

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 6****Public Health Service****42 CFR Part 1****Centers for Medicare and Medicaid Services****42 CFR Part 404****Office of the Inspector General****42 CFR Part 1000****Office of the Secretary****45 CFR Part 8****Administration for Children and Families****45 CFR Parts 200, 300, 403, 1010, and 1300**

[Docket No. HHS–OS–2020–0012]

RIN 0991–AC24

**Securing Updated and Necessary Statutory Evaluations Timely; Proposal To Withdraw or Repeal****AGENCY:** Department of Health and Human Services (HHS).**ACTION:** Proposed rule.

**SUMMARY:** The Department of Health and Human Services (HHS or Department) is proposing to withdraw or repeal a final rule entitled “Securing Updated and Necessary Statutory Evaluations Timely” (SUNSET final rule) and published in the **Federal Register** of January 19, 2021. The SUNSET final rule was originally scheduled to take effect on March 22, 2021. However, after a lawsuit was filed on March 9, 2021, seeking to overturn the SUNSET final rule, HHS issued an administrative delay of effective date that extended the effective date of the SUNSET final rule until March 22, 2022. HHS is now proposing to withdraw or repeal the SUNSET final rule.

**DATES:** Submit either electronic or written comments on the proposed rule by 11:59 p.m. on December 28, 2021.

**ADDRESSES:** You may submit comments through the Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the “Submit a comment” instructions.

**Warning:** Do not include any personally identifiable information (such as name, address, or other contact

information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to comments received.

*Inspection of Public Comments:* All comments received before the close of the comment period will be available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <https://www.regulations.gov>. Follow the search instructions on that website to view the public comments.

**FOR FURTHER INFORMATION CONTACT:**

Daniel J. Barry, Acting General Counsel, 200 Independence Avenue SW, Washington, DC 20201; or by email at [reviewnprm@hhs.gov](mailto:reviewnprm@hhs.gov); or by telephone at 1–877–696–6775.

**SUPPLEMENTARY INFORMATION:****Table of Contents**

- I. Executive Summary
  - A. Purpose and Coverage of the Proposed Rule
  - B. Summary of Major Provisions
  - C. Legal Authority
  - D. Costs and Benefits
- II. Table of Abbreviations/Commonly Used Acronyms in This Document
- III. Background
  - A. History of the SUNSET Rulemaking
  - B. The Department’s Review
- IV. Legal Authority
- V. Explanation of Proposed Rule To Withdraw or Repeal the SUNSET Final Rule
  - A. Implementation Burdens on the Department and Stakeholders
  - B. Potential Harms From the Possible and Actual Expiration of Regulations
  - C. RFA Considerations
  - D. APA Considerations
  - E. Vague and Confusing Provisions
- VI. Preliminary Economic Analysis of Impacts
  - A. Introduction, Summary, and Background
  - B. Market Failure or Social Purpose of Regulatory Federal Action
  - C. Purpose of Proposed Withdrawal or Repeal Rule
  - D. Baseline Conditions
  - E. Benefits of Proposed Withdrawal or Repeal Rule
  - F. Costs of Proposed Withdrawal or Repeal Rule

- G. Analysis of Regulatory Alternatives to the Proposed Withdrawal or Repeal Rule
- VII. Federalism
- VIII. Consultation and Coordination With Indian Tribal Governments
- IX. Analysis of Environmental Impact
- X. Paperwork Reduction Act
- XI. References

**I. Executive Summary***A. Purpose of the Proposed Rule*

HHS issued the SUNSET final rule on January 19, 2021. 86 FR 5694. The SUNSET final rule provides, among other things, that all regulations, subject to certain exceptions, issued by the Secretary of the Department of Health and Human Services (Secretary) or his delegates or sub-delegates shall 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.<sup>1</sup> The SUNSET final rule was scheduled to take effect on March 22, 2021. However, after a lawsuit seeking to overturn the SUNSET final rule was filed on March 9, 2021, HHS issued an administrative delay of effective date, effective as of March 19, 2021, which postponed the effective date of the SUNSET final rule, pending judicial review, until March 22, 2022. 86 FR 15404 (Mar. 23, 2021).

After reconsideration of the comments submitted on the SUNSET proposed rule (85 FR 70096 (Nov. 4, 2020)), HHS is now issuing this notice of proposed rulemaking to withdraw or repeal the SUNSET final rule.

*B. Summary of Major Provisions*

We are proposing to withdraw or repeal the SUNSET final rule in its entirety.

*C. Legal Authority*

The primary statutory authorities supporting this proposed rule are the general rulemaking authorities for the various substantive areas under the Department’s umbrella, as well as a general authorization for agencies to issue regulations regarding the administrative processes to be followed by that agency. These provisions include: 21 U.S.C. 371(a); 42 U.S.C. 216; 42 U.S.C. 1302; 42 U.S.C. 1395hh; 42 U.S.C. 2003; and 5 U.S.C. 301.

<sup>1</sup> The terms “Section,” “Assess,” and “Review” were capitalized in the preamble to the final rule where those terms have the definitions ascribed to them in the text of the final rule. For ease of readability, these terms are not capitalized in the following discussion of this proposed rule unless directly quoting or paraphrasing the final rule.

*D. Costs and Benefits*

This proposed regulatory action would reduce the time spent by the Department performing retrospective assessments and reviews of its regulations as required by the SUNSET final rule, and time spent by regulated entities and other stakeholders, including the general public, small and large businesses, non-governmental organizations, Tribes and state and local governments, on comments related to these assessments and reviews. We

monetize the likely reductions in time spent by the Department and the general public as cost savings. Our primary estimate of these cost savings in 2020 dollars, annualized over 10 years, using a 3% discount rate, totals \$69.9 million. Using a 7% discount rate, we estimate \$75.5 million in annualized cost savings. Table 1 reports these primary estimates alongside a range of estimates that capture uncertainty in the amount of time it will take the Department to perform each regulatory assessment and review, and uncertainty in the amount

of time the public will spend on comments. The impact of the proposed withdrawal provisions is analyzed in the Preliminary Economic Analysis of Impacts for this proposed rule. We seek comment on these preliminary estimates and analysis.

**II. Table of Abbreviations/Commonly Used Acronyms in This Document**

As used in this preamble, the following terms and abbreviations have the meanings noted below.

Term	Meaning
ACA	Affordable Care Act.
ACF	Administration for Children and Families.
ACUS	Administrative Conference of the United States.
APA	Administrative Procedure Act.
CFR	Code of Federal Regulations.
CHIP	Children’s Health Insurance Program.
CMS	Centers for Medicare & Medicaid Services.
COVID–19	Coronavirus Disease 2019.
EO	Executive Order.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
FSMA	FDA Food Safety Modernization Act.
HHS or Department	U.S. Department of Health and Human Services.
IHS	Indian Health Service.
OCR	Office for Civil Rights.
OIRA	Office of Information and Regulatory Affairs.
PDV	Present Daily Value.
PHS Act	Public Health Service Act.
RFA	Regulatory Flexibility Act.
SAMSHA	Substance Abuse and Mental Health Services Administration.
SBA	Small Business Administration.
SEISNOSE	Significant Economic Impact Upon a Substantial Number of Small Entities.
SECG	Small Entity Compliance Guide.
SUNSET	Securing Updated and Necessary Statutory Evaluations Timely.
UA	Unified Agenda.

**III. Background**

The SUNSET final rule, if implemented, would significantly alter the operations of HHS with considerable repercussions for a diverse array of stakeholders. We note that the process to promulgate the rule was extremely unusual, if not unprecedented. The rule is expansive in scope and impact, faced considerable opposition from stakeholders (and very little support), and lacked a public health or welfare rationale for expediting rulemaking. In contrast to the Department’s historical approach to rulemaking in these circumstances, HHS completed the rulemaking—from the publication of the proposal to publication of the final rule—in less than three months. Upon a thorough review of the rule, we find that, given the lack of a public health or welfare reason to expedite the rulemaking and other procedural shortcomings, the Department should now reconsider the commenters’ significant objections to the proposal.

Moreover, based on a reanalysis of the regulatory impact of the rule, we now believe that the rule rested on a flawed understanding of the resources required for this undertaking, which implicates the likelihood that HHS regulations would expire if the final rule were to go into effect. That in turn will require the Department to make resource allocation decisions which could impede the Department’s routine operations and hamper its ability to carry out other key priorities and goals, particularly during an ongoing public health emergency. Now that we have reconsidered the public comments and the regulatory impact analysis, including a consideration of the impacts that are not quantified or monetized, we believe that the rule prioritized regulatory review over other Department operations to a degree that may negatively impact many stakeholders and the general public in a variety of ways. We disagree with that approach as a matter of policy and therefore are proposing to withdraw the rule in its entirety.

*A. History of the SUNSET Rulemaking*

1. Proposed Rule, Comment Period, and Final Rule

On November 4, 2020, HHS published a notice of proposed rulemaking entitled “Securing Updated and Necessary Statutory Evaluations Timely” (SUNSET proposed rule). 85 FR 70096. Under the proposed rule, subject to certain exceptions, Department regulations would expire at the end of (1) two calendar years after the year that the SUNSET rule first became 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 was latest. Thus, under the SUNSET proposed rule, unless HHS assessed and, if required, reviewed most of its regulations within a certain timeframe specified in the rule (for most existing regulations, within two years) and every ten years thereafter, the regulations would automatically expire.

The SUNSET proposed rule also provided that if a review led to a finding that a regulation should be amended or rescinded, the Department must amend or rescind the regulation within a specified timeframe (generally two years). In addition, the SUNSET proposed rule contained certain publication requirements, including that (1) the Department publish the results of all “Assessments” and “Reviews,” including the full underlying analyses and data used to support the results, in the **Federal Register**, and (2) the Department announce the commencement of an “Assessment” or “Review” of a particular regulation on the agency website, with an opportunity for public comment. The SUNSET proposed rule provided that comments to the proposed rule had to be submitted by December 4, 2020, except for comments on the portion of the rule amending 42 CFR parts 400–429 and parts 475–499 (Medicare program regulations), which were to be submitted by January 4, 2021.

On November 16, 2020, HHS announced a public hearing, scheduled for November 23, 2020, to receive information and views on the proposed rule (Public Hearing). 85 FR 73007. Despite the short notice, over twenty interested parties provided oral comments at the Public Hearing. *See* Transcript, Public Hearing on the Securing Updated and Necessary Statutory Evaluations Timely Notice of Proposed Rulemaking (Nov. 23, 2020) (available at <https://www.regulations.gov/document/HHS-OS-2020-0012-0501>) (Public Hearing Transcript). All of the commenters, which included industry/trade organizations, medical organizations, and public interest organizations,<sup>2</sup> criticized the proposed rule in its substance, the rulemaking process, or both.

In addition to the oral comments, a wide range of stakeholders submitted over 500 comments on the proposed rule. Almost all of the comments opposed the proposal. Comments opposing the rule were submitted by, for

example, health care and medical organizations; Federally Qualified Health Centers and advocates for beneficiaries of Federal health care programs; State Attorneys General and other state government representatives; Tribal governments and Tribal organizations; large industry associations and trade associations; consumer and public interest groups; and interested individuals. Only a handful of commenters supported the rule, and two of those comments were submitted by an individual who, under an agreement with HHS, also provided a draft regulatory impact analysis for the SUNSET final rule. *See* 86 FR 5737 n.210. Other commenters supporting the rule included independent business advocacy organizations and a nonprofit legal organization.

On December 18, 2020, the Office of Information and Regulatory Affairs (OIRA) in the White House Office of Management and Budget received the SUNSET final rule for review and clearance and posted on the OIRA dashboard for E.O. 12866 Regulatory review (Ref. 1). This preceded the January 4, 2021, conclusion of the comment period for the parts of the proposed rule relating to 42 CFR parts 400–429 and parts 475–499.

HHS issued the SUNSET final rule on January 19, 2021. 86 FR 5694. The final rule provides that all regulations issued by the Secretary or their delegates or sub-delegates in titles 21, 42, and 45 of the Code of Federal Regulations (CFR), subject to certain exceptions, shall 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. Thus, the final rule contains the same basic expiration framework as the proposed rule, but extends the timeframe for assessment and any applicable review of most existing regulations from two calendar years to five calendar years. The final rule also provides for a one-time “continuation” of a regulation that is subject to expiration if the Secretary makes a written determination that the public interest requires continuation. The continuation period, stated in the determination, is not to exceed one year. In addition, the final rule contains exemptions for a small set of HHS regulations applicable to the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare & Medicaid Services (CMS). The final rule

maintains the timeframe for amendment or rescission of regulations, and includes a new **Federal Register** publication requirement in addition to the publication requirements proposed in the SUNSET proposed rule.<sup>3</sup>

## 2. Litigation and Delay of Effective Date

On March 9, 2021, the County of Santa Clara and several other plaintiffs sued the Department seeking to overturn the SUNSET final rule under the Administrative Procedure Act (APA). Complaint, *County of Santa Clara v. HHS*, Case No. 5:21-cv-01655-BLF (N.D. Cal. Mar. 9, 2021) (*Santa Clara*) (Ref. 2).

On March 18, 2021, the Acting Secretary of HHS signed, pursuant to 5 U.S.C. 705 of the APA, an administrative delay of effective date (Administrative Delay Order), effective as of March 19, 2021, which extended the effective date of the SUNSET final rule until March 22, 2022. 86 FR 15404.

