

December 17, 2021

Attn: RIN: 0991-AC24
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Submitted via www.regulations.gov

RE: Securing Updated and Necessary Statutory Evaluations Timely; Proposal To Withdraw or Repeal (RIN: 0991-AC24); Docket No. HHS-OS-2020-0012

These comments are submitted for the record to the U.S. Department of Health and Human Services (HHS) on the proposed rule, [Securing Updated and Necessary Statutory Evaluations Timely; Proposal To Withdraw or Repeal](#) (proposed rule), published in the October 29, 2021 edition of the Federal Register.

The proposed rule would withdraw or repeal the final rule, [Securing Updated and Necessary Statutory Evaluations Timely](#) (SUNSET rule), published in the January 19, 2021 edition of the Federal Register. The SUNSET rule provides that all HHS rules, with some exceptions, would “expire at the end of (1) five calendar years after the year that the SUNSET final rule first becomes effective, (2) ten calendar years after the year of the regulation’s promulgation, or (3) ten calendar years after the last year in which the Department ‘Assessed’ and, if required, ‘Reviewed’ the regulation, whichever is latest.”

The purpose of the SUNSET rule is to ensure that HHS complies with Section 610 of the Regulatory Flexibility Act (RFA). [Section 610](#) requires agencies to establish a plan to review their rules and to complete review of those rules within 10 years to “determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities.” As explained in the preamble to the SUNSET rule, Section 610 review is a congressional mandate and “not optional.” Despite the mandate, many agencies have [failed](#) to conduct timely reviews. HHS is no exception; an internal artificial intelligence review of the Department’s regulatory code found that 85 percent of regulations issued prior to 1990 had not been edited, about 300 Code of Federal Regulations (CFR) mentions referenced CFR sections that no longer exist, and dozens of instances of duplicative paperwork requirements (86 FR 5701). As HHS stated in the SUNSET rule preamble, “this suggests that humans performing a comprehensive review of Department regulations would find large numbers of requirements that would benefit from review, and possibly amendment or rescission.”

The proposed rule is problematic because, as explained below, it would continue the current HHS practice of failing to comply with a statutory mandate, lacks adequate reasoning, and fails to consider several obvious alternatives. Accordingly, the proposed rule should be withdrawn, or at a minimum, substantially revised.

The Proposed Rule Would Continue the Current Practice of Failing to Comply with a Statutory Mandate and Lacks Adequate Reasoning

HHS offers several reasons to justify its proposal. While these reasons are examined below, one major flaw pervades the entire proposal. HHS fails to consider that repealing the SUNSET rule would hinder the Department's ability to comply with Section 610. Further, HHS offers no recognition that its Section 610 reviews are currently lacking.

The SUNSET rule was promulgated to address the Department's failure to comply with Section 610 of the RFA. The proposed rule would return to HHS's practice of avoiding Section 610 reviews. Section 610 review is a requirement. Returning to the status quo would mean noncompliance, and should not be considered

Among the justifications offered for the proposed rule, a primary reason is that the SUNSET rule "would create a tremendous economic and workload burden on the Department, and would pursue the objective of regulatory review at great expense to the public and to the small business community it purports to benefit." Since the SUNSET rule just adds an enforcement mechanism to Section 610 review, the underlying point of this argument is that such review is too costly to comply with – and therefore is not currently taking place. HHS, however, is required to comply with Section 610. The Department would not look kindly on regulated entities that fail to comply with existing laws and regulations because those entities deem them too burdensome – yet it seemingly claims this privilege for itself.

The Department also cites the increased burden on stakeholders if they must review rules to consider how they could be improved. This argument overstates the potential burden on stakeholders, as most will not spend the time to review rules except for those relatively few that most negatively, and unnecessarily, affect them.

