct costs).

¹⁰ Proposed Repeal, 86 Fed. Reg. at 58,046.

¹¹ Nat’l Ass’n of State Ombudsman Programs, Comments on Proposed Rule on Good Guidance Practices at 5–6 (Sept. 16, 2020) <https://www.regulations.gov/comment/HHS-OS-2020-0008-0079> (“As an example, on March 13, 2020, CMS issued QSO-20-14-NH: (revised) Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes. This guidance laid out steps to control and prevent the spread of COVID-19 in facilities. Given how quickly the virus spread in facilities and how vulnerable nursing home residents are to the virus, it was critical that the guidance be issued very quickly to assist nursing home providers in taking appropriate measures. Had the guidance been subject to the additional burdens and time constraints called for in the proposed rule, it would have taken longer for providers to act, costing the lives of both residents and staff.”).



the Children's Health Insurance Program (CHIP), which serve especially vulnerable and marginalized populations.¹² The Department arbitrarily declined to even recognize these health costs when issuing the GGP Rule.

Forgone health benefits could result not just from delays in issuing guidance but also from the opportunity cost of devoting staff time and other HHS resources to responding to petitions to withdraw guidance from the repository, rather than preparing analyses in support of new guidance documents or regulations. Given HHS's central role in facilitating the federal government's response to the ongoing coronavirus pandemic, such opportunity costs could be severe and include, for example, forgone avoided mortalities. In the Proposed Repeal, HHS corroborates this concern by finding that the GGP Rule "diverts limited agency resources that the Department now believes are better directed elsewhere."¹³

Costs to Regulated Entities:

By concluding that the Proposed Repeal would have no measurable costs on regulated entities, the GGP Rule contradicted concerns from commenters on how their interests could be negatively and expensively affected by the GGP Rule.¹⁴ For example, comments from the Texas Office of the State Long-Term Care Ombudsman express concern about jeopardizing investments made over many years, explaining that "[b]uildings have been built, programs have been planned, professionals have been hired and trained, and nursing facility residents have been protected, based on the expectations contained in [the 749-page State Operations Manual (SOM) for Long-Term Care Facility Surveyors issued by the Centers for Medicare and Medicaid Services (CMS)]."¹⁵ The comments further explain how during the COVID-19 crisis, CMS has issued many Quality, Safety and Oversight memoranda (QSOs) that have provided timely and critical support and guidance to nursing homes on how to respond to the risks posed to their residents by COVID-19.¹⁶ These comments conclude that if the SOM or relevant QSOs were excluded from the database and automatically withdrawn, the "multibillion-dollar infrastructure built upon those documents" could be put at risk.¹⁷ These entities would also need to make costly future investment decisions in the dark at the risk of being found out-of-compliance with the law and being subjected to civil penalties.

¹² *May 2021 Medicaid & CHIP Enrollment Data Highlights*, MEDICAID.GOV, <https://perma.cc/C6V2-VS26> (last visited Nov. 18, 2021).

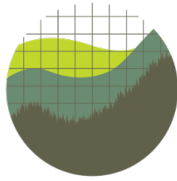
¹³ Proposed Repeal, 86 Fed. Reg. at 58,046. For further discussion, see *id.* at 58,049.

¹⁴ See GGP Rule, 85 Fed. Reg. at 78,784 ("[T]he Department does not anticipate that this rulemaking will impose measurable costs on regulated parties.").

¹⁵ Tex. Off. of the State Long-Term Care Ombudsman, Comments on Proposed Rule on Good Guidance Practices at 5–6 (Sept. 16, 2020) <https://www.regulations.gov/comment/HHS-OS-2020-0008-0079> [hereinafter Texas Ombudsman Comments].

¹⁶ *Id.* at 6.

¹⁷ *Id.*



Additionally, as HHS now recognizes in the Proposed Repeal, regulated entities are engaged in expensive, multi-year development programs for products, such as medical devices, that will ultimately need FDA approval, and these entities would be harmed if HHS delayed or failed to issue clarifying guidance necessary to inform these companies' investments.¹⁸ Rather than meaningfully grappling with these costs to regulated entities, HHS dismissed them.

