# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## FARM CREDIT ADMINISTRATION

### 12 CFR Part 628

**RIN 3052–AD42**

### Risk Weighting of High Volatility Commercial Real Estate (HVCRE) Exposures

**AGENCY:** Farm Credit Administration.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Farm Credit Administration (FCA or we) is extending the comment period on its proposed rule that would revise the regulatory capital requirements for Farm Credit System (FCS or System) institutions to define and establish a risk-weight for high volatility commercial real estate (HVCRE) exposures. FCA is extending the comment period for an additional 61 days, until January 24, 2022, so interested parties will have additional time to provide comments on the proposed rule.

**DATES:** The comment period for the proposed rule published on August 26, 2021 (86 FR 47601) is extended from November 24, 2021, to January 24, 2022.

**ADDRESSES:** For accuracy and efficiency reasons, please submit comments by email or through FCA's website. We do not accept comments submitted by facsimiles (fax), as faxes are difficult for us to process and achieve compliance with section 508 of the Rehabilitation Act of 1973. Please do not submit your comment multiple times via different methods. You may submit comments by any of the following methods:

- *Email:* Send us an email at *reg-comm@fca.gov.*
- *FCA website: http://www.fca.gov.* Click inside the ''I want to . . .'' field near the top of the page; select ''comment on a pending regulation'' from the dropdown menu; and click ''Go.'' This takes you to an electronic public comment form.
- *Mail:* Kevin J. Kramp, Director, Office of Regulatory Policy, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

You may review copies of comments we receive on our website at *http://www.fca.gov.* Once you are on the website, click inside the ''I want to . . .'' field near the top of the page; select ''find comments on a pending regulation'' from the dropdown menu; and click ''Go.'' This will take you to the Comment Letters page where you can select the regulation for which you would like to read the public comments.

We will show your comments as submitted, including any supporting data provided, but for technical reasons we may omit items such as logos and special characters. Identifying information that you provide, such as phone numbers and addresses, will be publicly available. However, we will attempt to remove email addresses to help reduce internet spam. You may also review comments at our office in McLean, Virginia. Please call us at (703) 883–4056 or email us at *reg-comm@fca.gov* to make an appointment.

**FOR FURTHER INFORMATION CONTACT:**

*Technical information:* Ryan Leist, *LeistR@fca.gov,* Senior Accountant, or Jeremy R. Edelstein, *EdelsteinJ@fca.gov,* Associate Director, Finance and Capital Markets Team, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4414, TTY (703) 883–4056, or *ORPMailbox@fca.gov;* or *Legal information:* Jennifer A. Cohn, *CohnJ@fca.gov,* Assistant General Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (720) 213–0440, TTY (703) 883–4056.

**SUPPLEMENTARY INFORMATION:** On August 26, 2021, FCA published a proposed rule in the **Federal Register** that would update FCA's regulatory capital requirements to reflect the increased risks that exposures to certain acquisition, development or construction loans pose to System institutions. The proposed rule would also ensure that the System's capital requirements are comparable to the Basel III framework and the standardized approach the Federal banking regulatory agencies have adopted, with deviations as appropriate to accommodate the different operational and credit considerations of the System.

The comment period is currently scheduled to close on November 24, 2021. *See* 86 FR 47601. FCA is extending the comment period for an additional 61 days, until January 24, 2022, so interested parties will have additional time to provide comments on the proposed rule in consideration of other rulemakings that are also open for public comment.

Dated: October 15, 2021.

**Dale Aultman,**

*Secretary, Farm Credit Administration Board.*

[FR Doc. 2021–22826 Filed 10–19–21; 8:45 am]

**BILLING CODE 6705–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 45 CFR Part 1

**RIN 0991–AC29**

**[HHS–OS–2020–0008; HHS–OS–2021–0001]**

### Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures

**AGENCY:** Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Department of Health and Human Services (HHS or the Department) is proposing to repeal two final rules: ''Department of Health and Human Services Good Guidance Practices,'' published in the **Federal Register** of December 7, 2020; and ''Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions,'' published in the **Federal Register** of January 14, 2021.

**DATES:** To be assured consideration, comments must be received at the address provided below, no later than 11:59 p.m. November 19, 2021.

**ADDRESSES:** You may submit comments through the Federal eRulemaking Portal: *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet

search engines. No deletions, modifications, or redactions will be made to comments received. Inspection of Public Comments: All comments received before the close of the comment period will be available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.* Follow the search instructions on that website to view the public comments.

**FOR FURTHER INFORMATION CONTACT:** Daniel J. Barry, Acting General Counsel, 200 Independence Avenue SW, Washington, DC 20201. Email: *GoodGuidance@hhs.gov.* Telephone: 877–696–6775.

**SUPPLEMENTARY INFORMATION:**

## I. Overview of the Proposed Rule

HHS is proposing to repeal two rules that were issued in December 2020 and January 2021 to implement Executive Orders (E.O.s) issued on October 9, 2019. One rule relates to guidance document procedures and the other relates to civil administrative enforcement and adjudication procedures. The Department codified both rules collectively in 45 CFR part 1.

On January 20, 2021, the President, under a new administration, revoked both E.O.s that served as the basis for these rules and directed agencies to promptly take steps to rescind any rules and policies implementing or enforcing the revoked E.O.s, as appropriate and consistent with applicable law. Accordingly, the Department has reconsidered these rules and now believes that they create unnecessary hurdles that hinder the Department's ability to issue guidance, bring enforcement actions, and take other appropriate actions that advance the Department's mission. The Department continues to abide by its longstanding commitment to follow applicable principles of due process and administrative law, as a matter of policy; however, upon further reflection, we now conclude that these rules significantly burden the Department and are inconsistent with the policies and goals of the current Administration. Both rules created a single set of procedures for guidance documents and civil enforcement for the entire Department, which we believe is contrary to the efficient and effective administration of the wide array of programs by the Department, given the diversity of those programs. For these reasons, as discussed in greater detail in this document, and consistent with the President's January 20, 2021, directive, we are proposing to repeal both rules.

## II. History of the Rulemaking

On October 9, 2019, the White House issued two E.O.s: Executive Order 13891, ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' 84 FR 55235 (Oct. 15, 2019) (E.O. 13891) and Executive Order 13892, ''Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication,'' 84 FR 55239 (Oct. 15, 2019) (E.O. 13892). These E.O.s served as the basis for two rules promulgated by the Department in December 2020 and January 2021: ''Department of Health and Human Services Good Guidance Practices,'' 85 FR 78770 (Dec. 7, 2020) (GGP rule or the HHS GGP final rule, effective January 6, 2021), and ''Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions,'' 86 FR 3010 (Jan. 14, 2021) (the Civil Enforcement rule, effective January 12, 2021). The Department codified both rules collectively in 45 CFR part 1. Shortly after the rules became effective, on January 20, 2021, the President, under a new administration, issued Executive Order 13992, which revoked both E.O.s that served as the basis for these rules. 86 FR 7049 (Jan. 25, 2021).

### *A. Revoked Executive Orders*

E.O. 13891, ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' required agencies to treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract; take public input on guidance documents into account; and make all guidance documents available on a single website. 84 FR 55235. E.O. 13892, ''Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication,'' imposed a number of procedural hurdles on agencies engaged in civil administrative enforcement or adjudication. 84 FR 55239. As noted, both of these E.O.s have since been rescinded. 86 FR 7049.

However, prior to the rescission of these E.O.s, and consistent with the directive in E.O. 13891, the Department published the GGP rule. Although E.O. 13892 did not require rulemaking, the Department also published a final rule to implement E.O. 13892, the Civil Enforcement rule.

