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December 4, 2020

Hon. Alex M. Azar II,
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 (RIN 0991–AC24)

Submitted electronically at www.regulations.gov.

Dear Secretary Azar:

The Association of American Medical Colleges (AAMC) welcomes the opportunity to comment on the U.S. Department of Health and Human Services (HHS) proposed rule, Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) 85 Fed. Reg. 70096 (November 4, 2020). As discussed in the comments below, while the AAMC appreciates the Department's attention to the important process of retrospective review of regulations, this blunt approach raises serious concerns about the use of agency resources, the lack of content-based prioritization of rules for review, and the need for the regulated community to keep track of which rules are coming up for review, or which may be sunset without warning. Given these significant concerns, the AAMC strongly recommends that this proposed rule be withdrawn.

The AAMC is a not-for-profit 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; more than 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 their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

I. Regulatory reform through retrospective review is a critical responsibility of federal agencies but should be based on thoughtful prioritization of which rules should be reviewed.

The AAMC shares HHS' interest in improving the accountability and performance of regulations through enhancing implementation of the Regulatory Flexibility Act (5 U.S.C. 610, *Periodic Review of Rules*), and furthering the efforts of federal agencies to periodically review existing regulations. As an organization that supports research, clinical care, and medical education at its member institutions in a

highly regulated environment, the AAMC encourages efforts to increase the collection and use of evidence throughout the policy making and implementation process from the proposal of new regulations and policies to the evaluation of the effectiveness of those activities. This proposed rule, however, does not provide the Department, the agencies, or the regulated community with an approach that would facilitate productive retrospective reviews. **By setting a rigid and arbitrary timeline for the review of each regulation and allowing those regulations that are not reviewed according to this timeline to simply expire, the Department will lose the ability to ensure the effective review of the regulations that could most benefit from assessment or revision while at the same time imposing uncertainty in the regulated community.**

As a primary driving force for the Notice of Proposed Rulemaking (NPRM), HHS contends that the agency needs stronger incentives to perform retrospective review since "absent a sunset provision or automatic expiration date, Congressional and Presidential directives to perform periodic retrospective reviews of regulations have limited success."[1] The NPRM's preamble asserts a need for the Department *to incentivize itself to perform retrospective reviews* in light of the "limited number of retrospective reviews that the Department has performed over the last 40 years."[2] The Department cites various reports[3] to support its proposal, which it describes as an effort that would "sunset burdensome regulations unless their necessity is publicly demonstrated to the American people."[4] Missing from HHS' references are the landmark reports and RFIs from the National Academies of Sciences, Engineering, and Medicine (NASEM), the Government Accountability Office (GAO), and others that have identified specific ways to address regulatory burden, including evidence-based processes to evaluate regulation through retrospective review. **Notably, not one of these reports or surveys suggests that a blanket approach like the one being proposed by HHS would be effective in making regulations more effective or reducing regulatory burden.**

- The NASEM Report, *Optimizing the Nation's Investment in Research*,[5] examined specific regulations governing federally funded research and their impact on the U.S. research enterprise. Instead of a broad and unstructured elimination of regulations, the NASEM report identified specific regulations which added to research regulatory burden and which should be reviewed. These recommendations were incorporated in large part into the 21st Century Cures Act (Cures Act).[6]
- The 2016 GAO report, *Opportunities Remain for Agencies to Streamline Administrative Requirements*,[7] recognized the need for more robust analysis and data to quantify the impact and burden of research regulations on academic institutions, citing the AAMC's Conflict of Interest

[1] 85 Fed. Reg. 3843, pg. 70103.
[2] Id. at 70099.
[3] Id. at 70097.
[4] HHS Press Release, *HHS Proposes Unprecedented Regulatory Reform through Retrospective Review* (Nov. 4 2020). Available at: https://www.hhs.gov/about/news/2020/11/04/hhs-proposes-unprecedented-regulatory-reform-through-retrospective-review.html.
[5] National Academies of Science, Engineering, and Medicine, *Optimizing the Nation's Investment in Academic Research, A New Regulatory Framework for the 21st Century* (2016).
[6] Pub L No. 114-255, Section 2034, *Reducing Administrative Burden for Researchers*, "HHS and the NIH must review and revise policies, including policies on conflicts of interest and laboratory animals, to reduce the administrative burden on researchers while maintaining the integrity and credibility of research findings."
[7] Government Accountability Office, *Opportunities Remain for Agencies to Streamline Administrative Requirements* (2016).

(COI) Metrics Project[8] as an example of how data can be used to measure the impact of a single set of regulations, and suggesting a model for the targeted assessment of regulations, policies, and other government agency activities.