Another explanation for the proposed rule is that assessment and review of rules is unnecessary because most "work as intended." Simply because the Department and some commenters believe this to be true is not evidence that rules do not need to be reviewed. First, Section 610 review is a requirement, not an option, as mentioned above. Second, if a rule finalized in the 1980s or 1990s is working "as intended," that means it is likely out of date, given that requirements promulgated then could not have envisioned the technological and informational improvements that have taken place in the following decades. Even if such a rule works well, it still needs to be assessed to see if it can work even better or achieve the same outcome with less burden.

HHS believes its proposal is additionally justified because the SUNSET rule could result in the expiration of regulations that lead to public harm. HHS could easily prevent such expiration by reviewing rules within the required timeframe. It is worth reemphasizing that such review is already statutorily required. The argument is essentially that HHS has no intention or capability to comply with existing requirements, and that if its feet were held to the fire because of consequences for this failure, it would still not be able to comply. A better solution would be to figure out how to comply with the existing requirement, rather than eliminate a mechanism that would ensure compliance.

HHS also argues that the SUNSET rule goes beyond the requirements of Section 610, which requires review of rules that “have or will have a significant economic impact on a substantial number of small entities,” by requiring assessment of all rules. This argument, however, glosses over the fact that to determine whether a rule has such impact, it must be assessed through this lens. It is likely that most of the Department’s regulations not previously identified as having small entity impact would remain so, and thus only a simple assessment of these rules would be necessary – a minimal burden that should take place already given the statutory requirements of Section 610.

HHS Fails to Consider Obvious Alternatives that Would Improve its 610 Review Compliance

The Department’s consideration of alternatives to its proposed rule demonstrates that HHS has no intention of pursuing many of the obvious ways it could modify the SUNSET rule to improve its compliance with Section 610 while eliminating some of the rule’s components that it finds problematic.

HHS believes that the SUNSET rule’s requirement to assess virtually all of the Department’s rules goes beyond the intent of the RFA and would be too burdensome for it to handle. The alternatives presented alongside the proposed rule, however, would fail to meaningfully address these concerns.

HHS considers two alternatives – one with a deadline of two years to assess (and, if necessary, review) all existing rules older than 10 years and one with a deadline of 10 years – to the SUNSET rule’s deadline of five years. The first alternative would exacerbate the problem as HHS sees it and is thus not a serious alternative. The second would merely give the Department more time to do its initial assessment. The presentation of these alternatives seems designed to allow HHS to “check the box” that it considered alternatives – but both options would still be too problematic, in the Department’s view, to actually propose.

HHS seems to have willfully avoided considering any of myriad ways to limit the scope of rules subject to assessment and review that would make the SUNSET rule much easier to implement. A few options include limiting the number of rules to only: Those that have already been certified as having small entity impact, those deemed significant under Executive Order 12,866, those considered major for purposes of the Congressional Review Act, and those that have unfunded mandates.

In failing to consider these obvious alternatives, as well as others, HHS demonstrates its lack of seriousness in considering alternatives to the proposed rule. Instead, HHS chose to evaluate alternatives that would make the proposed alternative the clear “best option,” in its view. The Department should evaluate other alternatives that get at the heart of its primary criticism of the SUNSET rule, which is the *number* of rules that would need to be assessed and reviewed. Based on HHS’s spotty success in complying with Section 610, even reducing the rules assessed from virtually all to some specific subset would improve its record.

Conclusion

The SUNSET rule was promulgated to address a serious problem – HHS does not do a good job of complying with Section 610 of the RFA. Rather than focusing on how the Department can modify

the rule to lessen its potential burden while still improving its compliance, it instead proposes to jettison the entire thing. The Department's reasons for doing so are flawed and fail to appreciate that HHS is failing in its obligation to meet a statutory mandate. Its considered alternatives seem designed entirely to meet the bare minimum of rulemaking procedure, at best, while painting the proposed alternative in the best light. It seems clear from the proposed rule that HHS began this reconsideration of the SUNSET rule with the endpoint of repealing it set in stone rather than it emerging as the best option to address the problem the SUNSET rule was aimed at fixing.

HHS should withdraw the proposed rule or, at a minimum, seriously consider ways it can modify the SUNSET rule to improve its Section 610 review process.

Respectfully submitted,

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