### *B. GGP Rule*

On August 20, 2020, consistent with the requirements of E.O. 13891, HHS published a notice of proposed rulemaking entitled ''Department of Health and Human Services Good Guidance Practices,'' the stated purpose of which was to ''promote the appropriate issuance and use of guidance documents . . .'' 85 FR 51396. The rule's stated intent was to increase accountability, improve the fairness of guidance issued by the Department, guard against unlawful regulation through guidance, and safeguard the important principles underlying the United States administrative law system. *Id.*

The major provisions of the HHS GGP proposed rule were: (1) A requirement that each guidance document issued by the Department generally include certain information, including a statement that the guidance does not have the force and effect of law and is not binding unless specifically incorporated into a contract; (2) heightened procedures for ''significant guidance documents,'' including a period of notice and comment, a requirement for HHS Secretary (Secretary) approval on a non-delegable basis, and a requirement for submission to the Office of Information and Regulatory Affairs (OIRA) for review under Executive Order 12866; (3) creation of a repository for all guidance documents 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.

HHS proposed that its new requirements for guidance would apply to all components of the Department except for the Food and Drug Administration (FDA). 85 FR 51396. The preamble to the HHS GGP proposed rule explained that FDA already operates under a set of GGP regulations, *see* 21 CFR 10.115, as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 371(h); no other agency within HHS functions under a similar set of regulations or statutory

provisions. 85 FR 51396. FDA's GGP regulations have been in effect for more than two decades. *See* 21 CFR 10.115. The preamble also explained that FDA would be proposing amendments to its GGP regulations to address E.O. 13891 separately. 85 FR 51396.

The Department followed the notice of proposed rulemaking with a correction on August 26, 2020. 85 FR 52515. The correction changed certain dates by which documents would be required to be in the guidance repository or else be deemed rescinded.

During the comment period for the notice of proposed rulemaking, the Department received nearly 90 comments on the proposed rule. 85 FR 78771. The comments are available at *https://www.regulations.gov/document/HHS-OS-2020-0008-0001/comment.*

The Department issued the HHS GGP final rule on December 7, 2020. 85 FR 78770. In response to public comment and the Department's further consideration of the policies addressed in the rule, the HHS GGP final rule made several changes to the proposed rule. First, in addition to the requirement in the proposed rule that the Secretary approve, on a non-delegable basis, all significant guidance documents, the final rule added the requirement that the Secretary approve, on a non-delegable basis, all non-significant guidance documents that the Secretary determines would implicate a policy matter of priority to the Secretary; potentially create a serious inconsistency; or otherwise interfere with an action taken or planned by another HHS agency or the Office of the Secretary. *Id.* at 78786.

Second, the HHS GGP final rule added more detail on what information the Department needs to provide when responding to a petition to amend or withdraw guidance, including a statement on whether the Department agrees or disagrees with the petition and its rationale. 85 FR at 78787.

Third, although FDA had been excluded from the scope of the HHS GGP proposed rule, the final rule included FDA within its scope. 85 FR at 78785. The preamble to the HHS GGP final rule explained that one commenter had urged HHS to amend FDA's good guidance practices regulations to be consistent with the requirements in the HHS GGP proposed rule. 85 FR 78771. HHS agreed with this comment, and then explained that, because the FDA regulations had not yet been amended to address E.O. 13891, FDA would be included in the HHS GGP final rule until the Secretary issued a final rule amending FDA's separate GGP regulations. *Id.*[1]

The Department codified the GGP rule in 45 CFR 1.1 through 1.5.

*C. Civil Enforcement Rule*

On January 14, 2021, HHS issued a final rule entitled ''Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions.'' 86 FR 3010 (Jan. 14, 2021). The Civil Enforcement rule, which was issued as a procedural rule without notice-and-comment rulemaking, stated that it was intended to provide regulated parties with greater transparency and fairness in administrative actions and to be consistent with the requirements of E.O. 13892. 86 FR 3010. The Department stated that ''[t]he rule is designed to ensure accountability, fairness of how the Department uses guidance, proper use of guidance documents, and opportunities for third parties to be heard, and to safeguard the important principles underlying the United States administrative law system.'' 86 FR 3011.

The rule contains a number of provisions, including the following: (1) A requirement that the agency avoid unfair surprise by only applying standards and practices in a civil enforcement action that have been publicly stated; (2) a requirement that if the agency relies on a decision to assert new or expanded claims of jurisdiction, it must publish the initial decision in the **Federal Register** or the Department's guidance repository before the conduct over which the jurisdiction is sought occurs; and (3) a requirement that the Department give parties—before the agency takes a civil enforcement action—written notice of its initial legal and factual determinations, an opportunity to respond in writing and in certain cases orally, and a written response to the affected entity (when timely requested).

The Department codified the Civil Enforcement rule in 45 CFR part 1, by revising §§ 1.1 and 1.2, and adding §§ 1.6 through 1.9.

## III. Legal Authority

The legal authority for this proposed rule is 5 U.S.C. 301. That provision states in relevant part that ''[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.'' Both the HHS GGP final rule and Civil Enforcement rule relied on the same authority.

## IV. Discussion of Proposed Rule

This proposed rule, if finalized as proposed, would repeal both the GGP rule and the Civil Enforcement rule, codified collectively in 45 CFR part 1. 45 CFR part 1 would be reserved. This repeal is consistent with the policies of the Biden-Harris Administration as reflected in at least three E.O.s issued by President Biden. First, Executive Order 13992, which is titled ''Revocation of Certain Executive Orders Concerning Federal Regulation,'' 86 FR 7049 (Jan. 25, 2021) (E.O. 13992), revoked both EOs 13891 and 13892 and directed agencies to promptly take steps to rescind any orders, rules, regulations, guidelines, policies, or portions thereof, implementing or enforcing the revoked EOs, as appropriate and consistent with applicable law. As explained in Section II, History of the Rulemaking, the Department drafted the HHS GGP final rule and Civil Enforcement rule in direct response to the revoked EOs; hence, the department has reconsidered these rules and has determined it is appropriate to rescind these rules in accordance with section 3 of E.O. 13992.

Further, E.O. 13992 states that it is the policy of the current Administration to use available tools to confront the urgent challenges facing the nation, including the coronavirus disease 2019 (COVID–19) pandemic, economic recovery, racial justice, and climate change. *Id.* E.O. 13992 explained that to tackle these challenges effectively, executive departments must be equipped with the flexibility to use robust regulatory action to address national priorities. *Id.* The order also stated that it was revoking ''harmful policies and directives that threaten to frustrate the Federal Government's ability to confront these problems'' and was empowering agencies to use appropriate regulatory tools to achieve these goals. *Id.* As explained in greater detail in this document, the Department concludes that both the HHS GGP final rule and Civil Enforcement rule inappropriately constrict the Department's ability to efficiently interpret and enforce regulations. Thus, both rules are inconsistent with the policy expressed in E.O. 13992 Sec 1, and we are proposing that they be rescinded.

Second, the E.O. titled ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' 86 FR 7009 (Jan. 25, 2021) (E.O. 13985), states that it is

[1] In fact, the Department did not issue a proposed or final rule to amend FDA's GGP regulations to address E.O. 13891 before January 20, 2021, when E.O. 13891 was revoked.

the policy of the Biden-Harris Administration for the Federal Government to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. The E.O. directed agencies to recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity. *Id.* Further, both the HHS GGP final rule and the Civil Enforcement rules 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. 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 effectiveness of the program directly affects the children, older adults, people with disabilities, and families these programs serve. Thus, a rule that hinders the publication of guidance may in turn harm the programs and the populations served, who rely on guidance documents to clarify program coverage requirements and have fewer resources to determine, for example, how and why guidance may be rescinded. Further, commenters pointed out that agency specific websites, such as Medicaid.gov, provide easy access to all the applicable guidance. While the rule did not preclude agencies from maintaining topical websites that contain agency specific guidance, it is much easier for organizations with limited resources serving marginalized communities to check the topical websites for new guidance than to check the repository to determine how and why and whether guidance may have been rescinded.

