

December 22, 2021

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

RE: HHS-OS-2020-0012, Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal (RIN 0991-AC24)

Submitted electronically at www.regulations.gov

Dear Secretary Becerra:

The Association of American Medical Colleges (AAMC) welcomes the opportunity to comment on the U.S. Department of Health and Human Services (HHS) proposal to withdraw or repeal the final rule, “Securing Updated and Necessary Statutory Evaluations Timely” (SUNSET final rule) published in the Federal Register on January 19, 2021 (86 Fed. Reg. 5694). The AAMC is a nonprofit association dedicated to transforming health through medical education, patient 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.

The AAMC strongly agrees with HHS’ conclusion that the SUNSET final rule should be withdrawn in its entirety and opposes any modification of the final rule in lieu of the proposed withdrawal. This conclusion is aligned with our earlier comments¹ to HHS on the SUNSET proposed rule² and our additional comments below. In contrast to the Department’s historical approach to rulemaking,³ the SUNSET proposed rule failed to provide a meaningful timeframe for robust notice and comment from a diverse cross section of the community and excluded the required consultation with Tribal Nations despite the potential disruption of funding for tribal programs and activities.⁴ The legal justification in the SUNSET final rule also incorrectly concluded that the rule was consistent with the requirements of the Administrative Procedures Act (APA) and Regulatory Flexibility Act (RFA). The AAMC greatly appreciates the Department’s reconsideration of commenters’ “significant objections” to the proposed rule⁵ and conclusion that the requirements imposed by the final rule do not serve “the Department’s public health and welfare mission.”⁶

¹ AAMC Comments on the SUNSET Proposed Rule, <https://www.aamc.org/media/49841/download?attachment> (Dec. 4, 2020).

² 85 Fed. Reg. 70096 (Nov. 4, 2020).

³ 86 Fed. Reg. 59906, pg. 59907 (“[...] the process to promulgate the rule was extremely unusual, if not unprecedented. The rule is expansive in scope and impact, faced considerable opposition from stakeholders (and very little support), and lacked a public health or welfare rationale for expediting rulemaking. In contrast to the Department’s historical approach to rulemaking in these circumstances, HHS completed the rulemaking—from the publication of the proposal to publication of the final rule—in less than three months”). Id.

⁴ Id. at 59911. See, HHS Tribal Consultation Policy at <https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf> (last visited Nov. 25, 2021).

⁵ Id. at 59907.

⁶ Id. at 59908.

I. The automatic expiration of regulations is contrary to the Administrative Procedures Act and Regulatory Flexibility Act and creates regulatory uncertainty.

In our response to the proposed rule, the AAMC expressed concern for the automatic expiration of regulations within the prescribed timeframe, emphasizing that “the risk of regulations expiring through HHS’ failure to commence a timely review is high, and far outweighs the benefit of the proposed systematic retrospective review, which is speculative at best.”⁷ While the Department may amend specific regulations to include their planned expiration upon pre-determined conditions or time period,⁸ the SUNSET final rule side steps the notice and comment period *prior to the expiration* of a regulation and without any reasoned justification or explanation.⁹ As articulated in *County of Santa Clara v. HHS*, this is in direct violation of the APA and inconsistent with the Congressional intent of the RFA.¹⁰ **It also serves as a primary basis for HHS’ proposed withdrawal of the final rule, and we strongly agree with HHS that “[b]oth the potential for automatic expiration of rules, as well as the diversion of resources from existing regulatory programs, would create regulatory uncertainty, and that uncertainty could have several negative repercussions for stakeholders, including interference with planning, contracting, and product development.”**¹¹

II. The SUNSET final rule undermines the goals of advancing equity across the Federal Government and diverts critical resources from the COVID-19 pandemic.

In the proposed rule, HHS states that the SUNSET final rule is based on policies inconsistent with the goals of the current administration, citing the Executive Order President Biden issued on his first day in office, *Revocation of Certain Executive Orders Concerning Federal Regulation* (E.O. 13992, Jan. 25, 2021), revoking the Executive Order, *Reducing Regulations and Controlling Regulatory Costs* (E.O. 13771, Jan. 30, 2017). E.O. 13992 “[...] equip[s] executive departments and agencies with flexibility to use available tools such as robust regulatory action to confront the urgent challenges facing the Nation, including the coronavirus disease 2019 (COVID–19) pandemic, economic recovery, racial justice, and climate change.”¹² It also supports the revocation of “harmful policies and directives that threaten to frustrate the Federal Government’s ability to confront these problems and empowers agencies to use appropriate regulatory tools to achieve these goals.”¹³

The AAMC agrees that the final rule undermines the goals of E.O 13992 and we echo the concerns expressed by HHS and commenters about the impact of the SUNSET final rule on certain populations including children, elderly adults, people with disabilities, people of color, and other groups who have been historically underserved, marginalized, and/or impacted by poverty. As noted in our letter on the proposed rule, the “expiration of critical regulations under CMS stands to impact not only stakeholders, but also patients who rely on Medicare and Medicaid for their care, including the elderly, the disabled, and indigent.”¹⁴ **We also posited that the final rule would have a tremendous impact on the Department’s ability to monitor and respond to the COVID-19 Public Health**

⁷ Supra Note 1.

⁸ 85 Fed. Reg. 3843, pg. 70106.

⁹ 86 Fed. Reg. 59920.

¹⁰ Complaint, *County of Santa Clara v. HHS*, Case No. 5:21-cv-01655-BLF (N.D. Cal. Mar. 9, 2021), (County of Santa Clara sought to overturn the final rule under the Administrative Procedure Act).

