



**Association of
American Medical Colleges**
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400 F 202 828 1125
www.aamc.org

November 18, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Submitted at www.regulations.gov

Re: Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures, HHS-OS-2020-0008; HHS-OS-2021-0001

Dear Secretary Becerra:

The AAMC (Association of American Medical Colleges or the Association) welcomes the opportunity to comment on the Department of Health and Human Services (HHS or the Department) proposed rule, “Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures” 86 *Fed. Reg.* 58042 (Oct. 20, 2021). The AAMC strongly supports the proposed rule and appreciates HHS’s willingness to revisit regulations that are problematic for the Department and stakeholders.

The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America’s medical schools and teaching hospitals and the millions of individuals employed across academic medicine, including more than 186,000 full-time faculty members, 94,000 medical students, 145,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Additional information about the AAMC is available at aamc.org.

The AAMC supports the proposed rule, which would repeal two rules: the “Department of Health and Human Services Good Guidance Practices,” (*Good Guidance Practices Rule or GGP Rule*) 85 *Fed. Reg.* 78770 (Dec. 7, 2020) and the “Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions” (86 *Fed. Reg.* 3010 (Jan. 14, 2021) (*Civil Enforcement Rule*)). Both previous rules were issued under Executive Orders (EOs), which have now been revoked. The proposed repeal of the Good Guidance Practices Rule will provide more clarity and certainty to regulated entities and will significantly address the procedural difficulties in implementing the requirements while bringing HHS policy in line with the current administration’s efforts to address national health issues. The repeal of

the Civil Enforcement Rule will eliminate conflicts with current agency processes, and ensure that the processes with which regulated entities have become familiar over many years continue. As the preamble to the proposed rule also notes, these two rules create a “single set of procedures for guidance documents and civil enforcement for the entire Department” p.58045), which does not allow for the effective and efficient administration of a department as large and diverse as HHS.

Good Guidance Practices Rule (GGP)

The GGP final rule, published December 2020, contains requirements consistent with EO 13891 that has since been revoked. Among the provisions are a 30-day public notice-and-comment period before publication of agency guidance; a requirement for approval by the HHS Secretary which cannot be delegated; a requirement for a repository of all guidance documents and a provision that guidance documents not in the repository are not effective and will be considered rescinded; and procedures for the public to petition HHS to withdraw or modify any particular guidance document.

In the preamble to the proposed regulation, the four reasons the Department provides for repealing the GGP are that it: (1) delays or prevents the issuance of guidance documents; (2) imposes inflexible requirements that do not adequately account for agencies’ different operations; (3) mandates the use of a guidance repository and provides for automatic rescission of guidance documents without requiring the agency to consider policy implications; and (4) diverts limited Department resources that can be directed elsewhere (p.58046). These deficiencies in the GGP are likely to confuse regulated entities and the public. In particular, the automatic recession of a guidance document not included in the repository is unreasonable and places a burden on regulated entities to determine if the document is in the repository before relying on it. Prior to the GGP, HHS agencies were allowed to issue guidance directly, without requiring documents to be published in a separate, central repository curated by the Department to be effective. The AAMC believes that the prior process worked well and reduced confusion as stakeholders were certain that documents issued by an agency could be relied upon. **The AAMC shares the concerns enumerated by the Department and believes that they provide strong support for the repeal of the GGP.**

Civil Enforcement Rule

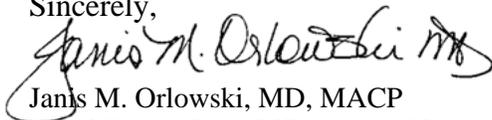
The Civil Enforcement Rule was issued as a procedural rule without notice-and-comment rulemaking and reflected EO 13892, which sought to “provide regulated parties with greater transparency and fairness in administrative actions and to be consistent with EO 13892.” Executive Order 13892 was revoked on Jan. 20, 2021, along with EO 13891, the Good Guidance Practices Rule. In the proceeding ten months since promulgation, HHS has determined that the Civil Enforcement Rule creates unnecessary hurdles for the Department and stakeholders. We also share the Department’s concern that the application of this rule to all HHS agencies may cause confusion as “various agencies under the HHS umbrella each have procedural regulations, some of which have been specifically designed to govern a particular type of proceeding.” (p.58051).

The Civil Enforcement Rule requires HHS agencies to “apply standards or practices that have been publicly stated in a manner that would not cause unfair surprise.”¹ Further, the rule requires notice of certain initial decisions regarding the assertion of new or expanded claims or jurisdiction be published in the Federal Register or the Department’s guidance repository. It also requires that prior to taking a civil enforcement action, the Department give written notice of its initial legal and factual determinations, an opportunity for parties to respond in writing and in some cases orally and provide a written response to the affected entity. The AAMC is always concerned that member hospitals and other regulated entities know that they have a fair process when federal agencies determine that it is appropriate to use their enforcement authority. Our members are familiar with the processes that were used prior to the Civil Enforcement Rule. We do not believe that a case has been made for revising them. We are also concerned that these changes were made without the benefit of notice and comment rulemaking.

When the Agency brings an enforcement action, providers and other entities must be assured that Department actions are governed by fairness, adequate notice, and transparency. There are legitimate reasons why these principles may differ across HHS agencies, as each agency already has processes appropriate to the agency’s statutory authority and pre-existing, agency-specific procedures. Therefore, we believe that the Civil Enforcement rule is unnecessary and likely adds confusion for regulated entities and the public. Should the Department wish to make changes to enforcement processes it should do so after consulting with stakeholders to determine which processes would benefit from being revised. **The AAMC supports repeal of the Civil Enforcement rule.**

Thank you for your consideration of these comments. If you need additional information, please contact Ivy Baer (ibaer@aamc.org) or Bradley Cunningham (bcunningham@aamc.org).

Sincerely,



Janis M. Orlowski, MD, MACP
Chief Health Care Officer, AAMC

¹ *HHS Improves Agency Procedures Relating to Transparency and Fairness in Civil Enforcement Actions*, Press Release, The Department of Health and Human Services, Jan. 12, 2021.