Third, the E.O. titled ''Strengthening Medicaid and the Affordable Care Act,'' 86 FR 7793 (Feb. 2, 2021) (E.O. 14009), states that it is the policy of the Biden-Harris Administration for the Federal Government to protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American. The E.O. directs HHS, among others, to examine its regulations, policies, and the like to ensure that they are consistent with the policy of providing high quality and accessible health care for all, and do not undermine protections for people with pre-existing conditions under the ACA, reduce coverage under or otherwise undermine Medicaid or the ACA, or undermine the Health Insurance Marketplace or the individual, small group, or large group markets for health insurance in the United States. Because HHS frequently issues guidance to clarify policies and beneficiary protections under Medicaid, the additional regulatory hurdles and confusion created by the HHS GGP final rule would likely undermine those goals by impeding and delaying the issuance of Medicaid guidance.

In addition to being inconsistent with this Administration's E.O.s, these rules created a single set of procedures for guidance documents and civil enforcement for the entire Department, which is incompatible with the efficient and effective administration of a Department as large and diverse as HHS. The Department's mission is to enhance the health and well-being of all Americans, and it accomplishes that mission through the work of many individual agencies, including the Administration for Children and Families (ACF), the Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), FDA, the Indian Health Service (IHS), the National Institutes of Health (NIH), and the Office for Civil Rights (OCR). Each of HHS's agencies plays a critical role in protecting and advancing public health by, for example, confronting the COVID–19 pandemic; administering and overseeing the Medicaid and Medicare programs and Affordable Care Act marketplace; providing federal health services to more than two million American Indians and Alaska Natives; taking action to protect consumers from unapproved, misbranded, or adulterated human or animal medical products or tobacco products; investigating, detaining, and recalling contaminated foods; addressing medical product shortages; enforcing age-restrictions or other controls around access to certain regulated products; and quickly distributing grant funds that help vulnerable populations, low-income families, elderly Americans, Indian tribes, and persons with disabilities to receive key resources, especially during the COVID–19 pandemic. Each agency within HHS serves the overall mission but does so in unique ways, often addressing different stakeholders and using specialized regulatory tools.

The imposition of these uniform requirements interferes with agencies' established practices and has disrupted agencies' relationships with stakeholders. FDA also faces a separate challenge with the GGP rule of simultaneously implementing two distinct GGP regulatory frameworks—its own, and that of the HHS GGP final rule—which is particularly inopportune at a time when rapid scientific advancements, as well as ongoing efforts to address the COVID–19 pandemic, warrant that FDA retain the ability to issue and revise guidance documents in a timely manner. As discussed in greater detail in Section A.1, like FDA, other HHS agencies rely on this flexibility to issue timely guidance and quickly share valuable information with stakeholders. Further, as discussed in section B, HHS agencies have developed their own processes for civil administrative enforcement that are unique to the specific requirements of each program. Accordingly, the Department no longer believes that a one-size-fits-all approach to Department guidance or civil administrative enforcement is appropriate and has concerns that the rules, imposing one set of requirements for its vastly different HHS agencies, may hinder the agencies' abilities to efficiently address public health issues, including but not limited to public health emergencies.

In light of the reasons explained in this section, the Department has taken a renewed and critical look at the HHS GGP and Civil Enforcement rules and has concluded that both rules frustrate the Department's ability to efficiently direct and operate in the interest of public health and are inconsistent with the policies and goals of the current Administration. The rules make Department operations more cumbersome and burdensome, impeding the Department's ability to quickly communicate its regulatory interpretations, policies, and recommendations, and use robust tools such as circulars, bulletins, advisories and other guidance documents to protect and advance the national public health and to promote the Department's mission. Accordingly, for the reasons previously stated, as well as specific concerns with each rule discussed in this section, HHS is proposing to repeal both rules in their entirety and remove 45 CFR part 1.

As a procedural matter, we have chosen to engage in notice-and-comment rulemaking for both rules. The Civil Enforcement rule was issued without notice and comment under the Administrative Procedure Act (APA), 5 U.S.C. 553, because the Department determined that it was a rule of agency organization, procedure, or practice. 86 FR 3010. The requirements for notice and comment prior to finalization also do not apply to regulations that involve ''a matter relating to agency

management or personnel.'' 5 U.S.C. 553(a)(2). Because the Department issued the Civil Enforcement rule without going through notice-and-comment rulemaking, HHS could repeal the Civil Enforcement rule without prior notice and comment based on the well-established principle ''that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance.'' *Perez* v. *Mortg. Bankers Ass'n,* 575 U.S. 92, 101 (2015). Similarly, although the Department chose to issue the GGP rule through notice-and-comment rulemaking, we note that generally the HHS GGP final rule involves matters relating to agency procedure and practice that did not require notice-and-comment rulemaking before promulgation. We also note that other departments and agencies have recently rescinded similar rules, and most have proceeded without notice-and-comment rulemaking at both the initial rulemaking and repeal stage. Nevertheless, to ensure transparency and public participation, and because the provisions of the two rules are codified in the same part of the Code of Federal Regulations with some overlapping and related provisions, the Department has opted in its discretion—for substantive and procedural clarity—to proceed with notice-and-comment rulemaking to repeal both rules together and in their entirety.

*A. GGP Rule (45 CFR 1.1 Through 1.5)*

1. Department-Wide Concerns Regarding the HHS GGP Final Rule

The Department is proposing to repeal the HHS GGP final rule for the following interrelated reasons: (1) It delays or prevents the issuance of guidance documents, which provide valuable information to stakeholders and the general public, including historically underserved populations; (2) it imposes uniform, inflexible requirements on agencies that do not adequately account for the agencies' different operations and are likely to cause confusion among regulated entities and members of the public; (3) it mandates the use of a guidance repository and provides for the rescission of guidance absent any active policy consideration by the agency, which may lead the public to believe that certain active policies are rescinded; and (4) it diverts limited agency resources that the Department now believes are better directed elsewhere.

*Delay or Prevent Issuance of Guidance Documents.* The procedures required in § 1.3 for the issuance of guidance documents have 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. For example, the rule establishes substantial, time-consuming, and resource-intensive requirements for the issuance of ''significant guidance documents.'' *See* 45 CFR 1.3(b). Required procedures for significant guidance documents include submitting such documents to the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) for review prior to publication, providing a public notice-and-comment process, generating an agency response to major concerns raised during the comment period, complying with applicable requirements for significant regulatory actions as set forth in Executive Orders, and obtaining approval by the Secretary on a non-delegable basis. *Id.* Each of these steps takes considerable time, effort, and Department resources to accomplish. Moreover, under the rule, all of these steps are required in *combination* before a significant guidance can be finalized.

As a matter of the policy, the Department is no longer convinced that these burdens are justified for non-binding agency guidance documents. The additional procedures provide little value, because the Department already has all the tools it needs to ensure adequate public notice and participation in the guidance process, and a one size fits all approach of the procedures fails to accommodate the range of guidance practices of HHS operational divisions. Moreover, the net effects of this requirement are serious burdens on the Department and an overall process that could unduly extend the time needed to promulgate significant guidance. This result is particularly concerning if the definition of significant guidance is construed to apply to a large number of guidance documents, in light of the potential cumulative effects.

The GGP rule imposes additional steps on the process of issuing non-significant guidance as well. For non-significant guidance, § 1.3 requires Secretarial approval under certain circumstances, which could delay the issuance of these guidance documents by drawing on the Secretary's finite time and resources. Further, this requirement could delay even non-significant guidance that do not require Secretarial approval because the process requires the Secretary to make an affirmative decision on whether a document requires Secretarial approval.