¹¹ 86 Fed. Reg. 59906, pg. 59910.

¹² Id.

¹³ Id.

¹⁴ Supra Note 1.

Emergency, reallocating significant resources away from the pandemic and, “unwisely and unnecessarily [tying] the Department’s hands or [risking] the failure to adequately address either the pandemic or the mandated reviews.”¹⁵ We appreciate the Department’s acknowledgment of the impact of the final rule on the agency’s ability to manage the COVID-19 pandemic and the need for HHS to “[...] continue to remain flexible and focused on the management and utilization of HHS resources to address COVID–19 and its impacts as well as future public health emergencies.”¹⁶

The SUNSET final rule is also in diametric opposition to the goals of E.O. 13985 (Jan. 25, 2021), “*Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*,” and would sharply increase the inequities it is designed to minimize or rectify. The executive order requires federal agencies and departments establish comprehensive plans, including methods and approaches to address equity gaps in government programs, policies, and activities. In furtherance of these efforts, the Office of Management and Budget (OMB) issued a Request for Information on the *Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government*. In response to this request, the AAMC Center for Health Justice¹⁷ provided detailed recommendations on how the Federal Government can “implement[] policies and practices that are explicitly geared toward equity,” offering to work with the OMB and White House Domestic Policy Council to help identify opportunities for collaboration with AAMC’s constituent community and health equity partners to advance these efforts.¹⁸ **We sincerely appreciate the Department’s concerns about the impact of the SUNSET final rule on health equity and justice and how the final rule would impede the progress of E.O. 13985 and 13992. These issues are of great importance to the AAMC and our offer to assist HHS with the review of certain regulations, policies, or activities to advance these efforts remains.**

III. The SUNSET final rule significantly miscalculated the time and resources needed to carry out the regulatory review process.

In HHS’ proposal to withdraw the SUNSET final rule, the Department describes the basis for its reconsideration, contending that in light of the allegations in *County of Santa Clara v. HHS*,¹⁹ the feedback submitted to the public docket and received at the Public Hearing, and the changed policy of the current Administration, the final rule made at least two errors in the justification for the mandatory review of certain HHS regulations.²⁰ The first was the miscalculation of resources needed to pursue this significant undertaking, thereby preventing HHS from carrying out “key priorities” and “mission-critical objectives.”²¹ Second was the assumption that no regulations would expire. The results of this unfounded conclusion would be that, “[p]reventing the automatic expiration of regulations [...] would require prioritizing retrospective review above many other Department programs and missions.”²²

While the AAMC believes retrospective review is a critical responsibility for federal agencies and supports improving the accountability and performance of regulations through the periodic review of existing regulations under the RFA (5 U.S.C. 610, Periodic Review of Rules), **we agree with HHS’ determination that the final rule rests on a significantly flawed understanding of the time and resources needed to carry out the agency-wide changes under the final rule. In our comments on the initial proposed rule, we cautioned that a more targeted approach was necessary in order to**

¹⁵ Id.

¹⁶ 86 Fed. Reg. 59906, pg. 59912.

¹⁷ AAMC Center for Health Justice, <https://www.aamchealthjustice.org/> (Last visited November 25, 2021).

¹⁸ AAMC Center for Health Justice Comment Letter to OMB, <https://www.aamc.org/media/55326/download?attachment> (July 2, 2021).

¹⁹ Supra Note 10.

²⁰ 86 Fed. Reg. 59906, pg. 59909.

²¹ Id.

²² Id.

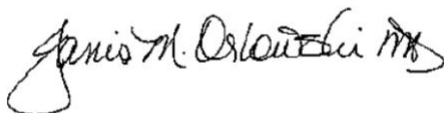
meaningfully evaluate existing regulations and the resources needed for that evaluation. In those comments, we cited key efforts highlighting the need for objective metrics and rigorous data collection to inform regulatory review.²³

The AAMC appreciates the opportunity to comment on the Department's proposal and strongly urges the withdrawal of the SUNSET final rule, an unprecedented regulation that raises serious concerns about the allocation of agency resources and lack of content-based prioritization of rules for review. It also inappropriately shifts the burden of review onto the regulated community, requiring they monitor rules pending review or those that may sunset without advance notice. We believe that the systematic evaluation of regulations should be a regular part of the rulemaking process and have provided input on how the agency might develop a meaningful plan for regulatory review, including the careful identification of regulations impacting the academic medicine community that should be assigned priority status for retrospective review. If HHS would like to discuss these efforts further, please contact our colleagues Heather Pierce (hpierce@aamc.org), Ivy Baer (ibaer@aamc.org), or Daria Grayer (dgrayer@aamc.org).

Sincerely,

A handwritten signature in blue ink that reads "Ross McKinney, Jr., MD". The signature is fluid and cursive, with the initials "R.M." clearly visible at the end.

Ross McKinney, Jr., MD
Chief Scientific Officer

A handwritten signature in blue ink that reads "Janis M. Orlowski, MD, MACP". The signature is fluid and cursive, with the initials "J.M.O." clearly visible at the end.

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

²³ Supra Note 1 (AAMC Comment Letter on the SUNSET Proposed Rule) See, AAMC Conflict of Interest Metrics Project (www.aamc.org/metricsproject); National Academies of Science Engineering and Medicine report, *Optimizing the Nation's Investment in Research*, Government Accountability Report; Government Accountability Office, *Opportunities Remain for Agencies to Streamline Administrative Requirements*; Federal Demonstration Partnership, *Faculty Workload Survey*; Centers for Medicare and Medicaid Services, *Request for Information on Reducing Regulatory Burden to Put Patients Over Paperwork*. Id.