



December 22, 2020

Honorable Alex M. Azar II  
Secretary of Health and Human Services  
c/o Mr. James Lawrence  
Docket HHS-OS-2020-0012/RIN 0091-AC24  
200 Independence Avenue, SW  
Washington DC 20201

*Comments Submitted Electronically to <http://www.regulations.gov>*

**Re: RIN 0991–AC24: Docket No. HHS–OS– 2020–0012, “Securing Updated and Necessary Statutory Evaluations Timely”**

Dear Mr. Secretary:

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), I am pleased to submit comments in response to the proposed rule “Securing Updated and Necessary Statutory Evaluations Timely” (SUNSET). This SUNSET notice proposes to require periodic review of Agency rules and sunset those in which no action is taken. The Alliance is a nonprofit multidisciplinary trade association representing physician specialty societies, clinical and patient associations whose mission is to promote evidenced-based quality care and access to products and services for people with chronic wounds.

While the Alliance generally shares the intended goal of this proposed rule, we oppose the Agency’s approach as we believe that it:

1. Is too broad in scope and its application would prove highly disruptive
2. Violates the Administrative Procedures Act and
3. Would have tremendous unintended consequences given the sweeping breadth of the thousands of rules being implicated.

As a result, we urge the HHS to withdraw this proposal. Our specific comments are below:

**Proposed Rule Is Too Broad and Disruptive and Would Divert Department Resources Into An Unnecessary and Burdensome Review Process**

The SUNSET proposal would place significant new administrative burdens on HHS Agencies at a time when resources and time must be allocated to addressing this unprecedented Public Health Emergency (PHE) and other threats to the health and well-being of all Americans. The proposal would create a new, unnecessary requirement for HHS to retroactively assess regulations. However, HHS already has the authority to assess, adjust, and rescind regulations as needed. Among other types of annual reviews, HHS reviews and updates

Medicare regulations to reflect policy and technical changes and new program parameters while providing opportunities for public comment.

As stated in the proposed rule, HHS estimates that in the first two years of this proposed rule's implementation, it would have to assess 2,480 rules. Many of these rules will be subject to the more burdensome review process as well. Because the SUNSET proposal defines "Regulation" to mean "a section of the Code of Federal Regulations," HHS staff would be required to assess and possibly review each individual section of the Code of Federal Regulations that is subject to the rule. HHS estimates that the proposed rule would cost nearly \$26 million dollars over 10 years and require 90 full-time staff positions to undertake the required reviews. Interestingly enough, HHS has not requested nor has Congress appropriated any additional funds to fulfill this proposed rule. Therefore, if this rule were to be finalized, HHS would face tradeoffs in allocating limited resources to conduct these retrospective reviews versus continuing to conduct mission-critical activities amid the COVID-19 pandemic that has already killed more than a quarter of a million Americans. The Alliance urges HHS to prioritize their responses to current health crises instead of implementing this arbitrary blanket requirement to assess longstanding regulations.

### **Proposed Rule Violates The Administrative Procedures Act (APA)**

This proposed rule attempts to place an expiration date on nearly every existing rule issued by HHS without going through the notice and comment period required to repeal a rule. Repealing a rule that was lawfully finalized under the APA without public notice and comment would appear to be arbitrary and capricious. Under the Administrative Procedures Act, Congress established clear procedures and standards for Agencies seeking to modify or rescind a rule. The APA requires Agencies to go through the same rulemaking process to revise or rescind a rule as they would for a new rule, with public notice and the opportunity to comment. However, the SUNSET proposed rule would impose a retroactive expiration date on several duly promulgated regulations that underwent the APA rulemaking procedures. This would amount to a blanket amendment of thousands of separate, distinct rules across HHS without following the requirements of the APA. In doing so, Agencies would be allowed to circumvent the existing rulemaking process and pick and choose which existing regulations to eliminate without public notice or comment. The Alliance does not support this approach and urges the Agency to withdraw the proposal.

Moreover, we are very concerned about the precedent created by an automatic sunset, which would allow future administrations to reject regulations by simply neglecting them and choosing not to review and affirm. This would bypass the regulatory process and deprive the American people of the opportunity for comment and input.

### **Unintended Consequences**

States, insurance issuers, providers and beneficiaries all rely on a duly promulgated regulatory framework. Many of these regulations are interdependent on one another. By sunsetting one regulation – there may be unintended consequences on other regulations not only within the Medicare program but also with the states and other payers making it difficult if not impossible for regulated entities to ascertain a complete picture of the regulatory framework if one piece was to disappear. These could also have unintended consequences for health care systems and clinicians treating patients as well as individuals and beneficiaries served by HHS programs and processes.

## Conclusion

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. While we share the goal of streamlining regulations and removing unnecessary and outdated burdens, we believe this proposal not only violates the APA, but will be burdensome to the HHS and ultimately detrimental to all stakeholders including patients. The Alliance urges the HHS to withdraw the SUNSET proposal.

If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Marcia Nusgart R.Ph.".

Marcia Nusgart R.Ph.  
Executive Director