### B. The Department’s Review

The Department has reexamined the SUNSET final rule in light of the allegations in the *Santa Clara* complaint, the many comments submitted to the docket and raised at the Public Hearing, and changed policy views in the current Administration. This review has considered the processes followed in issuing the rule, its policy goals and objectives, the projected effects and analysis of impacts in its implementation, and the legal evaluation of and support for its provisions, including whether the rule is consistent with HHS statutory obligations and its mission to promote and protect the public health. It should be noted at the outset that HHS already conducts retrospective reviews, and the Department is open to feedback regarding how to improve these existing processes. The purpose of this review, however, has been to reconsider whether the new requirements imposed in the SUNSET final rule would achieve the goals of retrospective review in a manner that best serves the Department’s public health and welfare mission. As described further below, based on our review, we now believe that the SUNSET final rule should be withdrawn in its entirety. However, we request comment on whether, consistent with the goals of retrospective review as well as other current policy priorities and considerations discussed in this proposed rule, the Department should

<sup>2</sup> Commenters at the Public Hearing included: National Health Law Program, Center for Science in the Public Interest, Consumer Federation of America, Food & Water Watch and Food & Water Action, American Frozen Food Institute, American College of Obstetricians and Gynecologists, Lambda Legal, Center on Budget and Policy Priorities, American Lung Association, United Fresh Produce Association, Consumer Brands Association, Campaign for Tobacco-Free Kids, The National Confectioners Association, National Immigration Law Center, Prevent Blindness, American Feed Industry Association, Disability Rights New Mexico, Pet Food Institute, Public Citizen, American Medical Association, and Service Employees International Union.

<sup>3</sup> The final rule also moved the location of some of the regulatory text from having a general provision covering an entire title to having a separate, duplicate provisions in different chapters of HHS regulations.

consider modifying, rather than withdrawing or repealing, the SUNSET final rule.

Our current view is that, to be consistent with the Department's usual practices when engaging in rulemaking, the Department should have engaged in a more robust consideration of the comments, should have more thoroughly examined the factual and legal basis of the rule, and should have given greater weight to the potential harms to stakeholders and the public health. Our thinking is informed by a reevaluation of the factual premises and conclusions in the SUNSET final rule that are central to the Department's analysis of the rule's implications and effects. In particular, based on a reanalysis of the regulatory impact of the rule, we now believe that the rule likely rested on a flawed understanding of the resources required for this undertaking, which implicates the likelihood that HHS regulations would expire, and which in turn will require the Department to make resource allocation decisions which could impede the Department's ability to carry out other key priorities. That diversion of resources will likely impede efforts to adopt new rules to address national priorities and advance equity for all, including historically underserved and marginalized communities. It is therefore potentially inconsistent with the current Administration's policies that aim to empower agencies to use appropriate tools to achieve those ends. In this section, we summarize the key considerations, addressed in greater detail throughout the preamble, that have led us to change our view of the overall merit of the SUNSET final rule and to propose to withdraw the rule in its entirety.

As an initial matter, based on our review, we have found that there were several procedural shortcuts taken in the rulemaking process which may have impeded full consideration of the commenters' significant objections to the proposal. The SUNSET final rule was issued on an unusually expedited timeline of less than three months for a rule of this significance, with potential impacts not just on small businesses but also the general public, larger businesses, Tribes, States, non-governmental organizations, and other regulated entities and stakeholders across a wide range of industrial sectors. The SUNSET rule was also unusually expansive in scope, requiring review and possibly regulatory or deregulatory activity across a variety of distinct substantive statutes<sup>4</sup> within the

jurisdiction of a several operating divisions (e.g., CMS, FDA, CDC, Substance Abuse and Mental Health Services Administration (SAMSHA), the Office for Civil Rights (OCR), and the Administration for Children and Families (ACF)). Furthermore, it appears that the comments were not adequately considered (as evidenced by the summary mention in the preamble to the SUNSET final rule, as discussed further elsewhere in this preamble), and, contrary to policy, the Department did not consult with tribal governments.

As for the substance, we note initially that the resources required to comply with the assessment and review requirements would be substantial. For each regulation covered by the SUNSET final rule, HHS agencies would need to: Collect data to conduct the relevant evaluation (which may require time for public notice and comment, and Office of Management and Budget (OMB) review and approval, under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, in addition to the time needed for data collection and analysis); engage subject matter experts and others to complete an assessment (and possibly a review); consult with state and local jurisdictions and Tribes; open and publicize public dockets for each assessment or review that the Department conducts; consider any comments to the public docket related to the evaluation; participate in interagency review; and publish the results of this process in the **Federal Register**, "including the full underlying analyses and data used to support the results." 86 FR 5712. If warranted by the results of this process, HHS agencies would then need to complete a rulemaking to amend or rescind the regulation, which would require an additional investment of agencies' resources and public input. If the Department cannot complete this extensive process within the final rule's timeframes, the regulations would then automatically expire. In addition, after that lengthy process, the Department would likely then need to revise guidance documents associated with both expiring regulations and regulations still in effect.

It appears that the SUNSET final rule made at least two errors in its justification for establishing this mandatory review process. First, based on the preliminary regulatory impact analysis for this proposed rule, it appears to have miscalculated the extent of the resources needed for this undertaking. In particular, we now believe that HHS underestimated the costs of complying with the rule at least by a factor of four. Second, and

relatedly, it assumed that regulations would not simply expire. *See, e.g.*, 86 FR 5710 ("HHS does not intend to allow a regulation to simply expire"); *id.* at 5712 ("the Department is committed to dedicating adequate resources to timely Assess and Review its regulations"); *id.* at 5714 ("the Department intends to timely complete the necessary Assessments and Reviews and has built in safeguards to mitigate the risk of inadvertent expiration"). Preventing the automatic expiration of regulations, however, would require prioritizing retrospective review above many other Department programs and missions. Based on our reconsideration and expert judgment, we no longer consider that resource prioritization to be in the best interests of the public health and well-being and therefore believe that this assumption—that no regulations would expire—was not well founded.

Because we now believe that the SUNSET final rule underestimated the burden on the Department and its agencies imposed by the regulatory review required by the rule and dismissed the likelihood that rules would expire, it similarly did not adequately acknowledge the difficult resource allocations decisions that the Department would confront in implementing the rule. With its finite set of resources, the Department would be faced with a quandary of how best to triage the needs of its existing programs (as well as new public health priorities) and the new regulatory review process under the SUNSET final rule. On the one hand, given the large scale of resources that would be required to conduct the required reviews, compliance with these new review requirements would lead to the diversion of resources from existing and new priority programs to the detriment of the other programs. This diversion of resources would degrade HHS' capabilities to carry out mission-critical objectives such as protecting the health of Americans, strengthening their economic and social well-being, and fostering sound, sustained advances in the sciences. On the other hand, the automatic expiration of regulations could also undermine mission-critical objectives. The Department's ability to redirect resources may be further complicated by statutory directives regarding programs and their funding as well as difficulties in finding, hiring, training, and transferring personnel to ensure adequate familiarity and technical expertise to conduct the analyses. Our reanalysis of the rule's regulatory impact, and particularly the estimated hours per assessment and

<sup>4</sup> See section IV below.

review, indicates that such staffing measures likely would be needed in order to comply with the rule.

It is not feasible at this time to determine with any specificity how the Department would make these difficult choices on when to divert resources from existing programs, to the extent permitted by statute and logistics, and when to let regulations expire without review. However, as described elsewhere in this proposed rule, we now predict, contrary to the statements in the SUNSET final rule, that it is very likely that some regulations will automatically expire without substantive review.

This quandary has several implications. Both the potential for automatic expiration of rules, as well as the diversion of resources from existing regulatory programs, would create regulatory uncertainty, and that uncertainty could have several negative repercussions for stakeholders, including interference with planning, contracting, and product development. Further, the actual expiration of regulations could lead to confusion among stakeholders, undermine predictability and confidence in many sectors regulated by the Department, and could harm the public health in numerous ways, discussed in greater detail below.

Commenters suggested that the legal analysis in the SUNSET final rule wrongly concluded that the final rule was consistent with the APA's requirements. As discussed further below (in section V.D), under the APA, HHS must consider the relevant factors and provide an adequate basis and explanation in the rulemaking record for its decision. Commenters asserted that the Department did not adequately consider the potential harms of each affected regulation automatically expiring, such as the facts and circumstances that would no longer be addressed upon automatic expiration of that regulation. In light of that absence, among other things, there may be a plausible argument that HHS's justification was inadequate under the APA.

The SUNSET final rule is also based on policies that are contrary to several policy goals of the current Administration. The SUNSET final rule cited for support an Executive Order entitled "Reducing Regulation and Controlling Regulatory Costs" (E.O. 13771), which placed limits on agencies' ability to issue new regulations. 86 FR 5696 (citing 82 FR 9339 (Jan. 30, 2017)). President Biden, on his first day in office, issued an Executive order entitled "Revocation of Certain Executive Orders Concerning

Federal Regulation," which revoked E.O. 13771.<sup>5</sup> 86 FR 7049 (Jan. 25, 2021) (E.O. 13992). As stated in E.O. 13992, the current Administration's policy is to equip executive departments and agencies with flexibility to use available tools such as robust regulatory action to confront the urgent challenges facing the Nation, including the coronavirus disease 2019 (COVID-19) pandemic, economic recovery, racial justice, and climate change. Accordingly, E.O. 13992 revoked "harmful policies and directives that threaten to frustrate the Federal Government's ability to confront these problems and empowers agencies to use appropriate regulatory tools to achieve these goals." *Id.*

Upon review, we now believe that the burdens imposed by the SUNSET final rule could undermine the Department's ability to fulfill its public health and human services missions, promote national priorities, and confront the challenges facing the nation—contrary to the policies expressed in E.O. 13992. Although the Department is committed to exploring ways to improve its processes for conducting retrospective reviews under the Regulatory Flexibility Act (RFA) and identify and retire obsolete rules, the approach in the SUNSET final rule appears to go beyond what is needed to meet those objectives, as noted by several commenters at the Public Hearing. *See, e.g.*, Public Hearing Transcript, Comments by the Consumer Federation of America, American Frozen Food Institute, and Disability Rights New Mexico. In essence, the SUNSET final rule would likely have led to a sharply diminished role for the Department in providing Federal leadership in public health and human services, a position with which the current Administration fundamentally disagrees.

Based on the many comments opposing the rule, the SUNSET final rule also appears to undercut the policy expressed on the first day of the current Administration in E.O. 13985 entitled "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," which lays out the current Administration's policy for the Federal Government to "pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality." 86 FR 7009 (Jan. 25, 2021). In addition, on January 26, 2021,

<sup>5</sup> The SUNSET final rule also cited "Regulatory Relief To Support Economic Recovery," (May 19, 2020) (E.O. 13924), which was revoked in Executive Order 14018. 86 FR 11855 (Feb. 24, 2021).

the current Administration issued a "Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships," directing the heads of executive departments and agencies to make respect for Tribal sovereignty and self-governance, commitment to fulfilling Federal trust and treaty responsibilities to Tribal Nations, and regular, meaningful, and robust consultation with Tribal Nations cornerstones of Federal policy pertaining to American Indians and Alaska Natives. 86 FR 7491. The current administration also issued an E.O. titled "Strengthening Medicaid and the Affordable Care Act," 86 FR 7793 (Feb. 2, 2021) (E.O. 14009), states that it is the policy of the Biden-Harris Administration for the Federal Government to protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American. The E.O. directs HHS, among others, to examine its regulations, policies, and the like to ensure that they are consistent with the policy of providing high quality and accessible health care for all, and do not undermine protections for people with pre-existing conditions under the ACA, reduce coverage under or otherwise undermine Medicaid or the ACA, or undermine the Health Insurance Marketplace or the individual, small group, or large group markets for health insurance in the United States.

If implemented, we now believe that the SUNSET final rule could negatively impact diverse groups of stakeholders, including historically underserved, marginalized, and adversely affected communities, and undermine the Department's public health mission. For example, as discussed in more detail below, numerous commenters expressed concern about the anticipated impacts on various populations including children, the elderly, the disabled, those living in poverty, and communities marginalized by racism and prejudice, who could lose eligibility for programs and services if the regulations underpinning the eligibility requirements were to expire. Public commenters, including Tribes and tribal representatives, assert that the SUNSET final rule would threaten the regulatory underpinnings of the Indian health system, completely disrupt the ability of that system's mission to provide care to tribal communities, undermine the delivery of HHS public health and social service programs for tribal members, and generate a level of uncertainty that is the antithesis of the goals of the HHS Tribal Consultation

Policy.<sup>6</sup> Furthermore, HHS now acknowledges that the SUNSET final rule does not provide for advance notice of regulations that might automatically expire, which we believe conflicts with the Department's policy to engage in meaningful consultation with Tribal Nations.

