PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

December 3, 2020

Secretary Alex M. Azar II
HHS Commissioner
The U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
RE: Securing Updated and Necessary Statutory Evaluations Timely (85 *Federal Register* 70096)

Dear Secretary Azar:

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to comment on the Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) proposed rule, published November 4, 2020.

PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community, including members and staff of human research protection programs and institutional review boards (IRBs), investigators, and their institutions. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise understand the central importance of ethics to the advancement of science.

Regular retrospective review of regulations is critical to a healthy and effective regulatory environment. HHS has rightly identified that, in the absence of periodic review and assessment, regulations may become outdated and irrelevant to current realities, unnecessarily burdening the regulated community. However, we believe the proposed rule is too blunt an instrument for promoting the goal of effective retrospective review of regulations.

Per the notice, the rule's intent is to set expiration dates for all HHS regulations (subject to certain exceptions), unless HHS "periodically assesses the regulations to determine if they are subject to the [Regulatory Flexibility Act], and if they are, performs a review that

satisfies the criteria of the RFA." We have three primary concerns about this approach.

First, the timeframe proposed for review and assessment of rules is overly rigid: Not only must regulations be reviewed every 10 years or they expire, but HHS will have just two years from the date it publishes its review findings to amend or rescind a regulation. The most recent revisions to the Federal Policy for the Protection of Human Subjects, or Common Rule, provide a useful example of how this timeframe is inadequate.

In the years between the original promulgation of the Common Rule in 1991 and the point at which the regulations underwent formal reevaluation starting in 2011, biomedical and social science research had made substantial scientific and technological advances, and social norms that shape ethical thinking about research practices continued to evolve. The Common Rule was, in the proposed rule's terms, "evidence-based regulation that [became] outdated as conditions [changed]." As we articulated in our comments to the 2015 Common Rule NPRM, we support efforts to analyze and modernize existing regulations. Furthermore, it would no doubt have been beneficial to the regulated community for the Common Rule to have undergone review and assessment 10 years after its initial promulgation. That said, the process for revising the Common Rule took *eight years* from start to finish, and involved the input of thousands of stakeholders representing the regulated community and beyond. The proposed rule fails to account for the time and resources that may be required to conduct the iterative, stakeholder-engaged process of effective rulemaking for substantial and far-reaching regulations such as the Common Rule.

Second, by applying to all HHS regulations indiscriminately, the proposed rule risks failing to use limited resources wisely. For one thing, the rule stands to overburden HHS regulators with assessment and review processes, straining already-limited HHS resources. As noted above, the rulemaking process is resource-intensive and complex. Some rules may benefit from mandated regular scrutiny, while others, likely, will not. A better approach to regular retrospective review of regulations would identify regulations that are most likely to benefit from targeted review, for instance, because they apply to a domain that is quickly evolving, or because they have an outsized impact on the regulated community. To that end, the department might consider creating a priority list for regulations to review that it could work its way through in a particular order.

Furthermore, the application of the proposed rule indiscriminately to all HHS regulations increases the likelihood that regulators may simply "miss" regulations that merit retrospective review and are approaching their expiration date. The rule seems to acknowledge this possibility, noting that if a deadline for publishing an assessment or review of a regulation is approaching and HHS has not yet announced it has started its review, the public can submit comment requesting the department take up such review. Relying on the public to make sure a regulation is not expiring without review, far from alleviating regulatory burden, puts additional civic burden on the regulated community. It is, furthermore, an unacceptable abdication of the responsibilities of regulators.

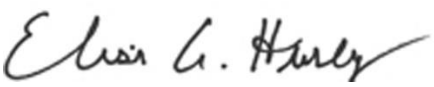
Third, the proposed rule's provision that any regulation that is not assessed within the 10-year timeframe will automatically expire is troubling. No details are provided regarding what the process around an "automatically expiring" regulation will be, leaving it unclear how the public will be notified and how it should understand the reasoning around and impact of those expirations. Questions we would like to see addressed in any further iteration of the rule include:

- Will the public be notified when rules are disappearing, and if so, when, and how? While the rule proposes mechanisms for the public to proactively remind the department that a regulation is expiring, and for public input when HHS announces an assessment and review of a regulation is being undertaken by HHS, there is no stated mechanism for alerting the public that a regulation, because of lack of attention, is expiring, or has expired.
- Will there be *any* assessment of the impact of the regulation's simply expiring on the regulated community or the domain covered by the regulation? Will that assessment be communicated to the public?
- Will the department be required to say anything about why it failed to take up the review of a regulation that simply expires?
- Will there be any mechanism for providing public input on whether the rule should indeed be allowed to expire, or to request, after the fact, that the regulation be reinstated or revisited?

Crafting and maintaining effective and efficient regulation requires opportunities for meaningful, sustained public engagement on a flexible timeline. Eliminating regulations out of neglect is not an acceptable way to do rulemaking. While regular retrospective review of regulations is crucial, we believe a more nuanced approach to regulatory reform than is proposed by the rule is needed.

Thank you again for the opportunity to comment. PRIM&R stands ready to provide any further assistance or input that might be useful during this process. Please feel free to contact me at 617.303.1872 or ehurley@primr.org.

Respectfully submitted,



Elisa A. Hurley, PhD
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cc: PRIM&R Public Policy Committee, PRIM&R Board of Directors