- In 2018, the Federal Demonstration Partnership (FDP) Faculty Workload Survey of researchers found that on average, 44.3% of their research time was spent fulfilling administrative duties instead of conducting important research.[9] These findings were consistent with similar surveys conducted in 2005 and 2012 and provide strong evidence of the need for *targeted* re-examination of existing regulations and sub-regulatory guidance, an approach that could not be adopted if the Department's resources were committed to reviewing whichever rules happened to be expiring.
- In 2018, Centers for Medicare & Medicaid Services (CMS) issued a request for information (RFI, 83 Fed. Reg. 29524) regarding the Physician Self-Referral Law; in 2019 the Agency issued an RFI (84 Fed. Reg. 27070) to solicit ideas on *Reducing Regulatory Burden to Put Patients Over Paperwork*. Unlike the proposed rule, these efforts represent a reasoned approach to gathering input from affected communities and selectively reviewing regulations to identify those that should be eliminated or revised. On the clinical side, CMS has made many regulatory changes that were generated from these RFIs. This process has been very successful and more thoughtful than the approach suggested in the proposed rule.

II. Retrospective review, when done in a meaningful manner, is a resource-intensive effort for both agencies and the regulated community. The NPRM vastly underestimates the resources needed to conduct these reviews.

The NPRM seeks comment on how to improve retrospective reviews as well as factors to improve rigor or methodology, and cited various reports and studies indicating that "[…] government protections of regulatory impacts would benefit from refinement based on experience after the regulations are implemented."[10] **The AAMC well understands the resources needed to undertake thorough retrospective reviews of regulations and, based on our experience, the AAMC cautions HHS that a more targeted approach than the NPRM proposes is needed to effectively address regulatory review.**

The AAMC COI Metrics Project[11] was designed to measure the cost and impact of the revisions to the regulations on financial conflicts of interest (FCOIs) in research funded by the Public Health Service (PHS).[12] This multi-year project collected data from 74 AAMC member institutions over a course of three years, the year before the August 24, 2012 implementation deadline and two years following implementation. Based on the findings from the COI Metrics Project, as well as other reports that catalogued administrative burden on the research environment, the NASEM concluded in its report that these efforts "call into question whether the new COI rule is accomplishing its intended goal of protecting the integrity of the scientific process and the welfare of research subjects, especially given the

[8] AAMC COI Metrics Project, www.aamc.org/metricsproject.
[9] *Federal Demonstration Partnership Faculty Workload Survey* (2018). Available at https://thefdp.org/default/assets/File/Documents/FDP%20FWS%202018%20Primary%20Report.pdf.
[10] 85 Fed. Reg. 3843, pg. 70100.
[11] Supra note 8.
[12] "*Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*," 42 C.F.R. Part 50, Subpart F.

documented increase in administrative burden to institutions and investigators in the year following implementation of the rule."[13] Efforts like the AAMC COI Metrics Project not only highlight the need for objective metrics and rigorous data collection to help evaluate existing regulations, but also demonstrate the resources needed to effectively evaluate an existing rule**. A robust and meaningful evaluation requires both substantial resources from the regulatory body and the provision of data by the regulated community. The burden on both sets of stakeholders should not be underestimated.**

In the NPRM's Regulatory Impact Analysis, HHS estimates that it oversees approximately 18,000 regulations, and about 12,400 of those are over ten years old and would need to be assessed within two years if this NPRM were finalized. HHS also indicates that because approximately five regulations on average are part of the same rulemaking process, the number of assessments in the first two years would be about 2,480.[14] The Department estimates that in the first two years after this rule is finalized, the mandated reviews will require in total between 20,160 and 44,900 hours by HHS staff.

The AAMC's concerns about this estimate are four-fold:

1) This is almost certainly a significant underestimation of the agency time needed for substantive review each of these regulations. The NPRM asserts that because many of its regulations are part of the same rulemaking process, the review time is condensed. While in some cases this may be true, since the review of each regulation will need to consider all related regulations and guidance documents that create each regulatory framework, this will undoubtedly increase the time needed to conduct a sufficient review, creating the possibility that the critical regulations may only receive a cursory review.
2) This estimation ignores the possibility that additional essential rulemaking or revision will occur during that same timeframe and fall to the same personnel who are being committed to this broad effort.
3) The estimate does not consider the need for the regulated community to engage in these efforts, an activity which will create additional responsibility and burden for both those stakeholders and the agencies.
4) Finally, even if these low estimates are correct, **committing the regulatory staff of HHS to tens of thousands of hours of additional required reviews when the country is relying on the Department to lead the fight against and recovery from the COVID-19 pandemic unwisely and unnecessarily ties the Department's hands or risks the failure to adequately address either the pandemic or the mandated reviews. Even without the additional challenges imposed by the pandemic, HHS staff engage in on-going regulatory activity on which the regulated community relies, and as new legislation if enacted, more regulation will be needed to implement statutory changes. Imposing the requirements of this proposed rule will reduce the effectiveness of each HHS agency or office.**

[13] Supra Note 5.
[14] 85 Fed. Reg. 3843, pg. 70112.