The Department has determined that the delay or non-issuance of guidance documents could have substantial negative consequences for the public, including for regulated entities. Guidance holds an important—and legally distinct—place in the Department's regulatory toolbox: It provides an approach to communicating the Department's policies and interpretations that can be more immediate and clearer than case-by-case adjudication, as well as faster and more flexible than legislative rulemaking. Through guidance, traditionally, the Department has been able to quickly and responsively communicate its agencies' non-binding current thinking regarding legal interpretations, recommendations, and policies. Guidance can be helpful, for example, to provide information relevant to a subset of regulated entities, address technical issues, give current examples, and keep pace with rapid advancements in science and technology. While this pathway has been important in a wide array of contexts, it is essential in areas of uncertainty, confusion, or rapid scientific or technological development, where clarity is needed to protect the public health and foster industry confidence and business investments.

Timely guidance is particularly important to parties that are subject to Department regulation. Guidance can assist regulated industries by helping guard against unequal treatment, unnecessary costs, and unnecessary risk. For example, for medical product developers who are engaged in expensive, multi-year development programs with the ultimate objective of finding a proper path to satisfy FDA's approval standards, guidance documents can provide recommendations on how to satisfy regulatory requirements and can describe how FDA staff applies those requirements to particular types of situations. This allows developers to design and invest in their product development strategy with more clarity and more confidence. The timely issuance of FDA guidance documents helps to accelerate the development and availability of innovative new products (or competitors to products already on the market) by: Encouraging particular methodologies, such as clinical trial models, to identify evidence that helps expedite product review; giving advice on how emerging technologies and breakthrough drugs and devices can meet FDA requirements for approval or clearance; and explaining FDA processes and procedures, including processes for premarket review, so developers can navigate those processes more quickly.

Having a robust, efficient guidance system has been especially critical during the COVID–19 emergency. 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. In the context of Federal financial assistance, guidance allowed the agency to issue grant funds quickly, which has been essential to providing states and tribes with information on permissible uses of funds to help vulnerable families, refugees, and foster children during the COVID–19 pandemic. For example, ACF's Children's Bureau used a guidance document to provide information to states on how they could use supplemental funding under the Child Abuse Prevention and Treatment Act and the Community-Based Child Abuse Prevention program provided by the American Rescue Plan Act. By issuing guidance quickly, Children's Bureau was able to, shortly after the passage of the law, provide states with information on how to apply for the funds and use them so that the funds could be used to promote the safety and well-being of children during the on-going pandemic.

The Department expressed a contrary assessment in the final rule, concluding that the benefits of receiving stakeholder input generally outweigh any administrative costs or incremental delays. 85 FR 78778. The Department also pointed to the exceptions process for significant guidance documents under § 1.3(b)(2)(ii), under which HHS could elect not to conduct a comment period if it were to find that notice and public comment are impracticable, unnecessary, or contrary to the public interest. *Id.* The Department considered this exceptions process to be sufficient to preserve flexibility during public health emergencies. *Id.*

As 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. The Department now disagrees that the exceptions process for significant guidance documents provides sufficient flexibility for the Department to respond to public health emergencies. To rely on the exception under § 1.3(b)(2)(ii), the Department would still need to make findings that public comment would be impracticable, unnecessary, or contrary to the public interest and incorporate the findings and a statement of the reasons into the guidance document. Even if the exceptions could be met during a public health emergency, these additional processes would still need to be followed and would still consume time and resources in a situation where time and resources are limited. In addition, the unprecedented nature of the COVID–19 pandemic has underscored the need for the Department to be able to act quickly during public health emergencies.

Retaining the HHS GGP final rule, with its relative lack of flexibility and procedural burdens that go far beyond what is needed for a transparent and inclusive guidance process, unduly hampers the Department's mission, particularly at this critical time. While the Department is aware that the GGP rule permits significant guidance documents to be exempted from applicable requirements ''if the Secretary [of HHS] and the Administrator of OIRA agree that exigency, safety, health, or other compelling cause warrants the exemption,'' the documents may be exempted only if several burdensome conditions are met. Specifically, for exemption, the Secretary and Administrator must come to the described agreement, the Secretary ''must make this finding,'' and ''the significant guidance document must incorporate the finding and a brief statement of reasons in support.'' *See* 45 CFR 1.3(b)(4). Thus, even where this pathway is taken, as a matter of policy HHS is now concerned that the procedural burdens of the rule may inappropriately delay guidance during an emergency.

The Department has reconsidered the relative merits of an efficient, flexible guidance process and weighed them against the processes finalized in the HHS GGP final rule. Ultimately, the Department favors an approach that is consistent with the Administrative Procedure Act (APA), which exempts non-binding documents like interpretive rules and general statements of policy from notice-and-comment rulemaking requirements.[2]

*Confusing and Unhelpful Uniform Standards.* As mentioned previously in this document, the GGP rule imposes identical requirements on agencies with different legal authorities and mechanisms for achieving their mission. This attempt to fit vastly different documents into one rubric is unnecessary, counterproductive, and likely to confuse the public about the role of different documents. HHS now believes that more flexibility is appropriate in light of the different roles and responsibilities of the agencies within the Department.

For example, § 1.3(a)(3)(i) of the GGP rule requires every guidance document to bear the following statement: ''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, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.'' Although the Department previously concluded that this statement is unlikely to be confusing, 85 FR 78778, upon reconsideration, the Department is now concerned that this universal statement is not appropriate for and cannot cover the range of HHS documents that fall within the definition of ''guidance document'' under § 1.2(a). A better approach would be for each agency to provide information that is appropriate to the agency's stakeholders and the expected uses of the particular document, while acknowledging the document's non-binding nature under the APA. An FDA guidance document may discuss enforcement priorities, for example, and any standard guidance statement for FDA guidance should account for that. An ACF document providing guidance on the requirements of a regulation can indicate that its provisions may become incorporated into the terms and conditions of a grant agreement, which has contractual aspects that bind both the government and the grantee.

Furthermore, the Department is concerned that the required statement that incorporation of provisions of a guidance document into a contract would render the guidance binding may be confusing to the public. While the terms of the contract may be binding, that is, the contractual parties must

[2] *See, e.g., American Hosp. Ass'n* v. *Bowen,* 834 F.2d 1037, 1045 (D.C. Cir. 1987) (''The reading of the [section] 553 exemptions that seems most consonant with Congress' purposes in adopting the APA is to construe them as an attempt to preserve agency flexibility in dealing with limited situations where substantive rights are not at stake.'').

follow the guidance due to the contract terms, the guidance itself remains non-binding. The GGP rule's required statement suggests, to the contrary, that the nature of the guidance is altered by the contract.

The Department is similarly concerned about the ambiguity of the term ''contract,'' especially as it relates to assistance agreements, such as grants and cooperative agreements. While it is understood that assistance agreements have contractual aspects, in several other contexts the Department draws a clear legal and programmatic distinction between contracts and assistance agreements. For example, the Federal Grants and Cooperative Agreement Act, 31 U.S.C. 6301–6308, distinguishes between grants and contracts by explaining that agencies should use contracts for the direct benefit of the Federal Government, and agencies should use grants when the principal purpose of an agreement is the transfer of anything of value for a public purpose. Nevertheless, both contracts and grants require entering into an agreement that binds both parties to its terms, including terms found in guidance documents. The undefined nature of such a key term in a required disclaimer term could create uncertainty and confusion within the Department and among the public.

Like the disclaimer on guidance documents, the definition of ''guidance'' in 45 CFR 1.2 is vague and overly broad and could lead to confusion over the type of documents subject to the rule's requirements. ''Guidance'' is defined, in part, as a ''Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation.'' *See* 45 CFR 1.2(a). In addition, the preamble to the HHS GGP proposed rule provided that ''guidance may come in a variety of forms, including, but not limited to, letters, memoranda, circulars, bulletins, advisories, and preambles and may include video, audio, and Web-based formats.'' 85 FR 51396. Contrary to the previous conclusion that this definition is not confusing, 85 FR 78772, upon reconsideration, this broad definition and understanding could be read to encompass an entire range of documents not intended to serve as guidance, such as resolution documents, agreements and case closure letters, and memoranda published on Department agency websites to inform and educate the general public and regulated entities about agency enforcement activities.