Public Monitoring Costs:

When issuing the GGP Rule, HHS acknowledged the possibility for guidance to be erroneously rescinded by an accidental failure to identify and upload the document to the repository by the effective date.¹⁹ The Department purported to address this concern by "encouraging" regulated parties to review the guidance documents posted to the repository and alert HHS within 30 days to prevent their rescission.²⁰ However, HHS never acknowledged the costs to regulated entities of monitoring a repository that currently contains close to 50,000 items,²¹ and that provides no means to easily identify which, if any, documents have been excluded. Commenters on the GGP Rule informed HHS of this problem: "there is no way for the public to know which guidance documents have been omitted from the Repository and have thus been rescinded, nor would there be a way to establish that a document's omission from the Repository was deliberate and intentional, the result of an agency's administrative carelessness or error, or to inappropriate political compromise."²² Nevertheless, HHS said it anticipated the rule would have no measurable costs on regulated entities and did not acknowledge any monitoring costs to the public.²³ Here again, HHS ignored "an important aspect of the problem," rendering the GGP Rule arbitrary and capricious.²⁴

B. The GGP Rule Failed to Justify Its Benefits Beyond Insufficient Conclusory Statements Contradicted by the Facts

In issuing the GGP Rule, HHS failed to provide any evidence-based discussion to support its contention that the GGP Rule would benefit "the public, and, in particular, regulated parties" by yielding "greater efficiencies and more transparency in how the Department operates and regulates."²⁵ Because "an agency's predictive judgments" about a rule's likely effects "must be based on some logic and evidence, not sheer speculation," HHS's conclusory statements

¹⁸ Proposed Repeal, 86 Fed. Reg. at 58,046–47.

¹⁹ *Id.* at 78,781.

²⁰ *Id.*

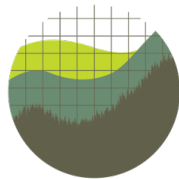
²¹ *Guidance Portal*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <https://www.hhs.gov/guidance/> (last visited Nov. 15, 2021) ("This Guidance Portal contains 47314 documents.").

²² Texas Ombudsman Comments, *supra* note 15, at 5.

²³ GGP Rule, 85 Fed. Reg. at 78,784.

²⁴ *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

²⁵ GGP Rule, 85 Fed. Reg. at 78,784.



regarding the GGP Rule’s benefits fell significantly short of the APA’s standard for reasoned decisionmaking.²⁶

In reality, as the Department now recognizes, the GGP Rule could reduce, rather than increase, efficiency and transparency. First, the rule has “the potential to delay or impede the issuance of a significant portion of HHS guidance documents that play an important part in effective communication with stakeholders and enhance public health.”²⁷ Thus, the rule could make “[HHS] operations more cumbersome and burdensome.”²⁸ Second, the GGP Rule’s policy of “automatic rescission of guidance documents not included in the repository” could create rather than eliminate stakeholder confusion about the Department’s positions on various legal issues, given the potential for human or technological error to delete documents unintentionally.²⁹

II. HHS Should Strengthen Its Case for the Proposed Repeal

HHS presents a strong case for repealing the GGP Rule, explaining how the GGP Rule’s removal will enable the Department to more efficiently and effectively protect public health, especially during the COVID-19 emergency. We make three recommendations to further strengthen the Proposed Repeal: (1) HHS should summarize the costs and benefits of the proposed repeal in a designated additional section where it expressly notes that the benefits of the Proposed Repeal outweigh its costs, (2) HHS should incorporate further information on the extensive benefits and minimal costs of the Proposed Repeal when possible, and (3) to the extent any public comments on the GGP Rule informed the Department’s decision to issue the repeal, HHS should incorporate those comments in the record for the Proposed Repeal.