III. The automatic expiration of rules that do not undergo timely review by agencies thwarts the spirit of notice and comment rulemaking.

Under the proposal, if HHS fails to review a regulation in the prescribed timeframe the rule will simply expire, an outcome that would undoubtedly throw the regulated community into uncertainty and misunderstanding about which rules were still in effect. In response, HHS maintains that it will conduct a timely assessment of all its regulations and review those required to be reviewed, recognizing "there is some risk that a Regulation could expire because the Department failed to timely Assess or Review it."[15] To mitigate this risk, HHS proposes creating a website, permitting the public to submit a comment requesting that the Department begin to assess the rule "where if the deadline for publishing an Assessment or Review is nearing and the Department has not yet announced that it has commenced the Assessment or Review." Further, HHS indicates that the "benefits of retrospective review, and the need to strongly incentivize it, are so great that the risk of a Regulation inadvertently expiring is outweighed by the benefit of institutionalizing retrospective review in this manner."[16]

The AAMC strongly disagrees with this assertion; 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. Existing regulations, both new and old, direct and dictate standards of care, quality, safety, and integrity in both clinical practice and research. As such, the impact of unintended deregulation without stakeholder input can be substantial. For instance, expiration of critical regulations under CMS stand to impact not only stakeholders, but also patients who rely on Medicare and Medicaid for their care, including the elderly, the disabled, and indigent. Take for instance the conditions of participation that establish health and safety regulations for hospitals. If these regulations were to expire, most hospitals would surely retain the high level of safety and quality that is required by the regulations. However, the few hospitals that would be negligent in maintaining safety standards would be a risk for those patients seeking care at those institutions. Under the current regulations, CMS' enforcement authority allows for corrective action to protect patients. However, enforcement action on an expired rule would no longer be viable putting patients at risk. It is hard to see how that outcome serves a public policy interest.

At its core, this represents an unacceptable shifting of the agency's responsibility to initiate notice and comment rulemaking to a burden on the regulated community. Assigning this unique agency duty of regulatory review to stakeholders is, by itself, inappropriate, but simultaneously introducing the risk of regulatory expiration places an unconscionable burden upon the regulated community. Stakeholders have competing and varied viewpoints over the regulations that govern them, and the agency must be the sole body tasked to reconcile the needs of numerous organizations and the populations these regulations are meant to serve. It is the agency's responsibility to review, update, and solicit feedback from stakeholders and the expiration of regulations under the arbitrary process proposed simply cannot be a possible outcome, particularly when the agency's role is left to those stakeholders meant to be regulated.
The AAMC objects to HHS' reliance on the public to essentially "remind" the agency of its obligations to conduct a timely assessment and review of certain regulations. Moreover, the assertion

[15] 85 Fed. Reg. 3843, pg. 70106.
[16] Id.

that the automatic expiration of regulations upon inaction by the Department does not violate the Administrative Procedures Act (APA) [17] provides little comfort to those already committed to engaging with the Department through the typical formal notice and comment rulemaking process. While the Department may amend specific regulations to include their planned expiration upon pre-determined conditions or time period,[18] **HHS' proposal to sidestep the notice and public comment process before expiration of a regulation is of great concern. We urge HHS to withdraw its proposal to expire or "sunset" certain regulations and instead, through more effective use of regulatory evaluation mechanisms, identify specific regulations that require the highest priority assessment and review.**

IV. The Department should withdraw the NPRM and instead employ available mechanisms to prioritize regulations for review and then ensure that the required reviews are undertaken with sufficient guidance and resources.

In light of the significant concerns about the proposed approach, the AAMC urges the Department to withdraw the proposed rule in its entirety. Instead, the AAMC suggests that the Department: 1) move quickly to undertake the retrospective review of specific regulations previously identified as requiring review as CMS has done as described above; 2) engage stakeholders in the regulated community to assist the Department in identifying and prioritizing other regulations that warrant review through the use of RFIs and other mechanisms (again as has been done successfully by CMS in recent years); and 3) adopt as Department policy a commitment to embedding evaluation criteria in the rulemaking process on a prospective basis.

The AAMC welcomes the opportunity to work with the Department to identify those regulations that should be assigned priority status for retrospective review. **As a starting point, we suggest prioritizing those mandated for review by the Cures Act.** Section 2034 of the Cures Act requires the Secretary of HHS to review regulations and policies related to the disclosure and reporting of financial conflicts of interest to reduce administrative burden on federally funded researchers. It also calls for the Secretary to harmonize the differences between the HHS Human Subject Regulations (45 CFR Part 46, Subpart A) and the FDA Human Subjects Regulations (21 CFR Parts 50 and 56). These regulations are well overdue for assessment and review and we strongly recommend that HHS prioritize them when identifying which regulations should be reviewed.