#### IV. Legal Authority

The primary statutory authorities supporting this proposed rule are the general rulemaking authorities for the various substantive areas under the Department's umbrella, as well as a general provision authorizing agencies to issue regulations regarding the administrative processes to be followed by that agency. These include:

- Section 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 371(a), which authorizes the Secretary to "promulgate regulations for the efficient enforcement of [the FD&C Act], except as otherwise provided in this section;"

- Section 215 of the Public Health Service Act (PHS Act), 42 U.S.C. 216, which provides that "The Surgeon General, with the approval of the Secretary, unless specifically otherwise provided, shall promulgate all other regulations necessary to the administration of the Service[ ];"

- Section 1102 of the Social Security Act, 42 U.S.C. 1302, which provides that the Secretary "shall make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [they are] charged under this Act;"

- Section 1871 of the Social Security Act, 42 U.S.C. 1395hh, which provides that "the Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title;"

- 42 U.S.C. 2003, which provides that "the Secretary of Health and Human Services is also authorized to make such other regulations as [they] deem desirable to carry out the provisions of this subchapter [transferring to the Indian Health Service (IHS) the authority to provide health care services to American Indians and Alaska Natives];" and

- 5 U.S.C. 301, which provides that "[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and

performance of its business, and the custody, use, and preservation of its records, papers, and property. This section does not authorize withholding information from the public or limiting the availability of records to the public."

Congress' grant of broad, discretionary rulemaking authority necessarily includes the authority not to promulgate—and therefore also to withdraw or repeal—a proposed or final rule. *See Natural Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1045 (D.C. Cir. 1979); *see also* 5 U.S.C. 551(5) (defining "rule making" to include formulating, amending, and repealing a rule).

#### V. Explanation of Proposed Rule To Withdraw or Repeal the SUNSET Final Rule

The Department proposes to withdraw or repeal the SUNSET final rule based on the following concerns: (A) Implementation of the rule could create burdens on the Department and on stakeholders that would divert resources from pressing public health matters and thus harm the public; (B) both the possibility of automatic expiration of HHS regulations, and the actual expiration of HHS regulations, could harm the public; (C) the final rule may be harmful to small entities, inconsistent with Congress' intent in enacting the RFA, and unnecessary to achieve the RFA's objectives or to incentivize the Department to conduct reviews of regulations; and (D) ambiguity in the definitions and exceptions in the final rule may increase the burden of the regulation and the risk of regulations automatically expiring. In addition, questions were raised as to whether the final rule is consistent with the APA, which merit further consideration.

##### A. Implementation Burdens on the Department and Stakeholders

###### 1. Burden on the Department

The framework set forth in the SUNSET final 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. As explained in more detail below, these harms are likely to be greater than any benefits of the retrospective review framework in the SUNSET rule. Although the SUNSET final rule acknowledged the submission of a large number of comments stating that the rule would burden the Department, divert its personnel resources, and adversely affect the Department's ability to

administer programs, and issue and modify regulations, the final rule essentially concluded that these concerns were outweighed by its finding that "widespread retrospective review is a worthwhile enterprise." 86 FR 5705. As previously discussed, that finding was predicated on what we now believe to be a flawed understanding of the regulatory impact of the rule. Our reanalysis of the burden of the SUNSET rule fundamentally alters any evaluation of the merits of the rule and gives new force to the comments concerning the burden. Also, as discussed, this Administration has different policy goals than the previous Administration, and these differences impact how these various issues, concerns, and goals are weighed. We now believe that the SUNSET final rule did not give sufficient consideration and weight to the large number of comments, discussed immediately below, raising concerns regarding the burdens on the Department's ability to effectively carry out its missions.

Numerous commenters opposed the proposed rule out of concern that the burden and the diversion of resources to assessments and reviews would negatively impact public health activities. Several commenters referred to the burden imposed on the Department as "undue," "unreasonable," "unnecessary," "onerous," and "misguided." In response to these comments on the proposed rule, the SUNSET final rule attempted to minimize these concerns by extending the period for the automatic expiration of regulations from two to five years, and ultimately concluded that its retrospective review scheme is sensible "even if it takes some time away from issuing new regulations." 86 FR 5705. We now believe that assertion rested on a flawed understanding of the resources required to implement the SUNSET final rule. The rule did not explain how HHS could devote numerous employees to full-time retrospective review without compromising the Department's and its sub-agencies' many other crucial tasks, such as protecting the country from future pandemics or other public health emergencies. We now believe that the SUNSET final rule underestimated the rule's regulatory impact and failed to appreciate the scope of its effects on the Department, including that the rule could compromise some of the Department's most important initiatives.

Commenters also emphasized particular apprehension about the impact of the rule on the Department's ability to address public health emergencies such as COVID-19 and the

<sup>6</sup> U.S. Department of Health and Human Services, HHS Tribal Consultation Policy (December 12, 2010) (available at <https://www.hhs.gov/about/agencies/iea/tribal-affairs/consultation/index.html>).

opioid crisis. The SUNSET final rule ultimately concluded that the new retrospective review requirements would not hamper the response to the pandemic because by that time the COVID-19 Public Health Emergency “is likely to have subsided.” 86 FR 5748. However, as explained further below, many commenters expected that implementation of the rule—by diverting staff and resources—would create immediate disruption to programs essential to the COVID-19 response for patients, beneficiaries of HHS health programs, and the larger health system. Commenters also expected that these demands would continue to evolve during the remainder and aftermath of the current pandemic, and noted that the same problems could occur with other public health emergencies in the future. Bolstering the commenters predictions, the trajectory of the COVID-19 pandemic seems far less certain than when the SUNSET final rule was published.

HHS has reconsidered these comments and now believes that the Department must continue to remain flexible and focused on the management and utilization of HHS resources to address COVID-19 and its impacts as well as future public health emergencies. The challenges of the continued current public health emergency suggest a risk of future harm because the SUNSET rule provides no good cause exception to avert the expiration of a regulation in the event of a pandemic, a public health emergency, or another declared national emergency. Although the final rule added a provision to permit the Secretary to extend the period for assessments and reviews, the extension can only be applied one time, for up to one year, per each section of regulation, and the extension can only be exercised through a determination published in the **Federal Register**. 86 FR 5725. Given the brief extension available for the assessment and review and the potential duration of an emergency (as evidenced by the current 18-month plus duration of the COVID-19 pandemic), the final rule was likely incorrect to conclude that this option would be sufficient to avoid the diversion of resources and the automatic expiration of regulations in the event of a pandemic, emergency, or other development that prevents the Department from timely assessing or reviewing certain sections. *Id.* at 5726.

As noted in public comments, the SUNSET final rule imposes multiple types of burdens on the Department. First, the rule’s assessment and review processes have substantial resource implications. Such processes require

Department evaluations of regulations based on certain criteria, which would involve information collection and analysis (potentially including public notice and comment, and OMB review and approval, under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*), engagement with subject matter experts, and consultation with state and local jurisdictions and Tribes. In addition, the Department would need to solicit and consider public comment related to those evaluations, participate in interagency review, and publish results in the **Federal Register**, including the full underlying analyses and data used to support the results.<sup>7</sup> Completing these steps for the thousands of regulations currently issued by the Department, and for future regulations, would be a colossal undertaking on any timeframe. But the SUNSET rule requires these processes on a compressed timeframe, meaning many assessments and reviews would need to occur simultaneously, thereby compounding the impact. Data collection may be infeasible under the timeframes required under the rule, which could compromise the quality and completeness of the work. As noted in the final rule, approximately 12,400<sup>8</sup> of the Department’s estimated 18,000 sections in the CFR are over ten years old, and each of these are regulations that could automatically expire five years after the SUNSET final rule’s effective date unless assessment and, as applicable, reviews are completed.<sup>9</sup> For example, under the timeline and definitions provided in the final rule, over 7,000 sections of the CFR that were promulgated by the FDA are more than ten years old, or would become more than ten years old during the first five years the rule would be in effect, representing over 95 percent of this agency’s current regulations. Although there are limited categorical exceptions and some specific regulations excepted from the rule, the enumerated exceptions are very limited and likely would not make a meaningful difference in the burden on the agency, including because HHS has yet to assess the applicability of these exceptions.<sup>10</sup>

<sup>7</sup> These analyses and data would need to be reviewed in light of any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure, thereby adding to the burden.

<sup>8</sup> 85 FR 5705.

<sup>9</sup> The SUNSET final rule defines “Section” as “a section of the Code of Federal Regulations” and provides the following example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (*see* 1 CFR 21.11). 86 FR 5751.

<sup>10</sup> In addition, based on a count from an HHS website that provides a listing of the rulemakings promulgated by HHS and includes the date that

Furthermore, this burden is recurring. As soon as the Department reviewed all the current rules, it would start having to review them again within a 10-year timeframe. And the expertise needed to conduct assessments and reviews and achieve the pace and scope set forth in the rule would require a reallocation of staff including subject matter experts, regulatory counsels, economists, and attorneys. This reallocation effort alone would entail a significant burden and would draw resources away from other public health and welfare activities.

Second, if a review concludes that a regulation should be amended or rescinded, the rule requires the Department to amend or rescind the regulation within two years of the date that the review results are published. The development of regulations is a deliberative and resource-intensive process that requires consideration of a wide range of factors, including current relevant facts, statutory obligations, and public-health and -welfare goals. Requiring the Department not only to assess and review its regulations, but also to amend or rescind them (in applicable circumstances) on a specific timeframe, amplifies the burden on the Department.

Third, as discussed further below, the SUNSET final rule contains ambiguities that would need to be clarified in order to operationalize the rule. This creates another hurdle to implementing the SUNSET final rule that is separate from the assessment, review, and rulemaking requirements. For example, under the rule, it is not clear when certain regulations would need to be assessed and whether the regulation falls within a categorical exception. The Department would need to develop processes and standard operating procedures to try to bring consistency and transparency to this process. While the Department expressed an intent to create a dashboard for monitoring assessments and reviews, the development,

each regulation was first issued in title 21, title 42, and title 45 of the CFR, U.S. Department of Health and Human Services, *List of HHS Rulemakings by Date of Promulgation* (available at <https://www.hhs.gov/regulations/federal-registry/index.html>), over 3,000 sections of the CFR were promulgated by HHS before the enactment of the RFA in 1980, which required the rulemaking process to include an analysis of whether regulations have a significant economic impact upon a substantial number of small entities (SEISNOSE). Although the final rule acknowledges that additional resources would be needed to review regulations that predate the RFA, the rule does not reflect the additional work to assess these regulations to determine if a review is necessary. For older regulations enacted before the RFA that are not otherwise exempt from the rule, the assessment phase would not necessarily have analysis or information from the original rulemaking record to inform an assessment.

monitoring, and updating of this dashboard would add to the burden on HHS. Collectively, these activities would likely delay the initiation of assessments and further strain the Department's ability to prevent regulations from automatically expiring.

Fourth, the SUNSET rule imposes on HHS the task of determining where to redirect resources to support assessments and reviews and thereby preserve regulations. Multiple, complex considerations would likely be relevant to this effort, including public health and legal considerations. Furthermore, to the extent that any regulations would expire under the SUNSET final rule—which the Department now predicts would be likely—HHS would need to consider how to prioritize its assessment and review processes to manage that risk. Overall, the economic and workforce burdens imposed on the Department by the SUNSET final rule are significant.

As noted above, commenters opposed to the rule expressed concern that the diversion of resources would disrupt public health activities and social service programs administered by specific HHS operating divisions. For example, commenters expressed concern that, in order to review or assess regulations within the rule's timeframe, FDA staff could be diverted from the review of medical product applications, food additive petitions, efforts to promote medical product innovation, competition, and access to medicine, and the regulation of the food and medicine supply for humans and animals. Commenters also described impacts on the administration of HHS social services programs, expressing concern that there will not be enough time and staff to efficiently review regulations and to serve citizens at the same time, including those who depend on safety net programs under the auspices of the ACF such as Head Start and the Low Income Home Energy Assistance Program. Multiple commenters who advocate for mental health issues also opposed the diversion of staff resources away from programmatic work that addresses inequities in access to health and mental health care.

Commenters nationwide who represent state and county health departments, as well as legal and social service organizations who advocate for beneficiaries, individual beneficiaries themselves, and concerned citizens, expressed concern that the CMS would be hampered in the day-to-day administration of public health programs for millions enrolled in the Children's Health Insurance Program

(CHIP), Medicaid, and Medicare. Some noted the burden of retrospective reviews could put a strain on the administration of the Affordable Care Act (ACA) and the development of new regulations and guidance to: Support health care coverage, innovation, and competition; enhance patient safety; and combat waste, fraud, and abuse. Commenters representing Federally Qualified Health Centers (FQHCs) expressed opposition to the rule because it would result in the diversion of resources from programs that support particular populations served by FQHCs such as Community Health Centers, Migrant Health Centers, Health Care for the Homeless, and Health Centers for Residents of Public Housing. Commenters representing or affiliated with American Indians and Alaska Natives described the potential impact of resource diversion from the administrative and operational activities of the IHS, which could diminish access to critical safety net programs for American Indians and Alaska Natives and decrease programmatic staff available to administer programs that provide critical protections for tribal youth. Some commenters also noted that the focus on the activities required by the SUNSET rule would impair the Department's ability to issue new regulations that would modernize the healthcare system, improve service delivery, and promote equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty.