HHS has rejected the alternative approach of addressing these problems by revising the rule. It would be difficult to establish definitions, standard descriptors, policies, and procedures that are clear and that are workable across the Department's many components. As a matter of policy, we now believe it is much better to allow flexibility in approach. With the repeal of this rule, the agencies would be able to develop policies, practices, and rules, consistent with applicable law and as appropriate to their context, and they would be able to update these over time as warranted. This more decentralized approach is also consistent with the revocation of E.O. 13891, which had taken a relatively centralized and standardized approach.

*Repository.* 45 CFR 1.4 provides for a repository that includes all Department guidance documents. Section 1.4(a)(2) of the rule deems any guidance document not in the repository rescinded. Although the Department plans to maintain a guidance document repository, it now considers the provisions of the HHS GGP final rule governing the repository to be inappropriate and unnecessary, particularly with respect to the rescission requirement for documents not in the repository.

Although the Department previously concluded that the automatic rescission of guidance documents not included in the repository would improve transparency and decrease confusion, 85 FR 78781, upon reconsideration, the Department now has serious reservations about that conclusion. The rescission requirement creates additional burdens among stakeholders by causing confusion about which guidance documents have been rescinded, superseded, or otherwise become obsolete. Even if a guidance document is posted on an HHS website, it is rescinded by the GGP rule if it is not in the repository, *see* § 1.4(a)(3)(ii); rescission can occur simply because a guidance is not uploaded to or is removed from the repository due to human error or technical failures, even if it is publicly available elsewhere. The Department acknowledged in the preamble to the final rule that accidental rescission can occur in this manner. CMS has since encountered difficulties, particularly when establishing automatic processes for publishing guidance documents in the repository. These difficulties have required time and resources to address, and at times CMS has had to resort to a cumbersome manual process to publish the guidance documents. A concern is that, if any document is omitted from the repository, even inadvertently, as a result of using the manual approach, it is rescinded.

The Department also questions whether this rescission approach is consistent with the APA. The APA requires that an agency consider relevant factors and make policy choices based on those factors.[3] It is not clear that rescission of a policy due to human error, oversight, or a technical failure meets these standards. In addition, the Department is concerned that serious questions and problems would arise if a guidance document is ''rescinded'' under the GGP rule, even for a finite period of time, when the guidance in question continues to reflect agency interpretations and policies. In that event, regulated entities would face a high degree of uncertainty as to the Department's current thinking—whether the current thinking is still the same as described in the rescinded guidance or has changed significantly—particularly in light of the possibility that the guidance may have been unintentionally rescinded because of human error or technical failure.

The GGP rule also does not address the situation in which guidance documents are in the repository, but a regulated entity cannot access or view them—for example, due to flaws in the repository search function. For such documents, individuals may incorrectly believe that documents are missing from the HHS repository, and therefore believe that guidance has been rescinded and/or no longer represents the Department's policy or interpretation. In that event, again, regulated entities would risk taking actions based on a misunderstanding of the Department's current interpretations and policies. Or, more likely, regulated entities may have the added burden of inquiring with the agency about whether the guidance is in the repository, either informally or by petition, which would consume time and resources for both the requestor and the Department.[4] The Department is also concerned that this structure may

[3] *See Motor Vehicle Mfrs. Ass'n* v. *State Farm,* 463 U.S. 29, 43 (1983) (courts ''consider whether the [agency's rescission] decision was based on a consideration of the relevant factors'') (citations and internal quotations omitted); *F.C.C.* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009) (''[T]he agency must show that there are good reasons for the new policy.'').

[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.

cause regulated entities to restructure their compliance processes and operations, which could be quite costly. With all these possible concerns in mind, the Department invites stakeholders to comment on their experience with the repository. Although we no longer think automatic rescission is appropriate, the Department intends to retain the repository and is interested in stakeholders' experience using it. Specifically, the Department is interested in knowing whether stakeholders have been able to easily find the guidance applicable to them in the repository and how the Department can improve its usability and utility.

As noted earlier in this section, the Department believes that there is value in an online guidance database, and currently plans to retain a guidance document repository. However, upon reconsideration, the Department does not see a need to establish this administrative tool by regulation. Particularly in light of the experience of the COVID–19 pandemic, the Department now believes that flexibility is preferable to rigid requirements. The Department's current understanding has also been reinforced upon observing the technical challenges associated with a centralized repository. The Department believes that the better approach would be to engage with the individual agencies to develop the most efficient and user-friendly repository system that has the flexibility to change with improving technology and experience, and not to be constrained by regulatory requirements. If the proposed repeal of the HHS GGP final rule is finalized, the Department currently intends for the repository at *www.hhs.gov/guidance* to remain active, but the additional requirements imposed by the GGP rule (*e.g.,* that removal from the repository would affect rescission of a guidance) would be removed. We propose the automatic rescission requirement will have no effect on the status of guidance documents regardless of when they were issued. If the HHS GGP final rule is repealed as proposed, guidance documents will remain validly issued regardless of whether they were ever inadvertently not included in the repository. HHS will seek to ensure the repository is as complete and up to date as possible.

*Unnecessary Diversion of Resources.* Other aspects of the HHS GGP final rule also raise concerns because they divert agency resources without providing adequate compensating benefit, or are simply unnecessary. Although the Department previously believed that the petition process would not unduly strain HHS resources and delay the issuance of new guidance documents, 85 FR 78783, we now have serious policy reservations about this allocation of resources. The Department has now determined that the petition process concerning the withdrawal or modification of guidance documents, established in § 1.5—which requires written responses from the Department on a short timeframe regardless of the petition's subject matter or merits or of competing public health priorities—is unnecessary and burdensome. This process allows a petitioner to petition for hundreds of guidance documents to be rescinded at once or allows one or many petitioners to re-petition regarding a single guidance document multiple times. Further, many agencies have well-established petition processes that are already in use by stakeholders seeking changes to or rescission of existing guidance, and there are equally well-established processes for stakeholders wishing to challenge agency decisions (including those involving applicability of a guidance) that are unique to the agency and the communities with whom the agency works. These processes include citizen petitions related to FDA guidance and the appeals process at 42 CFR part 498 for facilities that disagree with decisions involving application of guidance governing Medicare eligibility and participation. Further, many stakeholders are in regular communication with agencies and express their comments, suggestions, or concerns with guidance in their formal and informal discussions with agency employees. It is not necessary, in the Department's view, to require an expedited response to all guidance-related concerns, some of which may warrant extensive review and consideration.

The GGP rule also contains generalized statements related to the role and effect of guidance that are not necessary and could cause confusion. For example, § 1.3(a)(1) states, ''[u]nder the Administrative Procedure Act, the Department may not issue any guidance document that establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute.'' To the extent that provisions such as this one seek to capture a current understanding of principles established by the APA, the Department has reconsidered that effort and now sees little benefit in it. It is unnecessary because the APA governs agency conduct concerning guidance without the need for agency regulations.

If HHS were to finalize this proposed rule to repeal the HHS GGP final rule, appropriate parameters and procedures for guidance documents issued by HHS agencies would remain in place. Repealing the HHS GGP final rule would not change the existing state of the law on the non-binding effect of guidance documents or whether they lack the force and effect of law. Nor would such repeal permit an agency to use guidance documents to establish or change policies where rulemaking is otherwise required, or to require outside parties to take or refrain from taking certain actions that are not addressed by statute or regulation. *See generally Azar* v. *Allina Health Servs.,* 139 S. Ct. 1804 (2019) (finding that Medicare-related guidance cannot create additional burdens beyond those included in statute or regulation). The Department would retain appropriate internal procedures for approval of the issuance of guidance documents and would continue to make guidance documents available to the public. Further, OIRA would continue to review guidance documents in appropriate circumstances, as it did before the issuance of E.O. 13891. Stakeholders could still petition the Department to take certain actions related to guidance documents under their general rights to communicate with and to seek redress from the Federal Government. In summary, the Department no longer believes that the provisions of the HHS GGP final rule are warranted.