The AAMC refers the Department to our comments[19] to CMS in response to its RFI "Reducing Administrative Burden to Put Patients Over Paperwork" in 2019. We suggested areas for regulatory relief, including in the Agency's quality programs, graduate medical education requirements, and billing, documentation, and Medicare coverage requirements. The RFI process used to solicit feedback on areas where regulatory relief is needed is a good approach to identify rules that should be amended or rescinded. In response to our feedback, CMS took specific actions with regard to documentation of evaluation and management services involving residents and other issues that have been immensely helpful to the teaching hospitals and physicians.

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[17] 85 Fed. Reg. 3843, pg. 70106.
[18] Id.
[19] AAMC Comments on the Request for Information and Reducing Administrative Burden to Put Patients Over Paperwork, https://www.aamc.org/media/33786/download (August 12, 2019).

HHS should also partner with stakeholders in the regulated community to answer key threshold questions and identify the types of data that would best demonstrate the impact and effectiveness of the proposed regulation. Leveraging public input can also help identify which regulations are the most burdensome or outdated and thus prioritized for assessment and review. Recognizing that the required evidence will not always come from existing government data can both increase engagement in the rulemaking process and enhance the chances that the initiative will accomplish its desired goals. **The AAMC strongly recommends that HHS actively engage a diverse cross-section of stakeholders in its regulatory reform efforts, and ensure transparency in the regulatory process to uphold public trust.** As one current example, HHS could look to the efforts of the Food and Drug Administration's Office of Patient Affairs and the Center for Devices and Radiological Health, currently working to facilitate "[…] the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input [to] better inform medical product development and regulatory decision making."[20]

Ideally, the systematic evaluation of regulations should be a regular part of the rulemaking process, with the evaluation criteria and timeline embedded within each new rule so that the regulated community has an opportunity to opine on how and when each rule will be reviewed. The experience of the AAMC COI Metrics Project and other in-depth regulatory reviews demonstrate that the key to meaningful evidence generation involves an early consideration of whether the type of regulation or policy being considered would benefit from a data collection or prospective pilot program to evaluate potential outcomes and casual links. Further, integrating evaluation considerations early in the regulatory process (in an ANPRM) would help increase the accuracy of an agency's "speculations" and minimize the flaws of *ex ante* regulatory analysis, an issue raised in the Office of Management and Budget's 2015 *Draft Report to Congress on the Benefits and Costs of Federal Regulations*:

> "The result [of retrospective analysis] should be a greatly improved understanding of the accuracy of prospective analyses, as well as corrections to rules as a result of ex post evaluations. A large priority is the development of methods (perhaps including not merely before-and after accounts but also randomized trials, to the extent feasible and consistent with law) to obtain a clear sense of the effects of rules. In addition, and importantly, rules should be written and designed, in advance, so as to facilitate retrospective analysis of their effects, including consideration of the data that will be needed for future evaluation of the rules' ex post costs and benefits."[21]

In the absence of that prospective road map for review, the Department's efforts would be best deployed through the use of stakeholder groups, convened experts, and existing reports and recommendations to identify those rules most ripe for review. In a time of stretched agency resources and competing regulatory priorities, such a targeted approach would ensure that those regulations most in need of evaluation would receive the attention warranted in the timeframe required for thoughtful, meaningful review.

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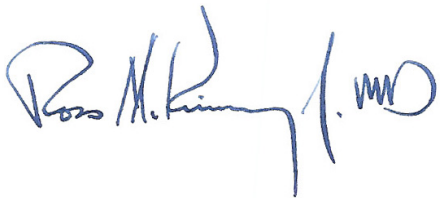
[20] *FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making*; Available at: https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical (last visited Nov. 29, 2020).

[21] *Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act* (2015); Available at: https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/2015_cb/draft_2015_cost_benefit_report.pdf

The AAMC is appreciative of HHS' interest in building the agency's evidence-based approach to regulation through retrospective review and would be happy to work with HHS on any of the recommendations discussed in this letter. The aggregated, de-identified results from the AAMC COI Metrics Project have been provided to the NIH to assist with its retrospective review of the PHS COI regulations and the White House Office of Science and Technology Policy to help with the Office's current assessment of the impact of various agencies' COI regulations and policies on the research environment. If HHS would like to discuss specific areas of regulation affecting the academic medicine community and how the agency might develop a meaningful plan for review that is tailored to those regulations or policies, please contact our colleagues Heather Pierce (hpierce@aamc.org), Ivy Baer (ibaer@aamc.org) or Daria Grayer (dgrayer@aamc.org).

Sincerely,



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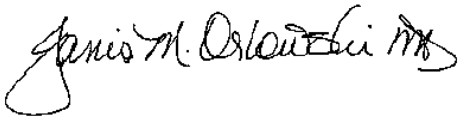

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