

December 17, 2021

The Honorable Xavier Becerra  
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 (Vol. 86, No. 207), October 29, 2021.**

Dear Secretary Becerra:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Health and Human Services' (HHS) proposal to withdraw or repeal the final rule entitled "Securing Updated and Necessary Statutory Evaluations Timely" (SUNSET).

The SUNSET rule set expiration dates for the vast majority of HHS regulations unless certain conditions are met. Specifically, the department must conduct a review of most of its regulations at certain intervals and then determine whether they should retain, modify, or eliminate the regulation. If HHS fails to conduct the review, the regulation expires. **The AHA [continues](#) to have substantial concerns about this rule and strongly supports HHS' proposal to withdraw it.**

We disagree with HHS' assertion that the risk of a regulation inadvertently expiring is outweighed by the benefit of institutionalizing retrospective review. We also disagree that the department's "risk mitigation" strategy is adequate. This strategy relies on the public flagging for the department when it may be at risk of missing a deadline based on a list of regulations posted by HHS. It would be difficult, if not impossible, for the public to accurately determine whether and when a regulation is subject to review, and if so, the deadline for informing the agency and commenting. Thus, there very well may be scenarios where a regulation was not assessed, but it is unclear whether it has expired or was exempt from this regulatory review process and is still in place. At best, this would leave those subject to the regulation with no guidance on what is expected of them. At worst, there would be



serious consequences of inadvertently removing rules, with negative impacts on beneficiaries, consumers and the public in general.

Examples of the above-mentioned confusion and consequence abound. One such example relates to the many Medicare Advantage (MA) and Part D marketing regulations that protect Medicare beneficiaries from misleading and high-pressure marketing tactics that could result in enrollment in an inadequate health plan or result in the purchase of unnecessary ancillary products or services. A substantial number of these regulations were established shortly after the passage of the Medicare Modernization Act with the core marketing regulations finalized in 2008, well beyond the 10-year timeline contemplated by this rule. Yet, these regulations remain just as vital today as when they were adopted. For example, regulations at 42 CFR 422.2268 establish standards for marketing by MA plans. Health plans may not, among other things, induce beneficiaries to buy their products through cash payments, discriminate against lower income beneficiaries by concentrating marketing in higher income areas only, or use aggressive outreach techniques, such as showing up at beneficiaries' homes unsolicited. If HHS unilaterally and without public input, removed any of these regulations, modified them in an inappropriate manner, or let them inadvertently expire, it would be problematic. Beneficiaries would no longer have these protections and the Centers for Medicare & Medicaid Services (CMS) would no longer be able to take any enforcement action against MA or Part D plans violating the rules.

**Finally, the AHA [continues](#) to have substantial concerns that this policy does not provide an adequate mechanism for obtaining public input on the substance of regulations being reviewed.** HHS has approximately 18,000 regulations, the vast majority of which would be subject to review under this rule. They encompass a massive range of topics and affect a huge number of providers, beneficiaries and citizens. While the public would be able to comment on regulations HHS is reviewing, it would not be in response to any proposal for action; thus, the public would be commenting without any context or indication of the department's thoughts on the substance of a regulation, any indication of what, if any, modifications it may be considering, or any indication of whether HHS is even considering modifications or deletion at all. Instead, the public would be commenting in a vacuum. This would not constitute a meaningful opportunity to comment. Thus, we strongly support withdrawal of the SUNSET rule.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Joanna Hiatt Kim, vice president of payment policy, at [jkim@aha.org](mailto:jkim@aha.org).

Sincerely,

/s/

Richard J. Pollack  
President and Chief Executive Officer