A. HHS Should Take Note of the Proposed Repeal’s Aggregate Costs and Benefits in a Designated Additional Section of the Preamble

Unlike in the GGP Rule, HHS provides a rational explanation for the Proposed Repeal and acknowledges associated benefits and costs. In the finalized repeal, however, it would be advisable for HHS to take note of the different costs and benefits identified throughout the Proposed Repeal in a designated Regulatory Impact Analysis section (RIA) of the preamble. The Proposed Repeal provides that “OMB finds that this rulemaking is a significant regulatory action under E.O.s 12866 and 13453.”³⁰ Executive Order 12,866 instructs that “significant regulatory

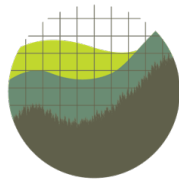
²⁶ See *State Farm*, 463 U.S. at 43; see also *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014) (explaining that “an agency’s predictive judgments about the likely economic effects of a rule’ are entitled to deference” (quoting *Nat’l Tel. Coop. Ass’n v. FCC*, 563 F.3d 536, 541 (D.C. Cir. 2009)), but clarifying that “deference to such . . . judgment[s] must be based on some logic and evidence, not sheer speculation” (quoting *Verizon v. FCC*, 740 F.3d 623, 663 (D.C. Cir. 2014) (Silberman, J., concurring in part and dissenting in part))).

²⁷ Proposed Repeal, 86 Fed. Reg. at 58,046.

²⁸ *Id.* at 58,045.

²⁹ *Id.* at 58,048.

³⁰ *Id.* at 58,052.



actions” should provide OIRA with an assessment of costs and benefits.³¹ While the Proposed Repeal discussed costs and benefits throughout the rule, it would add clarity to do so in an RIA.

In this RIA, HHS should affirmatively note why it believes the benefits of the Proposed Repeal (in the form of forgone costs from the GGP Rule) justify any costs (in the form of forgone benefits from the GGP Rule, such as potential increases in stakeholder engagement in the guidance-formulation process).³² Where possible, the Department should also include quantitative data on the repeal’s effects, as advised in the White House Office of Management and Budget’s guidance documents on regulatory analysis.³³

Finally, the RIA should include a discussion of equity considerations and effects on marginalized and vulnerable historically underserved communities. For decades, agencies have been directed to identify and seek to address adverse environmental and human-health impacts of all federal administrative programs (including regulations) on minority and low-income populations.³⁴ HHS observes in the Proposed Repeal that the provisions of the GGP Rule would “have a disproportionate effect on marginalized and vulnerable historically underserved communities, because they make it harder for agencies to take action to protect public health or remove bad actors from the market, which in turn harms those who need HHS services the most.”³⁵ HHS should improve this discussion with further analysis, and quantitative data where possible, documenting the expected negative impacts of the GGP Rule on marginalized and vulnerable populations.³⁶

³¹ Exec. Order No. 12,866, § 6(a)(3)(B)(ii), 58 Fed. Reg. 51,735, 51,741 (Sept. 30, 1993) (“For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA: . . . An assessment of the potential costs and benefits of the regulatory action . . .”); *see also* U.S. DEP’T OF HEALTH & HUMAN SERVS., OFF. ASSISTANT SEC’Y FOR PLANNING & EVALUATION, GUIDELINES FOR REGULATORY IMPACT ANALYSIS: A PRIMER 3 (2016), <https://perma.cc/JUB3-9XUX> (“An RIA is required for significant and economically significant regulatory actions.”).

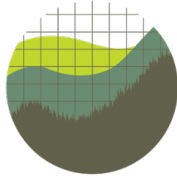
³² HHS notes that “[a]s a matter of policy, the Department is no longer convinced that the benefits of receiving stakeholder input outweigh any administrative costs or incremental delays in the case of public health emergencies,” but expresses doubt over a former conclusion is not equivalent to a finding. Proposed Repeal, 86 Fed. Reg. at 58,047.