2. Conflict With FDA Good Guidance Practices

The HHS GGP final rule also presents implementation problems for FDA. If HHS were not already proposing to repeal the rule in its entirety, HHS would have proposed to amend 45 CFR part 1 to remove FDA from the scope of that regulation. Indeed, it is also possible that, if the exclusion of FDA from 45 CFR part 1 can proceed separately on a faster track, the Department may choose to finalize that part of the repeal in advance of finalizing other aspects of this rulemaking.

As noted, FDA, unlike the other divisions of HHS, has long operated under a statutory provision concerning guidance and has its own GGP regulations, which address FDA's practices related to guidance documents, including practices and procedures for issuing, revising, and implementing guidance documents. FDA adopted its GGP regulations over 20 years ago at the conclusion of a public process that began in the 1990s. In May 1995, the Indiana Medical

Device Manufacturers Council submitted a citizen petition to FDA requesting, among other things, that FDA establish greater controls over the initiation, development, and issuance of guidance documents to ensure the appropriate level of meaningful public participation. In response to this petition, and after an opportunity for public comment, in February 1997, FDA published a guidance document on GGPs. 62 FR 8961 (Feb. 27, 1997). On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115). Section 405 of FDAMA added section 701(h) to the FD&C Act, which codified certain parts of the 1997 FDA GGP guidance document. In response to FDAMA, FDA issued a proposed rule on February 14, 2000, 65 FR 7321, to amend its administrative regulations to codify its policies and procedures for developing, issuing, and using guidance documents, including those set forth in section 701(h) of the FD&C Act. FDA issued a final rule establishing the GGP regulation on September 19, 2000. 65 FR 56468.

FDA currently issues its guidance documents consistent with section 701(h) of the FD&C Act (21 U.S.C. 371(h)) and 21 CFR 10.115, which include procedures for the following:

- Public participation in the development of guidance documents, including to propose topics for guidance, submit drafts of proposed guidance for consideration, comment on most guidance documents before implementation, and comment on revising or rescinding any guidance documents at any time after issuance;
- For most guidance documents, publication of a notice in the **Federal Register** announcing the guidance document's availability;
- Public availability of guidance documents, both on *FDA.gov*, and, upon request, in hard copy;
- Standard elements of guidance documents, including elements to make clear the non-binding effect of guidance documents, to identify the Center or Office issuing the guidance, and to identify the activities to which the guidance applies;
- Approval of guidance documents; and,
- An appeals process if FDA does not follow its GGP regulation or if an FDA employee treats a guidance document as binding.

FDA also operates under longstanding regulations regarding citizen petitions. *See* 21 CFR 10.30, 10.31. For years, stakeholders have submitted petitions under FDA's regulations that suggest that the agency take certain actions on guidance documents, particularly to amend guidance.

The Department is concerned that the HHS GGP final rule establishes standards and processes that overlap with but are distinct from those in section 701(h) of the FD&C Act, FDA's GGP regulation, and/or FDA's regulation governing citizen petitions. For example, section 701(h) of the FD&C Act and 45 CFR 1.3(b)(4) contain different standards for dispensing with prior public participation for certain guidance documents. Having two sets of regulations governing FDA guidance practices, as well as two sets of regulations governing citizen petitions related to FDA guidance documents, creates practical difficulties and confusion. For these reasons as well as the general concerns with the GGP rule discussed in this document, the Department no longer believes that this regulatory overlay on the FDA guidance processes adds value.

In addition, the application of the HHS GGP final rule to FDA guidance presents problems that were not considered or addressed at the time the Department made the decision to extend the rule to apply to FDA. For guidance documents erroneously rescinded based on their absence from the repository, the Department believed that rescission could be remedied simply through issuing the guidance consistent with ''the procedures in [the HHS] rule.'' 85 FR 78781. However, FDA has its own statutory mandate and regulations requiring promulgation of guidance through a notice and comment process in most cases. Therefore, if a guidance document is erroneously rescinded under § 1.4(a)(2) of the HHS GGP final rule, FDA would need to consider how to repromulgate its guidance in a manner consistent not only with the HHS GGP final rule, but also with its own statute and regulations. Repealing the HHS GGP final rule—and in particular, removing FDA from the scope of 45 CFR part 1—is important to stabilize and clarify the regulatory regime for FDA guidance documents, including the process for submitting citizen petitions related to FDA guidance documents. As discussed in this section, the Department now believes that any procedures going beyond those set forth in FDA's current regulations—such as those for significant guidance documents—are unwarranted for FDA guidance. In addition, it is inefficient and confusing for regulated entities as well as FDA staff to toggle back-and-forth between HHS and FDA GGP rules to try to figure out what the requirements are.[5]

*B. Civil Enforcement Rule (45 CFR 1.1–1.2, 1.6–1.9)*

The Department is proposing to repeal the Civil Enforcement rule because the rule: (1) Creates unnecessary hurdles and roadblocks in agency actions, likely to the detriment of the public; (2) conflicts with and undermines current agency processes; and (3) diverts critical Department resources.

*Creates Unnecessary Hurdles.* The processes and procedures set forth in the Civil Enforcement rule create unnecessary hurdles and roadblocks for agency actions, to the detriment of the public health and other national priorities. Section 1.9 requires the Department to follow certain steps before taking civil enforcement actions, including providing parties with an initial notice of the agency's legal and factual determinations, an opportunity to object or respond, and the Department's ''written response'' to the affected party's objections. The Department previously anticipated that existing HHS procedures already satisfied the requirements established in § 1.9. 86 FR 3012. Upon reconsideration, as a matter of policy, the Department now finds that the Civil Enforcement rule creates a rigid, burdensome, and resource-intensive path for Department staff, which is unnecessary when other tools in use, such as information negotiation, could be more efficient and effective.

Section 1.7(a) prohibits the Department from applying ''standards or practices'' in a civil enforcement action that have not been ''publicly stated.'' That new restriction on the Department's authority is inconsistent with settled case law,[6] and it could interfere with the Department's ability to enforce new laws and address

[5] The FDA GGP rule is an example of an agency developing procedures uniquely suited to its mission and statutory authorities. Trying to impose processes that were tailored to FDA upon all other agencies within the Department, or trying to force FDA to conform to a process for the entire Department, would create additional burdens and confusion.

[6] *See SEC* v. *Chenery Corp.,* 332 U.S. 194, 203 (1947) (''[P]roblems may arise in a case which the administrative agency could not reasonably foresee. . . . Hence, we refuse to say that the Commission, which had not previously been confronted with the problem of management trading during reorganization, was forbidden from utilizing this [adjudicatory] proceeding for announcing and applying a new standard of conduct''); *Martin* v. *Occupational Safety & Health Rev. Comm'n,* 499 U.S. 144, 154 (1991) (''Within traditional agencies . . . adjudication operates as an appropriate mechanism not only for factfinding, but also for the exercise of delegated lawmaking powers, including lawmaking by interpretation.'').

emerging threats, particularly through the use of adjudicatory proceedings.

Overall, through provisions such as these, the rule could impede and delay civil enforcement actions, as well as depress the overall number of actions, given finite Departmental resources. Slower and fewer enforcement actions could not only leave more bad actors in the market, but could embolden them, ultimately undermining the public interest.