Therefore, based on review of these comments and the Department's new cost estimates for the SUNSET rule, HHS now believes that the SUNSET final rule may have significantly underestimated the burden on the Department resources to comply with the rule and incorrectly evaluated the Department's ability to expend the necessary resources to prevent the automatic expiration of regulations. The Department also thinks it likely that these burdens would result in the diversion of significant resources from other HHS initiatives and priorities. The Department now believes that the harm and the costs resulting from this diversion are likely greater than any benefits of the retrospective review framework in the SUNSET rule. Department initiatives are each intended to further the health and well-being of Americans. Often, these respond to the most pressing issues of the day, which are diverse and range from foodborne illness to the opioid crisis to the COVID-19 global pandemic

to dealing with humanitarian crises, such as the care and custody of unaccompanied children at the border. Redirecting resources away from these types of initiatives in order to fully implement the SUNSET rule could mean neglecting the areas of greatest public health need, contrary to the Department's mission. As discussed above, many commenters identified examples of important programs threatened by the diversion of resources of SUNSET final rule, and the Department agrees with those examples. Ultimately, the Department no longer believes that the analysis of existing regulations, which may have little practical effect in many cases, should be elevated over HHS's other important regulatory initiatives.

## 2. Potential Burden on Stakeholders

HHS has also reexamined the burden the SUNSET final rule places on stakeholders to prevent the automatic expiration of regulations and the final rule's estimation that "the cost of monitoring Assessments will be relatively trivial." 86 FR 5744. The final rule describes "safeguards to mitigate the risk of inadvertent expiration," such as enabling the public to submit comments requesting that the Department commence an assessment or review, and making a dashboard that would be available on an HHS website that would enable stakeholders to monitor the status of assessment and reviews of regulatory sections that may expire. *Id.* at 5714. Various public commenters, however, opined that it is inappropriate and unfair to place such a heavy burden on the public. More than one commenter posited that the automatic expiration of regulations resulting from the Department's failure to complete assessments and reviews would constitute a penalty to the regulated, and not the regulators.

Many commenters opposed to the rule expressed concern that the monitoring burden would be overwhelming, particularly for health care providers, public health advocates, caregivers, and beneficiaries, among other stakeholders, who would have to divert time and effort from providing direct health care. In addition, commenters representing a wide range of industry stakeholders anticipated a higher burden on small entities that would not have the personnel and resources to both monitor the status of thousands of regulations being assessed contemporaneously, and simultaneously provide comments about data and information that should be considered in an assessment or review. Similarly, commenters expressed concern that members of the

general public would not have the ability or awareness to participate in the process envisioned, so that the construct would favor well-funded special interests who would have the resources to hire lawyers and lobbyists to advocate for their favored outcomes. Several commenters associated with trade associations and advocacy organizations described the immense effort that would be needed to engage organization membership and to research, draft, review, and submit consensus-driven comments with members and partner organizations. Some commenters noted that they expected the monitoring process to be chaotic as stakeholders seek the Department's prioritization of the assessment or review of regulations they are concerned might expire.

The Department believes that any retrospective review process should not impose an undue burden on the public. Based on these comments and the Department's new cost estimates for the SUNSET rule, the Department now believes that the SUNSET final rule likely underestimated the burden on stakeholders to monitor and comment on potentially expiring regulations.

#### *B. Potential Harm From the Possible and Actual Expiration of Regulations*

##### 1. Potential Harm From Uncertainty

HHS has given further consideration to the harms to the public health from the regulatory uncertainty created by the SUNSET final rule. Because of the above-described substantial burdens imposed on the Department by the breadth and scope of the regulatory review process required by the SUNSET final rule, the Department now acknowledges that, despite statements in the final rule that HHS did not intend to allow any regulations to simply expire, *see, e.g.*, 86 FR 5710, it is unrealistic to assume that no regulations would automatically expire as a result of the final rule. In fact, given the complicated resource allocation decisions discussed above, HHS is unable to forecast the number or identity of specific regulations that may expire without a completed review and assessment. It may therefore be difficult for stakeholders to know which regulations will remain in place because that will depend on whether the Department will actually be able, and will choose, to complete each regulation's assessment and/or review by the assessment or the review deadline. The potential automatic expiration of large swathes of rules, or even one complex rule, without a

reasoned justification such as a change in the governing law or a change in circumstances, could create uncertainty and unpredictability regarding regulatory programs going forward.

Several commenters supported the Department's efforts to explore ways to improve its processes for conducting retrospective reviews to reassess, update, and amend regulations. As discussed further in section V.3.C., HHS already exercises its authority to conduct retrospective reviews, and comments suggested improvements to achieve the goals of retrospective review productively and efficiently. However, as the comments explained, there is a stark difference, particularly from a planning standpoint, between thoughtful reconsideration of individual rules, with stakeholder participation and a reasoned justification, and automatic expiration of rules from lack of sufficient resources (by either or both stakeholders and the Department). Rather than the current baseline assumption that regulations will remain the same, absent a specific notice providing a basis for possible change, the new baseline would be uncertainty regarding the future validity of numerous regulations.

Commenters explained that the uncertainty created by the potential automatic expiration of countless rules could have numerous repercussions for stakeholders and for the public health. Public commenters explained the importance of a relatively steady regulatory environment. For example, several commenters explained that rules that implement HHS policies and programs, such as Medicaid and CHIP, establish the national standards for Federal/State partnership programs, so that States in turn can design processes and run programs on a day-to-day basis based upon these standards. Predictable and reliable communication and guidelines facilitate effective implementation of these programs, so that providers can understand what their obligations are, and beneficiaries can understand what they are entitled to receive. Further, many participants in the health care ecosystem have structured their financial arrangements and business operations to satisfy the myriad conditions set forth in the current regulations. The uncertainty regarding the future of those regulations could upset the assurance of regulatory continuity underlying those arrangements and therefore disrupt planning and entering into longer-term commitments. And, for programs that rely on Federal funding, commenters asserted that potentially expired regulations could impact the ability to apply for, or receive, funding sources

governed by those rules, which in turn would disrupt longer-term planning.

Commenters also contended that the increased unpredictability of the future of regulations under the SUNSET final rule would impede product development and innovation. Commenters asserted that uncertainty in regulation would be particularly harmful for drug development: Because new therapeutic products may require decades to develop and review, and because this process is expensive, drug sponsors rely on a predictable regulatory environment to plan their development programs. For instance, FDA has extensive regulations that address standards for clinical trials and premarket submissions, requests for orphan designation, patent term restoration, and exclusivity determinations. Although statutory provisions govern these programs, the statute does not specify in detail the substance or processes for these premarket submissions. As a result, the potential for expiration of the regulations, which clarify the application pathway and requirements, could curtail drug development, including progress on cancer therapies and therapies for those with unmet medical needs. Similarly, one commenter noted that the development of digital health care platforms typically takes 5 to 10 years, and the developers will need to understand the regulatory environment in which they will be developing their business. Another commenter asserted that investments are made in industrial biotechnology innovations based on the assumption that regulations will be in place for at least 10 years; consequently, some emerging industrial biotechnology companies will have difficulty finding investors in the face of regulatory uncertainty. Thus, as one commenter opined, "[i]nstead of innovation, this rule could easily lead to stasis."

We question whether the SUNSET final rule adequately considered the potential costs of regulatory uncertainty created by the rule. The final rule states that it "does not believe uncertainty among the regulated community will add significantly to the costs of this rulemaking" because "there is always a possibility that regulations could be amended or rescinded, even absent this rule." 86 FR 5709. HHS now believes the final rule's automatic expiration of regulations could instead be more haphazard and unpredictable, and therefore more disruptive, than the existing possibility of targeted changes to regulations based on a reasoned justification such as a change in the

governing law, technology, or other circumstances.

The Department also notes that E.O. 13563, "Improving Regulation and Regulatory Review," which the SUNSET final rule cited for support, includes among general principles of regulation that our regulatory system "must promote predictability and reduce uncertainty."<sup>11</sup> Upon reconsideration of the comments received, we now believe that, by introducing significant uncertainty about whether regulations will expire, the final rule may undermine these objectives.

## 2. Potential Harm From the Actual Expiration of Regulations

After further consideration, HHS believes that, because the SUNSET rule failed to appropriately consider the likelihood that any regulations would expire, it likewise did not take into account the harm to stakeholders and the public health that could result from regulations expiring. The resources needed to prevent the automatic expiration of regulations are now estimated to be significantly higher than identified in the SUNSET final rule. Given statutory spending directives and other statutory obligations, it could be difficult, and in some cases prohibited, for the Department to redirect sufficient resources to prevent expiration of certain HHS regulations. Further, any attempt to divert the amount of resources necessary to prevent the expiration of regulations would degrade HHS' capabilities to carry out mission-critical objectives such as protecting the health of Americans, strengthening their economic and social well-being, and fostering sound, sustained advances in the sciences. As a result, these constraints make it likely that regulations could expire without review.

This expiration is unlike the standard processes that agencies undertake to change rules. In general, it is more common for rules to be amended to account for a change in statutory authority or change in relevant circumstances; they are not simply rescinded in their entirety without a rule-specific justification or an opportunity for the public to comment on that justification, including identifying harms associated with the repeal.

Because the final rule did not acknowledge the substantial risk of expiration of regulations, it did not examine the wide array of harmful effects that could arise in this situation including: Causing serious harm to

millions of stakeholders who rely upon HHS programs, including underserved populations; upending established understandings across the public health spectrum as to how to comply with statutory requirements; and disrupting established industry standards that protect public health, create a level playing field for businesses, and boost consumer confidence.

The breadth and complexity of some regulatory programs with interdependent regulatory provisions, and their integration into programs run by State and local authorities, could magnify the repercussions of many automatically expiring regulations. For example, as one commenter explained, Medicare is the largest payor in the U.S. health care system and the largest piece of a system comprised of thousands of interlocking moving parts; thus, the entire health care system is impacted by the Medicare program and therefore relies on Medicare regulations to function. The Medicare regulations were not contemporaneously enacted and therefore are subject to different potential expiration dates under the SUNSET final rule. If some individual Medicare regulations not subject to exceptions in the SUNSET final rule begin to expire, it could be difficult for regulated entities to disentangle the downstream effects to ascertain the remaining regulatory requirements. The expiration of these regulations also increases the potential for bad actors to try to exploit the lack of regulations, potentially resulting in increased fraud and abuse.

Commenters explained that the confusion about what, if any, standards would govern in the event of a lapse in Federal regulations is likely to result in significantly increased regulatory complexity and implementation. Another commenter predicted that, if States will be directed to abandon expiring rules, and/or to suddenly implement new interpretations of statutory requirements in the event regulations automatically expire, they will be faced with enormous administrative costs such as computer system upgrades, staff training, amended services contracts, and public education on new requirements.

Commenters provided numerous examples of harms to stakeholders and the public health that could arise from the actual expiration of regulations. States Attorneys General commented that States depend on HHS to administer trillions of dollars in Federal funding to support their healthcare systems and the health and safety of their residents, which would be disrupted by the expiration of

regulations. Many commenters expressed particular concern about the anticipated impacts on various communities including children, the elderly, the disabled, those living in poverty, the LGBTQ community, patients living with HIV/AIDS, tribal members, communities of color who are often more reliant upon HHS programming as a result of systemic racism, and people who live in rural areas who rely more heavily on federally funded HHS programs. According to the commenters, these individuals will suffer worse outcomes in terms of health and well-being if they were to lose eligibility for programs and services upon expiration of regulations. This loss in program coverage could in turn increase the economic costs to public assistance organizations, which would need to devote more time, energy, and resources to finding ways to assist individuals absent these protections from the Federal Government.

For example, commenters asserted that implementation of Medicaid and the ACA depends heavily on regulations to clarify coverage requirements, program implementation, and the obligations of state programs serving people with low incomes. As discussed above, Federal regulations play an important role in HHS' partnership with States in implementing Medicaid, which, as one commenter described, has helped communities respond to economic downturns, natural disasters, epidemics, and public health emergencies since the program was enacted in 1965. Another commenter described the importance of detailed Federal regulations in implementing the accountable care organization program, which increases the quality of care for Medicare beneficiaries while reducing unnecessary costs, and that expiration of the governing regulations would interfere with those program goals. Another example included regulations that protect Medicare beneficiaries from misleading and high-pressure marketing tactics; expiration of those regulations could end compliance and enforcement actions against these bad actors. If the governing regulations were to expire, HHS programs and other programs reliant on HHS regulations might be free to operate without standards, consistency, or accountability, which could lead to real harm to, for example, the millions of children who rely on those programs. Similarly, advocates for HIV services commented that the SUNSET rule's potential to cause confusion over the validity and enforceability of Medicaid regulations

<sup>11</sup> 76 FR 3821 (January 21, 2011).

could lead to service and coverage delays, which, for people with HIV, can be detrimental, causing irreversible disease progression and prescription drug resistance. Commenters expressed concern regarding the expiration of other programs that support particular populations, which expiration could be devastating for the populations they serve.<sup>12</sup>

Numerous tribes and tribal organizations commented that the Indian health system relies on a number of regulations that tribes have worked for decades on with the Department to promulgate on a government-to-government basis. These include the regulations governing the IHS, Tribal Self-Governance, and Indian specific provisions in the Medicaid, Medicare, CHIP, and ACA Health Insurance Marketplace regulations. Commenters asserted that the SUNSET final rule would threaten the regulatory underpinnings of the Indian health system and completely disrupt the ability of that system's mission to provide care to tribal communities.

