AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the *Securing Updated and Necessary Statutory Evaluations Timely* (SUNSET) proposed rule, published in the *Federal Register* on November 4, 2020 (85 Fed. Reg. 70096).

The AMA supports thoughtful and well-considered evaluations of existing regulations to determine whether they continue to serve the effect they were intended to have and provide appropriate protection for American's health and appreciates the Department of Health and Human Services' (HHS or Department) regulatory relief efforts. However, we believe the Department's current proposal is ill-timed, ill-considered, and fails to provide adequate process to allow stakeholders and interested parties enough time to thoroughly and thoughtfully evaluate and comment on the proposal. **As a result, the AMA requests this proposed rule be withdrawn and re-considered after the COVID-19 Public Health Emergency (PHE) ends. Failing that, the AMA requests that the Department extend the current 30-day comment period by 150 days to a total of 180 days to allow enough time for the proposal to be properly vetted.**

Under this proposal, the vast majority of HHS regulations with a significant economic impact would be subject to automatic expiration two years after the final rule would take effect unless the Department conducts a review of each regulation consistent with the requirements laid out in this proposal.[1] Regulations that were issued within the last 10 years would be subject to expiration at the 10-year anniversary of their passage, and every regulation would be subject to expiration 10 years after its last review. The proposal also clarifies that, for purposes of this rule, a regulation is defined as a section of the Code of Federal Regulations (CFR) not a part or subpart of the CFR. As a result, the Department estimates it has roughly 18,000 regulations that would be subject to the requirements under this proposed rule.[2]

The AMA is greatly concerned that the Department is prioritizing this rulemaking when its resources and the resources of physicians and other stakeholders should be devoted to addressing the COVID-19 pandemic. COVID-19 infections are at their highest levels ever in the United States and the Department oversees a wide array of programs to combat the epidemic, including vaccine authorization and

[1] See 85 Fed. Reg. 70096, 70119 – 70120.
[2] Id. 70112.

distribution, diagnostic testing authorization and supply chain logistics, regulatory flexibility for Medicare beneficiaries to ensure continued care during the pandemic, the CARES Act Provider Relief Fund, and many other critical initiatives. The AMA strongly believes that the Department's full attention and resources should be focused on combatting the PHE. Additionally, we do not foresee meaningful engagement from physicians in an abbreviated regulatory review process while they remain focused on continuing to care for record numbers of patients diagnosed with COVID-19 and keeping the lights on in their practices as patient visits remain below pre-pandemic levels and new safety practices require the use of more scarce and costly personal protective equipment.[3]

Moreover, if implemented, this rulemaking would continue to significantly interfere with the Department's ability to focus on responding to the ongoing COVID-19 pandemic by diverting scarce resources to the review of regulations. By the Department's own estimate, in the first two years anywhere between 26,781 to 66,970 hours or the equivalent of the hours of 23.1 to 57.7 full time employees (FTEs) would be spent assessing whether regulations have a significant economic impact upon a substantial number of small entities and conducting reviews of those regulations that the Department determines have such an impact. Another 7,911 to 22,270 hours or 6.8 to 19.2 FTEs would be required for the next eight years for a potential ten-year total cost of nearly $22 million.[4] Presumably, similar time and costs would be required every 10 years moving forward in order to comply with this rule. The rule does not clarify how the Department intends to supplement its budget or workforce to meet this demand, nor does the rule propose a prioritization matrix in the event that resources are unavailable to review every regulation deemed significant and set to expire. Instead, it appears that this review would draw from the limited resources the Department currently has, taking away precious resources that would otherwise be used to combat the COVID-19 pandemic and protect the nation's health.

The AMA is also concerned that this proposed rule, if finalized, would create unnecessary regulatory uncertainty. The prospect of a rule slipping through this process and simply expiring would have serious implications for insurance markets, hospitals, physicians and patients, among other affected parties. Leading up to a review period, regulated industries and individuals affected by HHS regulation would not know whether a duly promulgated rule would continue beyond the sunset period and, as a result, would not be able to plan for future requirements. Moreover, it would be costly and, in some cases, very difficult for regulated entities to keep track of when certain regulations may be subject to expiration. The increased uncertainty could lead to physicians and other regulated entities to forgo future investments because of the lack of clarity regarding what the costs might be of future regulation or lack thereof. Physicians in particular depend on consistent and reliable regulations to make sound decisions on everything from investments in their practice to decisions on appropriate patient care.

This proposed rule also appears to violate the Administrative Procedure Act (APA), which requires that in order for a rule to be duly promulgated, it must go through notice and comment rulemaking as proscribed by section 553 of the APA.[5] If HHS had wanted to provide a sunset on each of the 18,000 regulations subject to this proposal, they could have proposed one initially with each and provided the public adequate notice and opportunity to comment on the sunset provision. By retroactively implementing a sunset provision on thousands of regulations that did not provide for one in the original proposal or final rule implementing those regulations, HHS would be depriving the public of adequate notice and

[3] See AMA, Physician Practice Financial Impact Survey Results, https://www.ama-assn.org/system/files/2020-10/covid-19-physician-practice-financial-impact-survey-results.pdf.
[4] See 85 Fed. Reg. at 70115.
[5] 5 U.S.C. § 553.

opportunity to provide comments on each of the regulations. Moreover, under this proposed rule, any time in the future a rule expires and is repealed, it would be done without notice and comment rulemaking, violating the APA which clarifies that a rulemaking includes formulating, amending, or *repealing* a rule.[6] The AMA believes this proposal should be withdrawn and re-considered rather than face the prospect of being overturned in costly litigation that would also take valuable resources away from combatting the PHE.

As described by HHS Chief of Staff Brian Harrison, this proposed rule would be "the boldest and most significant regulatory reform effort ever undertaken by HHS."[7] **A public comment period of 30 days is clearly inadequate for thoughtful review and comment on a proposal with such sweeping breadth and impact. If HHS declines to withdraw the proposed rulemaking, the AMA requests the comment period be extended at least 150 days, for a total of 180 days.** This would allow for sufficient time for the public to review the proposal and consider the impacts on the many different program areas this proposal would impact.

For the reasons above, we strongly urge HHS to withdraw this proposed rule and focus its efforts on combatting the COVID-19 pandemic. Our country is facing one of the greatest public health challenges it has ever seen, and it requires the full attention of HHS and the federal government as a whole to bring the pandemic under control and save the lives of Americans. This rulemaking would divert vital resources from these efforts at the worst possible time.

The AMA appreciates the opportunity to provide input on this proposed rule. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President, Federal Affairs, at 202-789-7409 or margaret.garikes@ama-assn.org.

Sincerely,

James L. Madara, MD

[6] 5 U.S.C. § 551(5) (emphasis added).

[7] **"**HHS Proposes Unprecedented Regulatory Reform through Retrospective Review" (November 4, 2020), https://www.hhs.gov/about/news/2020/11/04/hhs-proposes-unprecedented-regulatory-reform-through-retrospective-review.html.