³³ CIRCULAR A-4, *supra* note 9, at 23 (2003); OFF. OF MGMT. & BUDGET, EXEC. OFF. OF THE PRESIDENT, REGULATORY IMPACT ANALYSIS: A PRIMER 9–10 (2011), <https://perma.cc/2LZG-BQUC>.

³⁴ Exec. Order No. 12,898, § 1-101, 59 Fed. Reg. 7629, 7629 (Feb. 11, 1994) (“To the greatest extent practicable and permitted by law, . . . each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations . . .”); *accord id.* § 3-302(a).

³⁵ Proposed Repeal, 86 Fed. Reg. at 58,045. The GGP Rule further notes “that programs like Medicaid and CHIP rely on guidance to run the program effectively, and the effectiveness of the program directly affects the children, older adults, people with disabilities, and families these programs serve.” *Id.*

³⁶ *See* Memorandum from President Joseph Biden on Modernizing Regulatory Review to the Heads of all Departments and Agencies § 2(b)(ii), 86 Fed. Reg. 7223, 7223 (Jan. 26, 2021) (directing OMB to “propose procedures that take into account the distributional consequences of regulations, including as part of any quantitative or qualitative analysis of the costs and benefits of regulations, to ensure that regulatory initiatives appropriately



B. HHS Should Incorporate Further Information that Clarifies the Scope of Costs and Benefits of the Proposed Repeal When Possible

In its RIA or other summary section, HHS can summarize the many benefits of rescinding the GGP Rule that are identified and explained throughout the Proposed Repeal. In further clarifying the scope and distribution of benefits from removing the GGP Rule’s barriers to issuing guidance, HHS might wish to take note of additional information. HHS might also wish to take note of some of the below information on why costs are likely to be minimal and mitigated to support its conclusion that the benefits of the Proposed Repeal greatly outweigh the costs.

Further Clarifying Why Benefits of the Proposed Repeal Would Be Extensive:

- CMS and the states rely on subregulatory guidance to administer the \$660 billion (federal and state) Medicaid program³⁷ that affects more than 75 million Americans in 51 different states and territories.³⁸ Medicaid reports that 82,761,078 individuals were enrolled in Medicaid and CHIP in the 51 states that reported enrollment data for May 2021.³⁹ More than 39 million of those individuals were children representing 48.4% of total Medicaid and CHIP program enrollment.⁴⁰ The majority of Medicaid spending serves the disabled and elderly.⁴¹
- Medicaid and CHIP are primary sources of health coverage for all children, and children of color are disproportionately represented among beneficiaries because they are more like to be economically disadvantaged.⁴² Medicaid/CHIP coverage for children has been shown to expand access to health care and long-term benefits, which can help address the existing health disparities in access and utilization of care for children of color.⁴³

benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities”); CIRCULAR A-4, *supra* note 9, at 14 (recommending that regulatory analyses “provide a separate description of distributional effects . . . described quantitatively to the extent possible”).

³⁷ *State Health Facts: Total Medicaid Spending*, KAISER FAMILY FOUND., <https://perma.cc/R3VK-SP5E> (last visited Nov. 18, 2021).

³⁸ *May 2021 Medicaid & CHIP Enrollment Data Highlights*, MEDICAID.GOV, <https://perma.cc/C6V2-VS26> (last visited Nov. 18, 2021).

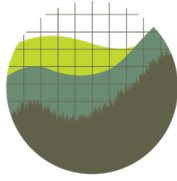
³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ Robin Rudowitz et al., *Medicaid Financing: The Basics*, KAISER FAMILY FOUND. (May 7, 2021), <https://perma.cc/H8NP-PS5H>.

⁴² TRICIA BROOKS & ALEXA GARDNER, GEO. UNIV. HEALTH POL’Y INST., SNAPSHOT OF CHILDREN WITH MEDICAID BY RACE AND ETHNICITY, 2018 at 1 (2020), <https://perma.cc/P45T-CB3M>.