Other commenters asserted that HHS regulations are essential to maintaining consumer confidence in the Nation's supply of consumer products, as well as a level playing field among industries. Some commenters noted that there are many rules setting industry standards that have remained untouched for years—not through neglect—but because they work as intended. For example, as described in several comments, the food industry relies on FDA regulations to provide clarity on statutory requirements, to maintain relationships of trust between all

members of the supply chain, to protect public health by providing safe and nutritious food, and to support both domestic consumer and worldwide confidence in the safety of the U.S. food products. Under the FDA Food Safety Modernization Act (FSMA), FDA over the last decade has promulgated, with considerable stakeholder input, an extensive set of detailed regulations governing prevention of foodborne illness throughout the production and delivery in the global food supply. Industry members have devoted significant resources to develop food safety plans consistent with the new regulations and in many instances have made significant capital investments in equipment, personnel, and facilities. Expiration of the FSMA regulations (while FSMA's statutory obligations remain in effect) could create confusion and uncertainty with regard to what standards apply, particularly because the statute required rulemaking for implementation and interpretation of the food protection provisions. It also could create inefficiencies given the time and resources that have been invested by the industry in recent years to ensure the highest levels of compliance.

In addition to food safety regulations, commenters identified other longstanding food regulations—involving nutrition and food labeling and food ingredients—that set essential standards for the food industry. A food manufacturing association asserted that, if food regulations are rescinded, consumers may become distrustful of the U.S. food supply and, as a result, individual States might feel the need to pass their own laws and regulations, meaning manufacturers would have to comply with a patchwork of potentially conflicting new rules. Compliance with a patchwork of State rules nationally can be costly to industry, and those costs may be passed to consumers or may put food companies out of business, reducing competition and consumer options. Additionally, another commenter asserted that any loss in confidence in the safety of U.S. pet food could result in lost sales and new requirements by foreign regulators seeking assurances that the pet foods they import from the U.S. are safe.

Many other effective regulations, some of which are decades old, bring similar efficiencies to the industry by clarifying applicable statutory obligations. As a commenter explained, heavily regulated manufacturers benefit from regulatory certainty that provides clarity for manufacturers and fosters consumer confidence that the products are properly regulated. By contrast, if

the regulations expire, disreputable companies will be tempted to cut corners to gain economic advantage over responsible companies, with the risk that consumers will be harmed and will lose confidence in the products. For example, as another commenter explained, color additive regulations, many of which are decades old, are fundamental to the industry's operation in the U.S., and provide confidence that color additives are safe in food, drugs, cosmetics, and medical devices. The expiration of those regulations could lead to significant confusion.

Commenters also explained that FDA issues many regulations relating to food, drugs, devices, cosmetics, and tobacco products that are essential to protecting the public health. To list just a few additional examples, these regulations provide: Safety standards for the blood supply, access to investigational treatments, protection of clinical trial participants, protection from harmful tobacco products, and good manufacturing practices that are the linchpin of many product supply chains. The expiration of these regulations could mean that regulated entities would be unsure how to comply with long-standing statutory requirements and may no longer be compelled to comply with long-standing safety standards.

Commenters also raised concerns that the SUNSET final rule could impede responses to public health emergencies. For example, the regulations established in 2006 to implement the Pandemic and All Hazards Preparedness Act took years to develop and have been essential to addressing the COVID-19 pandemic. The expiration of those rules could leave the Department unprepared to respond to future emergencies and result in unnecessary human suffering and loss of life.

HHS now believes that commenters have raised credible concerns that the SUNSET final rule would likely result in actual expiration of regulations and that these expirations would adversely impact them. Although these comments were raised regarding the SUNSET proposed rule, the SUNSET final rule discounted their seriousness, and did not give them sufficient consideration and weight. *See* 86 FR 5709. As discussed in greater detail elsewhere in this preamble, we now believe that the rejection of these comments was in error because, given the resources demands that would be required by the SUNSET final rule, the likelihood that regulations would automatically expire is high. Moreover, the potential automatic expiration of regulations would be contrary to the Department's role as the

<sup>12</sup> Specific HHS programs identified to be at risk included: The Health Care Program; Low Income Energy Assistance Program; Temporary Assistance to Needy Families; Early and Periodic Screening, Diagnostic and Treatment; Indian Child Welfare Act; Child Care and Development Fund; the Administration for Community Living; Child Care and Development Grant; Head Start; Early Head Start; Maternal Infant and Early Childhood Home Visiting Program; National School Lunch Program; School Breakfast Program; Supplemental Nutrition Program for Women, Infants, and Children; Child and Adult Care Food Program; Summer Food Service Program; Community Mental Health Services Block Grant; Supplemental Nutrition Assistance Program; the Refugee Resettlement Program; and Medicaid Waiver programs including: The Children's Autism Home and Community-Based Services Waiver Program; Adult Residential Waiver; Community Living Waiver; Adult Supports Waiver; Home and Community-Based Services Waiver for Persons with Traumatic Brain Injury; and the Frail Elder Home and Community-Based Services Waiver. More generally, commenters identified regulations protecting particular populations including those concerning Medicaid conditions of participation for nursing homes, substance use and addiction treatment and prevention programs, mental health services, access to childcare, foster care, adoption, and family violence services.

U.S. Government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

### C. RFA Considerations

#### 1. Rule Requirements Beyond RFA Requirements

The SUNSET final rule imposes requirements beyond the requirements of the RFA. These additional requirements may not be consistent with Congressional intent. The SUNSET final rule asserts that it “implements Congressional intent for periodic review of regulations” and “closely tracks the RFA’s goal of minimizing undue burden on small entities” 86 FR 5713–5714. Additionally, it asserts that, “assuming full compliance with the RFA, th[e] rule does not impose any additional burden on the Department beyond what was already called for in the RFA” because the RFA “already calls for the Department to assess which of its regulations have a significant economic impact upon a substantial number of small entities, and to review those regulations every ten years.” *Id.* at 5705. Many commenters disagreed with these assertions, and explained that the final rule would impose requirements beyond those set forth in the RFA. HHS remains committed to full compliance with the RFA, but, upon further consideration, HHS believes that the RFA does not require this final rule and finds the commenters’ perspectives for repealing the rule worthy of further consideration.

First, commenters assert that the final rule exceeds the RFA’s express requirements by mandating that the Department conduct assessments of thousands of HHS regulations within certain timeframes. Section 610 of the RFA is focused on the retrospective review of rules identified with a Significant Economic Impact Upon a Substantial Number of Small Entities (SEISNOSE). Section 610 contemplates periodic review of a subset of “rules issued by the agency which have or will have a [SEISNOSE]” and imposes certain public notice and comment procedures for such reviews.<sup>13</sup> Nothing in the express language of the statute requires the Department to conduct assessments of all HHS regulations in order to determine which regulations at time of reassessment have or will have a SEISNOSE. As one commenter noted,

<sup>13</sup> See 5 U.S.C. 610(c) (requiring agencies to “publish in the **Federal Register** a list of the rules which have a [SEISNOSE], which are to be reviewed pursuant to this section during the succeeding twelve months” and “invite public comment upon the rule”).

Congress “does not[ ] . . . hide elephants in mouse holes.” See *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 468 (2001). This principle suggests that it is unlikely that Congress intended to require widespread assessments of thousands of regulations via a requirement that the SUNSET final rule asserted was “implicit” in section 610. See 86 FR 5714. As explained below, commenters and the Small Business Administration (SBA) have identified numerous more targeted, efficient, and effective alternatives for identifying regulations that have or will have a SEISNOSE.<sup>14</sup>

Second, principles of statutory construction do not support a broader reading of section 610 to require agencies to simultaneously consider all regulations and to do so on a recurring basis to determine whether they have or will have a SEISNOSE. Had Congress intended to mandate this broader reading, it would have done so when it enacted the RFA or during any one of the numerous times it has amended the RFA since enactment.<sup>15</sup> This principle holds particularly true for section 610(a) of the RFA, given that the provision explicitly directed a one-time simultaneous review of all SEISNOSE regulations that existed on the date of enactment. See, e.g., *Salinas v. U.S. R.R. Retirement Bd.*, 141 S. Ct. 691, 698 (2021) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983) (“Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”)).

Third, the SUNSET final rule’s requirements for public notice and comment procedures—such as notifying the public on a Department-managed website when it commences the process of performing an assessment, publishing a notice in the **Federal Register** within a month of commencement, and issuing a notice in the **Federal Register** to publish the results of all assessments—appear to extend beyond the RFA’s notice and comment and other requirements for retrospective reviews. HHS agrees with commenters that section 610 requires notice and comment procedures for retrospective

<sup>14</sup> We also note that the RFA expressly includes a goal of avoidance of duplicative or unnecessary analyses. See 5 U.S.C. 605.

<sup>15</sup> See Office of Advocacy, U.S. Small Bus. Admin., *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act 2–3* (Aug. 2017) (available at <https://advocacy.sba.gov/2017/08/31/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/>) (summarizing amendments enacted in 1996, 2007, and 2010).

review, but it does not require notice and comment procedures to determine which regulations have or will have a SEISNOSE.<sup>16</sup> Similarly, the RFA provides no basis for an expedited timeline as specified in the SUNSET final rule for the completion of reviews, which was noted by commenters. Section 610(a) of the RFA provides only that the reviews required under that section be conducted “within ten years” of specific dates.

Fourth, the automatic expiration of any rule issued by the Department simply because it was not timely assessed or, as applicable, reviewed, appears to be contrary to Congressional intent. Section 610 neither provides for automatic expiration of rules with a SEISNOSE nor presumptively applies automatic expiration dates to regulations. Rather, section 610 contemplates informed rescission or revision of rules only if they have or will have a SEISNOSE and if the Department has determined, based on a multi-factor review, that such rules should be rescinded or revised to minimize any SEISNOSE. Additionally, we note that section 611(a) provides a remedy for agency noncompliance with the requirements of section 610: Judicial review of such noncompliance and relief deemed appropriate by the reviewing court.

Fifth, the framework for regulations to automatically expire without any consideration of the statutory objectives the rule implements appears to be inconsistent with the RFA’s intent to

<sup>16</sup> See 5 U.S.C. 610 (specifying factors agencies must consider in conducting reviews of rules that have or will have a SEISNOSE and requiring agencies to publish in the **Federal Register** plans for periodic reviews and a list of rules to be reviewed during the succeeding twelve months as well as invite public comment on rules to be reviewed); see also, e.g., *id.* 603(a) (requiring an initial regulatory flexibility analysis for proposed rules for which a notice of proposed rulemaking is required or published as well as public notice and comment and publication of the analysis); *id.* 604(a)(2), (b) (requiring a final regulatory flexibility analysis for final rules for which a notice of proposed rulemaking was required or published and requiring the analysis to include the agency’s consideration of public comments received and to be published in full or summary form in the **Federal Register**); *id.* 605(b) (permitting an agency head to exempt a rule from the requirements of sections 603 and 604 by certifying that a rule will not have a SEISNOSE and requiring the agency to publish the certification in the **Federal Register** “along with a statement providing the factual basis for such certification”); *id.* 608 (requiring findings supporting a waiver or delay of completion of the requirements of sections 603 and 604 to be published in the **Federal Register**); *id.* 609(a) (with respect to rules that will have a SEISNOSE, requiring agency heads to “assure that small entities have been given an opportunity to participate in the rulemaking for the rule through the reasonable use of techniques such as” publication in certain sources and direct notification of interested small entities).

balance the objectives of the RFA with the objectives of statutes critical to public health. The RFA's legislative history explicitly states that Congress did not intend for the RFA's requirements to "undermine . . . important [regulatory] achievements," specifically those in the area of public health. 126 Cong. Rec. 21,448, 21,451 (August 6, 1980). The legislative history further states that Congress intended "agencies to continue to enforce [substantive] laws in a fully effective fashion," *id.* at 21,451, and that "environmental, health or safety catastrophes must never be made more likely because of flexible regulations." *Id.* at 21,455. Indeed, Congress expressed this intent in section 610 itself by providing that rescission of regulations should only occur if "consistent with the stated objectives of applicable statutes." 5 U.S.C. 610(a).<sup>17</sup>

As described above, commenters argued that the monumental task of assessments would require diverting agency expertise and resources away from the Department's significant public health activities and would likely impair the Department's ability to respond to public health emergencies and administer critical public health programs. Commenters further argued that such results would undermine important public health statutory objectives and increase the likelihood of negative consequences for the public health. The RFA's legislative history explicitly addresses such concerns that the RFA "might require agencies to significantly compromise the objectives of underlying statutes authorizing rulemaking," 126 Cong. Rec. 21,455, and, as noted above, emphasized that "[i]t is not the intent of regulatory flexibility legislation to undermine . . . important [regulatory] achievements," *id.* at 21,451. Commenters also stated that the burden imposed on the Department by the final rule would impair the Department's ability to prevent the automatic expiration of regulations that would be imposed by the final rule, and, as discussed above, the actual expiration of regulations without any analysis would also undermine the objectives of those regulations' authorizing statutes contrary to Congressional intent.

HHS notes that the economic and workforce burdens impairing the Department's ability to achieve important statutory objectives related to

its mission would also be inconsistent with the RFA's intent to enhance administrative efficiency in the achievement of such objectives. The RFA's legislative history emphasizes that "regulatory flexibility should be considered a means of improving administrative effectiveness in enforcing the regulatory statutes which the Congress has enacted rather than an additional bureaucratic burden." 126 Cong. Rec. 21,456. One commenter noted that requiring the Department to conduct analyses of thousands of rules within a compressed time period, in addition to the already complex existing tasks of the Department, is not efficient. Although the final rule asserts that it "will contribute to 'the efficient administration of' the Department's functions . . . because the Reviews called for by this final rule will take into account both the continued need for particular regulations, as well as whether the burden of those regulations on small entities can be minimized," 86 FR at 5719, HHS now believes that the final rule could introduce greater inefficiencies if rules expire without any assessment or review of the need for the regulation or the impact of the regulation on small entities.