Although § 1.9 includes an exception for actions involving ''a serious threat to health, safety, or similar emergency,'' 86 FR 3013, the discretionary exception does not address fraudulent actors who drain the Department's resources when allowed to remain in Departmental programs. For example, it is not in the public interest for an HHS agency such as CMS to take fewer enforcement actions against providers and suppliers who fraudulently bill patients and harm the Medicare trust funds. Delayed action against fraudulent billing would allow further diversion of taxpayer dollars and loss of program funding, forcing divisions to reprioritize program resources. Additionally, the exception does not alleviate the burden on the Department, because the process, including the Department's written response to the party's objections, must still be followed ''as soon as practicable.'' 86 FR 3013. Finally, analyzing whether a particular action falls into the exceptions set forth in § 1.9(c) would itself require an expenditure of time and resources that could delay actions needed to be taken on a time-sensitive basis.

*Conflict with Existing Processes.* Although the Department previously concluded that the requirements set forth in the final rule would facilitate smoother operations, 86 FR 3013, upon reconsideration, the Department is now concerned that the requirements in §§ 1.6 through 1.9 may create conflict and cause confusion to Department staff and the public with respect to existing agency processes and regulations. The various agencies under the HHS umbrella each have procedural regulations, some of which have been specifically designed to govern a particular type of proceeding. *See, e.g.,* 21 CFR part 17 (procedures governing hearings concerning the imposition of civil money penalties by FDA); 42 CFR part 488 (CMS and State Agency survey, certification, and enforcement procedures for Medicare providers and suppliers); 42 CFR part 498 (Appeals procedures for determinations that affect participation in the Medicare Program); 45 CFR part 160, subpart E (Procedures governing hearings challenging the imposition of civil monetary penalties in HIPAA cases). The procedures required under the Civil Enforcement rule do not adequately account for these pre-existing, agency-specific procedures, nor do they account for the differences between agencies within the Department. Instead, the Civil Enforcement rule dictates an overlay of new, and in some cases redundant, requirements. These requirements may conflict with or diverge from the existing procedures established to provide parties notice and an opportunity to be heard. This overlay creates confusion for both HHS agencies and regulated parties and could delay or prevent civil enforcement.[7]

The procedural regulations already established within HHS comply with principles of due notice, fairness, and transparency. Parties that are subject to civil administrative enforcement actions and adjudications under the existing procedures established prior to the Civil Enforcement rule are routinely provided with sufficient notice of the action, adequately informed of laws and regulations to which they are subject to, fully instructed on contesting or appealing agency determinations prior to actions of legal consequence, and protected from unfair surprise. The Civil Enforcement rule did not provide any evidence to the contrary. Thus, overall, the Department has not identified grounds to justify the expenditure of resources on compliance with the rule, particularly given that such expenditure would divert resources from other important Department activities, as explained in the next subsection.

*Diverts Resources.* Further, the Civil Enforcement rule could require the expenditure of significant resources to respond to spurious challenges to valid enforcement actions and adjudications. The rule is likely to invite opportunistic litigation not only because parties will have new procedural grounds to object to agency actions, but also because many of the provisions in § 1.9 are opaque and susceptible to multiple interpretations. The additional time and resources that would be needed to address and defend against such challenges would significantly impede the Department's ability to take enforcement actions and would divert resources from mission-critical activities.

In summary, the Civil Enforcement rule deprives the Department and its agencies of necessary flexibility in determining when and how best to conduct civil administrative enforcement actions and adjudications based on particular facts and circumstances. The Civil Enforcement rule also unduly restricts the Department's ability to take timely action to enhance the health and well-being of all Americans.

*C. Reliance Interests*

In issuing this proposed rule, the Department has considered reliance interests that may have accrued in connection with 45 CFR part 1. As an initial matter, the Department doubts that any serious reliance interests have accrued. Both the HHS GGP and Civil Enforcement final rules became effective only a couple of weeks before the change in Administration and before the E.O.s on which they relied were revoked. They have been in place for only a few months, most of which time followed that revocation. It is unlikely that serious reliance has developed in that short amount of time. *Cf. Clark-Cowlitz Joint Operating Agency* v. *FERC,* 826 F.2d 1074, 1084 (D.C. Cir. 1987) (finding limited reliance interest where rule was in place for only six months, among other things). Under these circumstances, it is likely that regulated entities would have anticipated that the rules would be reconsidered and potentially rescinded, particularly after the revocation of E.O.s 13891 and 13892 on January 20, 2021. Indeed, other departments and agencies have already repealed rules issued pursuant to those E.O.s.[8]

[7] Further, we note that if the GGP rule is not repealed as part of this rulemaking, the limitations on use of guidance documents in 45 CFR 1.6(b), which were added as part of the Civil Enforcement rulemaking, may raise additional questions regarding the appropriate scope and use of guidance documents—especially in light of potentially conflicting directives in the HHS GGP final rule.

[8] As of May 28, 2021, over 10 other departments and agencies have repealed such rules. *See* Tennessee Valley Authority Final Rule, '''Promoting the Rule of Law Through Improved Agency Guidance' Regulations; Rescission,'' 86 FR 28488 (May 27, 2021) (rescinding rule on guidance); Environmental Protection Agency Final Rule, ''EPA Guidance; Administrative Procedures for Issuance and Public Petitions; Rescission,'' 86 FR 26842 (May 18, 2021) (rescinding rule on guidance); National Endowment for the Humanities and National Foundation on the Arts and the Humanities Final Rule, ''Processes and Procedures for Issuing Guidance Documents,'' 86 FR 26184 (May 13, 2021) (rescinding rule on guidance); U.S. Office of Government Ethics Final Rule, ''Removal of U.S. Office of Government Ethics Guidance Documents Regulations'' 86 FR 25801 (May 11, 2021) (rescinding rule on guidance); Railroad Retirement Board Final Rule, 86 FR 22866 (Apr. 30, 2021) (rescinding rule on guidance); Social Security Administration Final Rule, ''Rescission of Rules on Improved Agency Guidance Documents'' 86 FR 20631 (Apr. 21, 2021) (rescinding regulations on guidance); Department of Interior Final Rule, ''Procedures for Issuing Guidance Documents,'' 86 FR 19786 (Apr. 15, 2021) (rescinding regulations on issuing guidance); Council on Environmental

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Moreover, particularly given the timing of the issuance of these rules, it is difficult to see how the procedures or principles set forth in these rules would translate to a stakeholder making concrete changes in public or business decisions or practices that would implicate serious reliance interests. As explained in this document, consistent with the largely procedural nature of the rules, the rules codify steps that the agency would take in certain circumstances, such as when issuing guidance or prior to civil administrative enforcement actions, but they do not on their own change the substantive requirements governing regulated entities or related property interests. Finally, the Department considers the policies reflected in this proposed rule to advance the public interest. To the extent that any serious reliance interests are at stake, the Department believes that the public interests in efficient issuance of guidance and adequate civil administrative enforcement actions outweigh any such individual reliance interests. However, we invite parties to use the comment period for this proposed rule to explain why they believe they would be adversely affected by this proposed policy change and explain how they would need to adjust their practices, as appropriate.

## V. Required Regulatory Analyses

### *A. Executive Orders 12866 and 13563*

E.O. 12866, ''Regulatory Planning and Review,'' and E.O. 13563, ''Improving Regulation and Regulatory Review,'' direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select regulatory approaches that maximize net benefits.

In both the HHS GGP proposed and final rules, OMB determined that the rulemaking was not an economically significant regulatory action under these E.O.s. 85 FR 51399; 85 FR 78784. OMB made a similar finding with respect to the Civil Enforcement rule. 86 FR 3013. The preambles to these rules maintained that the rules primarily described procedural changes that would require Department expenditures to implement. Although the preambles theorized that stakeholders might eventually benefit from greater transparencies and efficiencies from these procedural changes, the rules did not identify any benefits that were likely to be immediately realized. *See* 85 FR 78784; 86 FR 3013.