⁴³ Karina Wagnerman & Tricia Brooks, *Medicaid and CHIP Help Address Racial/Ethnic Disparities in Children’s Health*, GEO. UNIV. HEALTH POL’Y INST. (Apr. 6, 2017), <https://perma.cc/K34E-4HN6>.



- In discussing the COVID-19 emergency, HHS could explain how the examples of essential guidance it already cites in the Proposed Repeal⁴⁴ have resulted in reduced mortalities and delivery of essential health services. HHS could also describe the amount of COVID-19-related financial assistance that has been better deployed as a result of COVID-19-related guidance, allowing states to more quickly achieve public health benefits.

Further Clarifying Why Costs of the Proposed Repeal Would Be Minimal and Mitigated:

- To the extent transparency benefits accrue from the creation of the guidance repository, those benefits are preserved by the Proposed Repeal because HHS plans to maintain the repository—eliminating only the harmful requirement of automatic rescission of any guidance document that the Department neglects to post to the repository, even inadvertently.
- To the extent that some measure of stakeholder involvement will be forgone by repealing the GGP Rule’s requirement for a public comment process on significant guidance, HHS could explain what other measures it has in place that ensure adequate stakeholder involvement. There are many different levels at which public participation can occur in the creation of guidance.⁴⁵ The Administrative Conference of the United States has explained that while public comment can be beneficial to guidance, a blanket approach to requiring public comment on guidance at resource-strapped agencies could result in the negative consequence of documents remaining in published draft form indefinitely, creating confusion for regulated entities and not achieving the goal of public participation.⁴⁶

C. HHS Should Incorporate Public Comments on the GGP Rule into the Record for the Proposed Repeal if They Inform Its Decisionmaking on the Proposed Repeal

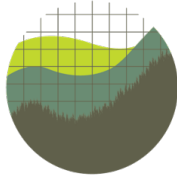
In the Proposed Repeal, HHS sometimes supports its reasoning by referencing comments submitted in response to the proposed GGP Rule.⁴⁷ When finalizing the repeal, HHS should cite

⁴⁴ See Proposed Repeal, 86 Fed. Reg. at 58,047 (“FDA COVID-19-related guidance documents have addressed shortages of essential products including gowns, masks, gloves, and ventilators; the development of vaccines and drug products to prevent and treat COVID-19; recommendations for validating COVID-19 tests and evaluating the impact of viral mutations on COVID-19 tests; and even COVID-19-related effects on the food supply chain. The expeditious publication of the Office of Civil Rights guidance related to the Health Insurance Portability and Accountability Act (HIPAA) during the COVID-19 pandemic also served to communicate critical information to health care providers and the public about sharing and accessing protected health information.”)

⁴⁵ ADMIN. CONF. OF THE U.S., FEDERAL AGENCY GUIDANCE: AN INSTITUTIONAL PERSPECTIVE 138–42 (2017), <https://perma.cc/N437-GS4Zhttps://www.acus.gov/sites/default/files/documents/parrillo-agency-guidance-draft-report.pdf>.

⁴⁶ *Id.* at 137, 171–81.

⁴⁷ See Proposed Repeal, 86 Fed. Reg. at 58,045 (“For the GGP rule, commenters serving underserved communities explained that programs like Medicaid and CHIP rely on guidance to run the program effectively, and the



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specifically to these comment letters and ensure that they are deemed part of the administrative record for the repeal, along with any other comments informing its analysis.

Respectfully,

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Jack Lienke, Regulatory Policy Director

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effectiveness of the program directly affects the children, older adults, people with disabilities, and families these programs serve.”); *id.* (“Further, commenters pointed out that agency specific websites, such as Medicaid.gov, provide easy access to all the applicable guidance.”); *id.* at 58,048 n.4 (“Several commenters noted that they have no trouble finding current guidance without the repository. One commenter pointed out Medicaid guidance can easily be accessed through the ‘Federal Policy guidance’ tab on *Medicaid.gov* website. Another commenter suggested that guidance documents on topical web pages was more helpful than the repository, which was not indexed.”).