In summary, this rule is not mandated by the RFA and may not be consistent with Congressional intent. As a matter of policy, we are therefore reconsidering the benefits of an additional rule that exceeds the requirements of the RFA.

## 2. Potential Harm to Small Entities Inconsistent With the RFA

Commenters argued that the final rule will impose undue and disproportionate burdens on small entities that undermine the RFA's purpose of alleviating the regulatory burden on such entities. The RFA seeks to address the "unnecessary and disproportionately burdensome demands . . . [of uniform regulatory requirements] upon small [entities] . . . with limited resources." 126 Cong. Rec. 21,449. After reconsidering the burden of the SUNSET final rule, the legislative history for the RFA, and the comments, it is now our view that implementation of the SUNSET final rule could harm small entities, contrary to Congressional intent in enacting the RFA. Below, we summarize the comments that discuss these issues in detail.

Commenters expressed concerns that the sudden expiration of regulations and the threat of sudden expiration of regulations would disproportionately burden small entities by creating regulatory uncertainty and a confusing regulatory landscape that would be difficult for these entities to navigate.

Commenters also noted that the sudden expiration of rules could result in reputational harm with customers whose confidence relies on compliance with regulatory standards, and other outcomes that would be particularly damaging to small entities. For example, as discussed above, the expiration of certain regulations could create instances where regulations expire but statutory requirements continue to be applicable, leaving it unclear to small businesses how the Department intends to implement the statutory requirements. As another example, if, as suggested in the preamble to the final rule (86 FR 5712), guidance documents based on expired regulations would cease to have effect, the expiration of regulations could leave stakeholders without needed information in relevant guidance, including Small Entity Compliance Guides (SECG).

Although several commenters representing small business industry associations expressed support for the final rule based on the assumption that the assessments and reviews would lead to deregulatory actions that could benefit small businesses, the vast majority of commenters disagreed with that assumption and opposed the rule. These commenters expressed the concern that small entities who rely on regulations to level the playing field would suddenly lose the clarity provided by such regulations and associated guidance for industry, which would create confusion, costs, and vulnerability for small entities. Commenters noted that most small businesses would generally lack resources to monitor, understand, anticipate, and adapt to changes in the regulatory landscape caused by the automatic expiration framework. Congress's findings in the RFA's legislative history substantiate this concern, as Congress explicitly found that small entities often have limited access to regulatory expertise and capital as compared to larger businesses. *See* 126 Cong. Rec. 21,453.

Moreover, commenters also expressed concerns that the final rule's requirements and timelines would undermine small entities' ability to participate in assessments and reviews, which HHS notes is inconsistent with the RFA's intent to "give small businesses a greater opportunity to participate in shaping rules which would affect them." 126 Cong. Rec. 21,451. Commenters explained that the frenetic pace and scope of simultaneous assessment of rules would impair small entities' ability to effectively engage in the final rule's assessment and review process and for HHS to identify and

<sup>17</sup> The automatic expiration of rules without notice and comment appears to also be inconsistent with Congressional intent that the RFA's requirements "not alter procedural requirements contained in other statutes applicable to the agency" (126 Cong. Rec. 21,456).

meaningfully address data and information related to impacts on these entities.

Although the final rule suggests that regulatory uncertainty created by the final rule would be offset by increases in trust in the Department's RFA compliance, and greater transparency about when regulations were adopted, HHS has reason to doubt that assertion. First, this assertion may not have taken into account the high burden on the public, including small businesses, to calculate and track the expiration of regulations, or to participate in the assessment and review processes. Second, HHS no longer finds it appropriate to rely on conclusions regarding "sunset reviews" in other jurisdictions, including foreign governments and U.S. State legislatures, given the final rule's acknowledgment that "[t]hese jurisdictions' sunset provisions do not all work identically to this final rule." 86 FR 5747.

Commenters pointed out that the experience of foreign governments with sunset provisions would not be applicable to HHS, because these governments are not bound by the requirements of the APA. Other entities also may not have the same resource constraints as HHS, for example, with respect to earmarked funds. Finally, as explained at length throughout this preamble, HHS is no longer confident that, by giving industry five years until any regulations expire, the SUNSET final rule would mitigate the negative effects of expiration. We welcome comments regarding the experience of state and foreign governments with these laws.

Overall, the Department's current assessment that implementation of the SUNSET final rule has the potential to harm small entities, contrary to Congressional intent in enacting the RFA, suggests that there are no clear beneficiaries of this rule. These conclusions call into question the fundamental basis and justification for the SUNSET rule.

### 3. The Final Rule Is Unnecessary

Consistent with our assessment, discussed above, that the SUNSET final rule's impact exceeds the requirements of the RFA and could impose additional burdens on small entities, HHS now seriously questions the conclusion in the SUNSET final rule that simultaneous Department-wide assessments of thousands of regulations is an efficient way to achieve the RFA's objectives. Instead, HHS now believes more targeted alternatives suggested by commenters merit further consideration.

As commenters noted, there are more efficient and effective ways to identify rules that have or will have a SEISNOSE and require review. For example, the Department may request information or use other processes to seek input from small entities and the public to identify such rules in a more targeted way, and the public may use already-existing petition processes to ask HHS to issue, amend, or repeal a rule. Conducting the assessments required by the rule could amount to searching for a needle in a haystack, and would not provide an effective means for stakeholders to provide input or for HHS to consider and evaluate such input and other relevant information. As commenters who expressed support for retrospective review also noted, the quality of reviews is more important than quantity, and the final rule's framework would strain the Department without improving the quality of reviews.

Alternatives that employ a more targeted approach to identifying rules for review under section 610 of the RFA, which are less burdensome on the Department and stakeholders and incorporate meaningful participation by stakeholders, are consistent with guidance issued by the SBA's Office of Advocacy. That guidance explicitly recognizes that "[b]ecause of the breadth and volume of federal regulations, a review of all existing rules on a particular industry group can be an onerous task for a federal agency."<sup>18</sup> Additionally, the guidance states that "[i]nsights about an existing regulation received from regulated entities and other interested parties should be a key component of a retrospective rule review," and that "[b]y making the review process transparent and accessible, agencies are more likely to identify improvements that will benefit all parties at the conclusion of the review."<sup>19</sup>

A commenter noted that such alternatives are also consistent with the recommendations for best practices for retrospective review published by the Administrative Conference of the United States (ACUS), which is cited in the final rule,<sup>20</sup> whereas the automatic expiration framework is not. HHS now agrees that the targeted alternatives

<sup>18</sup> Office of Advocacy, U.S. Small Business Administration A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act. (Aug. 2017), p. 40.

<sup>19</sup> *Id.* at 83.

<sup>20</sup> See Admin. Conf. of the U.S., Recommendation 2014–5, Retrospective Review of Agency

Rules (2014) (available at [https://www.acus.gov/sites/default/files/documents/Recommendation%20202014-5%2020%2528Retrospective%20Review%2529\\_1.pdf](https://www.acus.gov/sites/default/files/documents/Recommendation%20202014-5%2020%2528Retrospective%20Review%2529_1.pdf)).

proposed by commenters are generally consistent with ACUS's recommendations, including the recommendation to prioritize retrospective reviews "[i]n light of resource constraints and competing priorities."<sup>21</sup> Although the final rule asserts that certain of its provisions are consistent with ACUS recommendations, *see, e.g.*, 86 FR 5726, the commenter further asserted that the automatic expiration framework is inconsistent with those recommendations, which do not endorse or reference sunset periods<sup>22</sup> and do recommend that retrospective review processes require consideration of and be tailored to the specific rule being reviewed.<sup>23</sup> ACUS issued new recommendations for periodic retrospective review in June 2021.<sup>24</sup> In the preamble to the recommendations, ACUS discusses the tradeoffs of periodic retrospective review, including the costs and time associated with collecting and analyzing data and the uncertainty created by the review process, and advises agencies to "tailor their periodic retrospective review plans carefully to account for these drawbacks."<sup>25</sup> The consultant research report to ACUS on this topic specifically addresses the SUNSET final rule and notes:

While recognizing the objective to promote retrospective reviews that may be needed, a strict sunset date is an especially strong, perhaps overly strong, incentive for periodic review. It raises questions under US administrative law regarding whether and how an agency can set an expiration date for thousands of its rules through a single new rule, without going through notice and comment rulemaking to rescind each rule or cluster of rules separately. Sunsetting rules may pose high social instability costs, as discussed above, if numerous rules on which stakeholders rely suddenly expire, potentially outweighing the benefits of the agency undertaking periodic reviews of some of these rules. Moreover, there does not seem to be a strong analytic basis presented for the

<sup>21</sup> *Id.*

<sup>22</sup> See generally *id.* The commenter noted that the concept of sunset periods is mentioned only in passing in a report prepared in connection with the recommendations. See Joseph E. Aldy, Learning from Experience: An Assessment of the Retrospective Reviews of Agency Rules and the Evidence for Improving the Design and Implementation of Regulatory Policy 62, 65 (2014), (available at <https://www.acus.gov/sites/default/files/documents/Aldy%2020Retro%20Review%2020Draft%202011-17-2014.pdf>).

<sup>23</sup> See ACUS Recommendations, *supra* n. 18, at 7.

<sup>24</sup> See Admin. Conf. of the U.S., Recommendation 2021–2, Periodic Retrospective Review (2021), available at <https://www.acus.gov/sites/default/files/documents/Redline%20-%20Periodic%20Retrospective%20Review%20-%20Final.pdf>.

<sup>25</sup> *Id.* at 3.

periodicity (5 or 10 years) required in the HHS sunset review rule.<sup>26</sup>

HHS agrees that the more targeted alternatives suggested by commenters are likely to achieve the goals of retrospective review more efficiently. We are now reconsidering the SUNSET final rule's apparent position that a burdensome and widespread assessment is necessary to identify regulations that have or will have a SEISNOSE. For example, the final rule primarily emphasizes what it perceives as the general benefits of "widespread review" with little explanation of the specific benefits of widespread assessment. *See, e.g.*, 86 FR 5698 (concluding that "it would not be unreasonable to think that the Department could make major improvements by conducting *widespread review* of its regulations, rather than merely reviewing the small number of regulations that interested parties ask the Department to consider revising").<sup>27</sup> Additionally, the final rule concludes that "stakeholder input cannot be the only source of information to spur reviews" because such input would not reflect the "dispersed costs" that "consumers, small businesses, and the public" experience, given that those groups "often find it costly to organize and lobby on behalf of their own interests" and "[c]oncentrated interests" that "find it relatively easier" to do so would not take such costs into account. *Id.* at 5740. However, HHS now doubts this conclusion because, as explained above, HHS received numerous comments to the SUNSET proposed rule from a diverse array of consumers, small businesses, and the public asserting the undue burdens and costs that rule would impose.

As stated earlier, while the Department can explore ways to improve its processes, HHS does have a meaningful track record of retrospective regulatory review. As required by section 610 of the RFA, the Department conducts periodic reviews of regulations with impacts on small entities and provides notification of these reviews in the annual Unified Agenda of Regulatory and Deregulatory Actions. Among HHS's other recent retrospective review efforts are the Department's 2011

Plan for Retrospective Review of Existing Rules, an initiative developed in accordance with E.O. 13563 and E.O. 13610, Identifying and Reducing Regulatory Burdens. The Department used this plan from Fiscal Year 2012 through Fiscal Year 2016 as a framework for its retrospective review of existing significant regulations to identify those rules that can be potentially eliminated as obsolete, unnecessary, burdensome, or counterproductive or that can be modified to be more effective, efficient, flexible, and streamlined. A number of commenters also specifically referenced a 2015 CMS initiative to modernize Medicaid Managed Care regulations for Medicaid and CHIP beneficiaries. We also note that the CMS Office of Burden Reduction and Health Informatics works, among other things, to eliminate overly burdensome and unnecessary regulations. More recently, in response to E.O. 13771, Enforcing the Regulatory Reform Agenda, HHS established a Regulatory Reform Task Force that oversaw an effort to evaluate existing regulations and make recommendations to the Secretary regarding their repeal, replacement, or modification, consistent with applicable law. HHS published summary reports of these reviews for Fiscal Years 2018–2020 on the HHS website (available at <https://www.hhs.gov/about/budget/fy2021/performance/regulatory-reform/index.html>). These efforts demonstrate the Department's ongoing commitment to retrospective review, which could be upended rather than strengthened by the SUNSET final rule.

The SUNSET final rule asserts that the threat of regulations expiring is necessary because "it is nearly impossible to see how a satisfying comprehensive review could occur without a sunset provision," 86 FR 5702, and concludes that the Department "needs to impose a strong incentive on itself to perform retrospective review." *Id.* at 5697. HHS now believes that there are numerous regulatory efforts that take place within agencies that routinely involve the review of regulations. Agencies are often requested to provide technical assistance to Congress on proposed legislation which quite often requires, among other considerations, an assessment of the proposal's impact on current regulations. FDA also reviews regulations in the course of responding to certain citizen petitions submitted under 21 CFR 10.30, requesting changes in FDA regulations.