In the current rulemaking, the Department is proposing to repeal two recent final rules, effective on January 6, 2021, and January 12, 2021, which would remove all of 45 CFR part 1. If finalized, this rulemaking would restore the status quo that existed just prior to the January 2021 effective dates. The Department may then take further action as needed to undo any minimal actions taken since those effective dates to implement the rules' procedural directives. Consistent with the conclusions reached in the preambles of the HHS GGP final rule and Civil Enforcement rule, and for the additional reasons described in this section, OMB finds that this rulemaking is a significant regulatory action under E.O.s 12866 and 13453. The Office of Management and Budget (OMB) has reviewed this rule as consistent with E.O. 12866 and 13453.

### *B. Regulatory Flexibility Act*

The Department has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.* The RFA requires an agency to describe the impact of a proposed rulemaking on small entities by providing an initial regulatory flexibility analysis, unless the agency determines that the proposed rule will not have a significant economic impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a) and 605(b). The Department considers a proposed or final rule to have a significant economic impact on a substantial number of small entities if it has at least a three percent impact on revenue of at least five percent of small entities. The Department anticipates that, if finalized, this rule would restore the status quo just prior to the respective January 6, 2021, and January 12, 2021, effective dates of the HHS GGP final rule and the Civil Enforcement rule, and undo changes, if any, to procedures followed by the Department during the interim period. This proposed rule would repeal two rules that the Department concluded, and the Secretary certified, would not result in a significant impact on a substantial number of small entities. Further, the Department believes that any effects associated with future regulatory actions, including any positive or negative impacts to small entities, should be attributable to those regulatory actions rather than to this proposed rule, if it is finalized as proposed. As a result, the Department has determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on the operations of a substantial number of small entities.

### *C. Executive Order 13132 (Federalism)*

E.O. 13132, ''Federalism,'' establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has Federalism implications. The Department has determined that this proposed rule would not impose such costs or have any Federalism implications.

### *D. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)*

HHS has analyzed this proposed rule in accordance with the principles set forth in 13175. HHS has tentatively determined that the proposed rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. In accordance with the Department's Tribal consultation policy, the Department solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

### *E. National Environmental Policy Act*

HHS had determined that this proposed rule would not have a significant impact on the environment.

### *F. Paperwork Reduction Act of 1995*

In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, 44 U.S.C. 3501–3521; 5 CFR part 1320, appendix

Quality Final Rule, ''Guidance Document Procedures Rescission,'' 86 FR 19149 (Apr. 13, 2021) (rescinding regulations on issuing guidance); U.S. Agency for International Development (USAID) Final Rule, ''Procedures for the Review and Clearance of USAID's Guidance Documents; Rescission'' 86 FR 18444 (Apr. 9, 2021) (rescinding regulations on issuing guidance); Department of Transportation Final Rule, ''Administrative Rulemaking, Guidance, and Enforcement Procedures,'' 86 FR 17292 (Apr. 2, 2021) (removing regulations regarding issuing guidance and conducting enforcement actions, among other things); Pension Benefit Guaranty Corporation Final Rule, ''Rescission of Pension Benefit Guaranty Corporation Rule on Guidance,'' 86 FR 17066 (Apr. 1, 2021) (rescinding rule on issuing guidance); Department of Energy Notice of Proposed Rulemaking, ''Procedures for the Issuance of Guidance Documents,'' 86 FR 16114 (Mar. 26, 2021) (proposing to rescind final rule on issuing guidance); Department of Energy Final Rule, ''Procedures for the Issuance of Guidance Documents,'' 86 FR 14807 (Mar. 19, 2021) (further delaying effective date of final rule on issuing guidance in order to conduct rulemaking to withdraw the rule); Department of Labor Final Rule, ''Rescission of Department of Labor Rule on Guidance,'' 86 FR 7237 (Jan. 27, 2021) (rescinding rule on issuing guidance).

A.1, the Department has reviewed this proposed rule and has determined that it proposes no new collections of information.

**List of Subjects in 45 CFR Part 1**

Government employees, Guidance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, and under the authority of 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR, subtitle A, subchapter A, by removing part 1.

## PART 1—[REMOVED AND RESERVED]

■ 1. Remove and reserve part 1.

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2021–22503 Filed 10–19–21; 8:45 am]

**BILLING CODE 4150–26–P**

## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

### 49 CFR Part 23

**[Docket No. DOT–OST–2021–0113]**

## Petition for Rulemaking; Airport Concession Disadvantaged Business Enterprise (ACDBE) Program

**AGENCY:** Office of the Secretary (OST), Department of Transportation (DOT).

**ACTION:** Notice of grant of a petition for rulemaking.

**SUMMARY:** This notification grants the petition for rulemaking submitted by the Airports Council International-North America (ACI–NA) requesting that DOT initiate rulemaking to revise and update agency rules pertaining to Participation of Disadvantaged Business Enterprise in Airport Concessions.

**DATES:** October 20, 2021.

**ADDRESSES:** National External Operations and Policy Programs, Federal Aviation Administration, 800 Independence Avenue SW, Room 1030, Washington, DC 20591.

**FOR FURTHER INFORMATION CONTACT:** Gene E. Roth, Director, National External Operations and Policy Programs, Federal Aviation Administration, 800 Independence Avenue SW, Room 1030, Washington, DC 20591, email *gene.e.roth@faa.gov*, telephone 202–913–7502; or Marc Pentino, Associate Director, Disadvantaged Business Enterprise Programs Division, Departmental Office of Civil Rights, Office of the Secretary, 1200 New Jersey Avenue SE, Washington, DC 20590, email *marc.pentino@dot.gov*, telephone 202–366–6968.

**SUPPLEMENTARY INFORMATION:**

### Background

On June 30, 2021 ACI–NA submitted a petition for rulemaking requesting that DOT begin the process necessary to initiate a rulemaking to revise and update 49 CFR part 23. Specifically, ACI–NA requested that a number of regulatory issues important to airports be addressed to modernize the ACDBE program, including the definition of concession, the requirements for ACDBE program submittals, and the treatment of long-term exclusive agreements.

DOT plans to initiate a rulemaking to update DOT's Disadvantaged Business Enterprise (DBE) and ACDBE regulations to alleviate burdens for lower-tiered recipients and aviation sponsors to have a DBE program, remove the ACDBE program requirement for non-hub primary airports, modernize the definition of ''regular dealer'' to reflect changing material handling practices in the field, enhance current requirements to ease the burden on prime contractors in finding competitive and qualified DBE subcontractors, adjust the DBE and ACDBE program personal net worth cap for inflation, formalize guidance establishing successful COVID–19 flexibilities, allow qualified DBEs to work on large multiyear projects, and make technical corrections and other necessary updates. For additional information, see the Department's Spring 2021 Unified Agenda, available at *https://www.reginfo.gov/public/do/eAgendaMain*. Select Department of Transportation from the drop-down menu for the current agenda, and then select RIN 2105–AE98.

### Conclusion

Having received this petition for rulemaking related to 49 CFR part 23, DOT has decided that ACI–NA's petition merits further consideration through the rulemaking process and hereby grants its petition for rulemaking using the existing RIN 2105–AE98.

The granting of the petition from ACI–NA, however, does not indicate that a final rule will be issued as requested by ACI–NA. The determination of whether to issue a rule and the content of the rule is made after the study of the requested action and the various alternatives in the course of the rulemaking proceeding, in accordance with statutory criteria.

Signed in Washington, DC, on October 13, 2021.

**Irene B. Marion,**

*Director, Departmental Office of Civil Rights, Department of Transportation.*

[FR Doc. 2021–22626 Filed 10–19–21; 8:45 am]

**BILLING CODE P**