It is also common for new HHS regulations to amend, revise or modify sections of regulations in order to

update, replace, or rescind requirements, or to add new definitions or clarifications, which inherently entail review of these sections. For example, the regulations FDA issued to implement FSMA<sup>28</sup> included both the addition of new sections of regulation and revisions and modifications to existing sections. Additionally, regulation provisions are reviewed to determine if guidance documents are needed to provide recommendations for complying with the regulation. This is particularly important when the regulation is necessarily general or broad to accommodate scientific and other innovation changes, and guidance is helpful to consider applicability of the regulatory provisions.

Upon reconsideration, as a matter of policy, HHS now seriously questions whether automatic expiration is an effective or necessary means to incentivize regulatory review. Commenters expressed concern that the automatic expiration of regulations would in fact create a strong incentive, under certain circumstances, to not conduct reviews and thus, allow the Department to effectively rescind such regulations without any justification, explanation, or the notice and comment procedures generally required for rescinding a rule. The Department is concerned that the SUNSET final rule could degrade confidence in our regulatory stewardship.

Among the evidence cited to explain the need for the SUNSET final rule was an artificial intelligence review of all HHS regulations that identified that 85% of regulations before 1990 had not been edited. 86 FR 5699.<sup>29</sup> However, the final rule incorrectly inferred that just because no edit has been made to a regulation, it has never been reviewed. There are numerous regulatory efforts that take place within agencies that involve the review of regulations without resulting in a change to the regulation. As noted above, some commenters explained that many rules setting industry standards have remained untouched for years—not

<sup>28</sup> See FSMA Rules & Guidance for Industry (available at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry#Rules> (accessed May 11, 2021)).

<sup>29</sup> The final rule stated that the findings of this artificial intelligence review indicated 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." 86 FR 5701–02. However, commenters expressed concern that the methodology of this search was never made public, and the final rule acknowledged that the "Department did not previously notify the public about this research project" as well as certain limitations on the capabilities of this tool. 86 FR 5710.

<sup>26</sup> Lori S. Benneer and Jonathan B. Wiener, Periodic Review of Agency Regulation (June 7, 2021) at 37–38 (report to the Admin. Conf. of the U.S.), available at <https://www.acus.gov/report/periodic-retrospective-review-report-final> (footnotes omitted).

<sup>27</sup> Commenters noted that any benefits derived from assessing thousands of regulations to determine their potential impact on small entities cannot reasonably be deemed to outweigh the benefit of more targeted alternatives that preserve HHS' ability to accomplish activities that protect and promote the public health.

through neglect, but because they work as intended. There have also been instances where an agency has included certain regulations on past Unified Agendas (UA) and yet never completed these proposals and thus these were eventually withdrawn from the UA. But this ultimate result does not mean that review did not occur. Often review of an existing regulation may result in an agency developing a draft of a new or amended regulation that, upon further deliberation or because of intervening events, the agency decides not to finalize.

The SUNSET final rule also credited this artificial intelligence review with the identification of broken links in regulations and regulations that require multiple paper copies and provided these as examples that show the need to “more firmly institutionalize retrospective review.” 86 FR 5699. HHS notes that the broken links and other typographical errors identified through this process were successfully addressed as part of the HHS “Regulatory Clean-Up Initiative,” a final rule published on November 16, 2020 (85 FR 72899) that made miscellaneous corrections, including correcting references to other regulations, misspellings and other typographical errors in regulations issued by FDA, CMS, the Office of the Inspector General, and the ACF. In addition, FDA issued a final rule to amend regulations on medical device premarket submissions to remove requirements for paper and multiple copies and replace them with requirements for a single submission in electronic format.<sup>30</sup> However, neither the assessment-and-review process required by the SUNSET rule, nor the threat of expiring regulations, were necessary to incentivize these actions. Rather, HHS now believes the Department’s ability to efficiently undertake such regulatory housekeeping in the future could be undermined if staff were overwhelmed by the implementation of the SUNSET final rule.

#### D. APA Considerations

Commenters questioned the legality of the SUNSET final rule under the APA, which may be an additional ground for reconsideration and repeal. Under the APA, agency action is unlawful and can be set aside by a court when it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” or “without

observance of procedure required by law.” 5 U.S.C. 706(2)(A), (D). Commenter asserted that the SUNSET final rule may be vulnerable under these standards in light of its stated justification for the rule and the process it followed in promulgating the rule.

#### 1. Consideration of the Relevant Factors

The APA requires an agency, in issuing a final rule, to “examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’” *Motor Vehicle Mfrs. Ass’n v. State Farm*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). That explanation must show that “the decision was based on a consideration of the relevant factors.” *Id.*

After a regulation is promulgated, the same process applies for amending or rescinding that regulation. 5 U.S.C. 551(5) (“rule making” encompasses the formulation, amendment, or repeal of a rule); *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 101 (2015) (“agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance”). Thus, an agency must “present an adequate basis and explanation” for the amendment or repeal; if the agency has “entirely failed to consider an important aspect of the problem,” the rule is “normally . . . arbitrary and capricious.” *State Farm*, 463 U.S. at 41, 43. In particular, when an agency changes course, including by amending a regulation, “a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.” *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515–16 (2009).

As discussed above, the SUNSET final rule establishes a retrospective review scheme and amends most of HHS’s regulations “to apply expiration dates unless certain conditions are satisfied”—*i.e.*, the completion of retrospective review. 86 FR 5716. To support this approach, the Department provided the rationale that “the benefits of retrospective review, and the need to strongly incentivize it, are so great that the risk of a regulation inadvertently expiring is justified by the benefit of institutionalizing retrospective review in this manner.” 86 FR 5723.

Several commenters questioned the validity of HHS’s approach. Commenters asserted that HHS cannot amend or revoke a legislative rule in a rulemaking that does not address the particulars of that legislative rule because it did not contain any particularized consideration of the

regulations subject to expiration, such as the facts, circumstances, and policies originally motivating the promulgation of these regulations. In the preamble to the SUNSET final rule, the Department acknowledged the submission of a large number of comments stating that the rule would violate the APA on this ground. 86 FR 5715. The Department rejected these arguments and asserted that the rulemaking was permissible by comparing the global amendment to an amendment to a specific rule to add an expiration date, or to amending a definition of a term that is more widely applicable to a set of regulations. *See* 86 FR 5703–04. We now question the relevance of that comparison: Because of the differences in scope, scale, and effect, it is far more likely that HHS could consider the relevant factors and produce the record needed to support the rulemaking for these more targeted amendments, in contrast to the global amendment proposed in the SUNSET final rule. The Department also addressed these comments by asserting that it had “considered the relevant factors” and “considered each individual Department regulation” in connection with deciding whether to exempt the regulation from the scope of the SUNSET final rule. 86 FR 5703, 5718. However, these statements were conclusory; the final rule did not contain particularized consideration of the rules that were amended. Because of this absence, the Department arguably did not adequately consider the factors relevant to the amendments as required under the APA.

These questions are particularly pronounced in the circumstance that the SUNSET final rule leads to the automatic repeal of a regulation. As reflected elsewhere in this preamble, the Department believes that at least some amended regulations are likely to expire. In the event of such expiration, the Department would be changing course on a policy embodied in a regulation. As noted above, such a change needs to be supported by a reasoned explanation.

In addition, the Department is concerned that the exemptions in the SUNSET final rule may not have been adequately justified. The Department exempted certain FDA regulations, for example, on the basis that they create product identities and are being reviewed under other processes. 86 FR 5731. It is not clear that the stated reasoning supports the exemption decisions or their scope. For example, it is not clear why other FDA regulations that are similar, such as those codifying the standards for human blood and blood products, were excluded.

<sup>30</sup> “Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify that Paper Copies To Be Required in Electronic Format.” Final Rule. 84 FR 68334. Dec. 16, 2019.

## 2. Length of the Comment Period

When HHS promulgated the SUNSET final rule, as discussed above, it provided a 30-day comment period for most comments. Many commenters asserted that the amount of time was inadequate under the APA, in light of the scale and complexity of the SUNSET proposed rule and in the absence of any public health or welfare emergency basis for the expedited timeline. The SUNSET final rule acknowledged the many comments received objecting to the length of the comment period, but concluded that the comment period was sufficient based primarily on the numerous comments received from a diverse array of stakeholders. 86 FR 5705–06.

The APA does not specify a duration for comment periods in the context of notice-and-comment rulemaking, but agencies must provide “adequate time for comments.” *Fla. Power & Light Co. v. United States*, 846 F.2d 765, 771 (D.C. Cir. 1988). The timing considerations will vary depending on the nature of the proposal and its impact on the public. Generally, the comment period for issuing new Department regulations is at least sixty days and can be longer depending on the issue and complexity. The SUNSET final rule was determined by OIRA to be an economically significant regulatory action. 86 FR 5737. Furthermore, the SUNSET final rule was vast in scope and impact, affecting thousands of regulations. In light of that, the Department believes commenters raised credible concerns that they could not adequately consider the rule in the time that was allotted for comments for the SUNSET proposed rule, and, as a result, the procedure may be vulnerable under the APA.<sup>31</sup>

### E. Vague and Confusing Provisions

The SUNSET final rule states that “it is crucial to the proper function of this final rule that the Department and public clearly understand the scope and timing of the Assessment and Review process.” 86 FR 5721. However, upon reconsideration, the Department has found many ambiguities that could impede the ability of the Department and the public to determine the scope and timing of the assessment and review process. This confusion may increase the burden on stakeholders trying to navigate the assessment and review process. Process ambiguities also

<sup>31</sup> Because the instant notice proposes to continue the status quo by withdrawing a rule that has not yet taken effect, and because commenters have already had the opportunity to submit comments on the topic, the Department believes that 60 days for commenting at this stage of the rulemaking is sufficient.

increase the risk of the automatic expiration of HHS regulations due to inadvertent noncompliance or misapplication of the requirements.

The final rule was revised to use the term “Section” rather than “Regulation” to refer to a section of the CFR. The preamble explained that this revision would enhance process clarity because “it is clear when a section of the CFR was first promulgated.” *Id.* However, in making this revision, the Department failed to consider that the rule also requires that assessments and reviews be performed on *all sections of the CFR* that HHS issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter). As a result, for any rulemakings that include revisions or cross-references to previously promulgated sections of regulations alongside newly promulgated sections of regulations, the scope and timing of the assessment process prescribed in the SUNSET final rule could be ambiguous.

For example, the FDA rulemaking “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (Preventive Controls for Human Food) was published on September 17, 2015 (80 FR 55907), and therefore would be expected by stakeholders to be less than ten years old. However, in addition to new sections first promulgated in 2015, the rule also included revisions to sections of the CFR that were first promulgated in 1975, 1979, 1986, 1995, 1997, 2001, 2004, and 2008. Under the final rule, it is not clear how the Department would determine when to assess CFR parts and sections that are comprised of pieces initially promulgated at various times.

Commenters also expressed concern about ambiguity in the categorical exceptions described in the proposed rule and included in the final rule.<sup>32</sup> Numerous commenters noted the lack of examples provided, and stated the lack of clarity for the categorical exceptions would leave the public unable to know

<sup>32</sup> Paragraph (g) in the regulatory text for each rule excluded (1) Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation; (2) Regulations whose expiration pursuant to this section would violate any other Federal law; (3) The SUNSET final rule; (4) Regulations that involve a military or foreign affairs function of the United States; (5) Regulations addressed solely to internal agency management or personnel matters; (6) Regulations related solely to Federal Government procurement; and (7) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency. 86 FR 5729.

which regulations would be eligible for the exceptions. Accordingly, some commenters stated that stakeholders would face a burden to conduct their own legal analysis.

Upon reexamination, the final rule may have failed to provide additional meaningful examples of these exceptions and only offered unspecific direction that categorical exceptions would be “rare” or only applicable to “a very small category.” *See* 86 FR 5731. The Department now recognizes the possibility that this lack of clarity could delay the completion of the assessment process and place further strain on the resources and effort needed to avoid the expiration of regulations.

In addition, many commenters stated that it was improper for the final rule to exclude the SUNSET rule itself from the requirements of paragraph (c) of each of the codified provisions, meaning that under the rule, the rule itself is not subject to assessment, review, or expiration. The final rule based this exemption on an assumption that the SUNSET rule would not “directly impose on the public costs that exceed benefits” because no rules would expire due to lack of assessment or review. 86 FR 5730. The Department now believes, as described above, that this assumption was likely incorrect.

## VI. Preliminary Regulatory Impact Analysis

### A. Introduction, Summary, and Background

#### Introduction

We have examined the impacts of the proposed withdrawal or repeal rule under E.O. 12866, E.O. 13563, the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). EOs 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed withdrawal or repeal rule is a significant regulatory action as defined by E.O. 12866.

The RFA requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed withdrawal or repeal rule would result in cost savings to regulated entities, we propose to certify that the proposed withdrawal or repeal rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed withdrawal rule would result in an expenditure in at least one year that meets or exceeds this amount.

Summary of Costs and Benefits

The proposed withdrawal or repeal rule would withdraw or repeal the SUNSET final rule. This proposed regulatory action would reduce the time spent by the Department performing retrospective assessments and reviews of its regulations, and time spent by the general public on comments related to these assessments and reviews. We would monetize the likely reductions in time spent by the Department and the general public as cost savings. Our primary estimate of these cost savings in 2020 dollars, annualized over 10 years, using a 3% discount rate, totals \$69.9 million. Using a 7% discount rate, we estimate \$75.5 million in annualized cost savings. Table 1 reports these primary estimates alongside a range of estimates that capture uncertainty in the

amount of time it will take the Department to perform each assessment and review, and uncertainty in the amount of time the public will spend on comments.

In addition to these monetized effects, the proposed withdrawal or repeal rule would also reduce regulatory uncertainty and regulatory confusion anticipated under the SUNSET final rule. It would also reduce the time spent by the Department on other activities that we have not monetized or quantified, such as the time developing SECGs, and would reduce the time spent by the public monitoring regulations undergoing assessment or review and set to expire. The proposed withdrawal rule or repeal would also result in forgone information as a result of not performing the assessments and reviews.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED WITHDRAWAL RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered	
<b>Benefits:</b>							
Annualized Monetized \$millions/year .....	.....	.....	.....	.....	7 3		
Annualized Quantified .....	.....	.....	.....	.....	7 3		
Qualitative .....	—Reduction in regulatory uncertainty and confusion. —Disbenefits from the information foregone from not performing assessments and reviews.						
<b>Costs:</b>							
Annualized .....	-\$75.5	-\$40.1	-\$110.9	2020	7	2022–2031	Cost savings from not performing assessments and reviews, and time spent by the public on comments.
Monetized \$millions/year .....	-69.9	-37.2	-102.7	2020	3	2022–2031	
Annualized Quantified .....	.....	.....	.....	.....	7 3		
Qualitative.							
<b>Transfers:</b>							
Federal Annualized Monetized \$millions/year.	.....	.....	.....	.....	7 3		
From/To .....	From:			To:			
Other Annualized Monetized \$millions/year.	.....	.....	.....	.....	7 3		
From/To .....	From:			To:			
<b>Effects:</b>							
State, Local or Tribal Government:							
Small Business:							
Wages:							
Growth:							

We request comment on our estimates of costs and benefits of this proposed withdrawal or repeal rule.

Background

On January 19, 2021, HHS issued the “Securing Updated and Necessary Statutory Evaluations Timely” final

rule. Under the SUNSET final rule, all HHS regulations less than ten years old, with certain exceptions, will cease to be effective ten years after issuance, unless HHS performs an assessment of the regulation and a more detailed review of those regulations that have a significant

economic impact upon a substantial number of small entities. The final rule also provides for regulations older than ten years to cease to be effective unless assessed and reviewed within an initial five-year period. HHS published a regulatory impact analysis (SUNSET

RIA) alongside the final rule, providing estimates of the likely impact of the policy on Departmental resources and time spent by the general public related to these efforts. Following the initiation of litigation, HHS issued an administrative delay of effective date, effective as of March 19, 2021, which extended the effective date of the final rule by one year to March 22, 2022. For the purposes of this analysis, we refer to the January 19, 2021, final rule and March 19, 2021, administrative delay collectively as the SUNSET final rule.

#### *B. Market Failure or Social Purpose Requiring Federal Regulatory Action*

The SUNSET final rule establishes automatic expiration dates for the Department's regulations, and a recurring assessment and review process that it can follow to avoid such expirations. The SUNSET final rule's RIA likely underestimates both the time commitment of a credible assessment and review process, and the time spent by the general public commenting on regulations undergoing assessment and review. Given the volume of regulations affected, our revised expectations of the time commitment necessary to conduct credible assessments and reviews, the timeframes for completing these retrospective analyses, and subsequent regulatory actions anticipated as a result of these analyses, it is likely that regulations will automatically expire without substantive review. The potential for regulations to automatically expire introduces regulatory uncertainty, with potential negative repercussions for stakeholders. The actuality of having regulations expire automatically could lead to regulatory confusion among stakeholders and harm the public health in numerous ways, as described in the preamble to the proposed withdrawal rule. This proposed withdrawal or repeal rule is therefore needed to improve the functioning of Government and to reduce the costs to the Department and the general public associated with the SUNSET final rule.

#### *C. Purpose of the Proposed Withdrawal or Repeal Rule*

The purpose of the proposed withdrawal or repeal rule is to revoke the SUNSET final rule. If finalized, this regulatory action would directly address the potential harm from the automatic expiration of the Department's

regulations. The proposed withdrawal or repeal rule would generate cost savings to the Department from reductions in staff time spent on assessments and reviews, and on related activities. It would also generate cost savings to the general public by reducing time spent on public comments related to these assessments and reviews, and on other activities, such as monitoring potentially expiring regulations. The proposed withdrawal rule would also reduce any regulatory uncertainty from the potential automatic expiration of rules.

#### *D. Baseline Conditions*

We adopt a baseline that assumes the requirements of the January 19, 2021, SUNSET final rule<sup>33</sup> remain in place over the period of our analysis, accounting for a one-year administrative delay of effective date.<sup>34</sup> The SUNSET RIA contains monetized estimates of the costs to the Department to perform retrospective analyses of existing regulations and the costs to the public to monitor and respond to anticipated regulatory actions taken by the Department following these retrospective analyses. For the purpose of estimating the time spent on retrospective analyses under the baseline of this analysis, we maintain the assumption in the SUNSET RIA that the Department will satisfy the requirements of the SUNSET final rule and no regulations will automatically expire.<sup>35</sup> We also maintain various assumptions in the SUNSET RIA relating to the timing of the effects and treatment of the one-year waiver provision that allows the Secretary to make one-time, case-by-case exceptions to the automatic expiration of a rule. We also maintain the SUNSET RIA's choice of a 10-year time horizon for the analysis and adopt a base year of 2022 for discounting purposes. In this section, we reconsider several other assumptions underlying the cost estimates in the SUNSET RIA, and discuss additional cost drivers not identified and monetized in the analysis. These revised estimates inform our baseline scenario of no further regulatory action.

#### *Regulations Subject to the SUNSET Final Rule*

We adopt the SUNSET RIA's estimate of 17,200 regulations potentially subject to the SUNSET final rule that would

need to be assessed in the first ten years. For each of these regulations, the Department will need to perform an assessment to determine whether the regulation imposes a significant economic impact on a substantial number of small entities. The SUNSET RIA estimates that roughly five regulations on average are part of the same rulemaking and could be assessed at one time. We maintain this assumption and terminology, which results in a total of 3,600 assessments in the first ten years. The SUNSET RIA assumes that 11% of these assessments, or 396, impose a significant economic impact on a substantial number of small entities, but reduces this figure to 370 to account for rulemakings that are likely to be reviewed for reasons other than the SUNSET final rule. This adjustment similarly reduces the estimate of the number of rulemakings impacted by the SUNSET final rule to 3,574.

For each of these 370 rulemakings, the Department will need to perform a review, which includes a retrospective regulatory flexibility analysis. The SUNSET RIA distinguishes between the 44 rulemakings that predate the Regulatory Flexibility Act and are unlikely to have an existing prospective regulatory flexibility analysis, and the remaining 326 rulemakings that are assumed to have an existing prospective analysis. The SUNSET RIA also estimates there will be 160 rulemakings assessed to have a significant impact on a substantial number of small entities that have not previously been identified as having a significant economic impact. An Agency will need to perform a review of these rulemakings under the SUNSET final rule.

The SUNSET final rule provides for an initial five-year period for the Department to address regulations older than ten years. We maintain the assumption in the SUNSET RIA that assessments and reviews required in the first five years will be completed evenly across this time period, and that the remaining assessments and reviews will be completed evenly across the next five-year time period. Table D1 presents the yearly count of assessments and reviews anticipated under the baseline scenario. These figures are broadly consistent with the figures contained in the SUNSET RIA; however, unlike that analysis, we do not reduce the number of assessments under the SUNSET final rule by the number of reviews

<sup>33</sup> 86 FR 5694.

<sup>34</sup> 86 FR 15404.

<sup>35</sup> This approach allows for a more direct comparison with the estimates contained in the SUNSET RIA and follows a common practice in

regulatory impact analysis to assess costs assuming full compliance with the regulation. We supplement the full-compliance estimates by identifying the likely impacts associated with less than full compliance. The HHS *Guidelines for*

*Regulatory Impact Analysis* (available at [https://aspe.hhs.gov/system/files/pdf/242926/HHS\\_RIAGuidance.pdf](https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf)), Chapter 4 "Assess Costs," contains a more complete discussion of this approach.

performed, since these assessments occur first and serve to identify regulations requiring review.

TABLE D1—BASELINE ASSESSMENTS AND REVIEWS UNDER THE SUNSET RULE

Year	Total assessments	Reviews			Total
		Pre-RFA	Post-RFA	Not specified	
2022	683.0	8.8	61.8	30.6	101.2
2023	683.0	8.8	61.8	30.6	101.2
2024	683.0	8.8	61.8	30.6	101.2
2025	683.0	8.8	61.8	30.6	101.2
2026	683.0	8.8	61.8	30.6	101.2
2027	31.8	0.0	3.4	1.4	4.8
2028	31.8	0.0	3.4	1.4	4.8
2029	31.8	0.0	3.4	1.4	4.8
2030	31.8	0.0	3.4	1.4	4.8
2031	31.8	0.0	3.4	1.4	4.8
Total	3,574.0	44.0	326.0	160.0	530.0

#### Time Per Assessment and Per Review

The SUNSET RIA contains estimates of the time per assessment and time per review performed under the SUNSET final rule. For each assessment, the SUNSET RIA assumes that it will require between 3 and 10 hours to assess a rulemaking. For each review, the SUNSET RIA assumes that it will require between 250 and 500 hours to review rulemakings that predate the RFA, and between 40 and 100 hours to review rulemakings that postdate the RFA.

The Department now believes the SUNSET RIA likely underestimates the time necessary to credibly assess whether a regulation imposes a significant economic impact on a substantial number of small entities. The SBA Office of Advocacy published “A Guide for Government Agencies: How to Comply with The Regulatory Flexibility Act,” detailing a step-by-step approach for analysts.<sup>36</sup> For each of the 3,574 rulemakings requiring an assessment under the SUNSET final rule, an Agency will need to define the problem and describe the regulated entities, estimate economic impacts by size categories, and determine which size categories incur significant impacts. The SBA guide presents a two-page checklist containing the elements of an adequate certification. In practice, when performing a threshold analysis, analysts will face novel conceptual issues and data challenges, both of which require thoughtful consideration and professional judgement. Furthermore, SBA indicates that it is not sufficient to rely on an assessment made at the time a regulation was published:

In some cases, even if an agency was originally able to certify properly under section 605 of the RFA that a rule would not have a significant economic impact on a substantial number of small entities, changed conditions may mean that the rule now does have a significant impact and therefore should be reviewed under section 610. For example, many more small businesses may be subject to the rule now than when the rule was promulgated. The cost of compliance with a current rule may have increased sharply because of a required new technology. (SBA, pp. 80–81)

We assume that, under the baseline scenario of the SUNSET final rule, the Department will follow the recommendations in the SBA guidance, and will perform a credible threshold analysis for each rulemaking to assess whether it imposes a significant economic impact on a substantial number of small entities. Each assessment will likely require time by an economist or other analyst to perform and document the threshold analysis, with input from at least one subject matter expert on the area of the regulation. Recognizing the need to fully respond to all the requirements, we modify the assumption in the SUNSET RIA and adopt an estimate of 40 to 100 hours to complete a credible threshold analysis for each rulemaking requiring an assessment.

As described earlier, the SUNSET RIA contains two estimates for the time necessary to perform a retrospective analysis. For rulemakings published before the RFA was enacted, the SUNSET RIA assumes between 250 and 500 hours per review. For rulemakings published after the RFA was enacted, the SUNSET RIA assumes that a prospective regulatory flexibility analysis is available and further assumes that this will reduce the time necessary to complete a review,

adopting a range of 40 and 100 hours per review. For the 160 rulemakings newly found to have a significant impact, the SUNSET RIA assumes that it will take between 40 and 100 hours to complete a review. The Sensitivity Analysis Section of the SUNSET RIA acknowledges that “[o]ne commenter noted that conducting a retrospective analysis can be as time-consuming and expensive as a prospective regulatory analysis, suggesting the Department’s estimates of the time and expense of Reviews may be understated.” Upon further consideration, the Department believes that the commenter is likely correct.

For the analysis of this proposed withdrawal rule, we adopt the SUNSET RIA estimate of 250 to 500 hours for all retrospective analyses, regardless of when the underlying rulemaking was published. If previously published prospective or retrospective regulatory flexibility analyses are generally available, analysts may be able to build off of these previous analytic efforts when developing a retrospective analysis under the SUNSET rule. All else equal, this would suggest the average time per retrospective may be closer to the lower-bound estimate of 250 hours. If these analyses are not generally available, this would suggest an average time per retrospective closer to the upper-bound estimate of 500 hours. We do not address the assumption in the SUNSET RIA that a prospective regulatory flexibility analysis is available for every rulemaking published after the RFA was enacted, because it does not impact the estimate of the overall time spent on reviews under the baseline scenario. Our approach also allows us to ignore the apparent internal inconsistency in the SUNSET RIA underlying the time

<sup>36</sup> Available at <https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf>.

per review of the 160 rulemakings that are newly assessed to have a significant impact.

The SUNSET RIA is not clear on what activities are included in its estimates of the time per review other than the time spent developing a retrospective analysis. We interpret the magnitudes of these estimates to exclude a consideration of time spent on activities other than drafting the retrospective analysis. For example, the agency may need to conduct a study or survey to gather data to inform its analyses. We

therefore include an additional 250 hours to 500 hours per review to account for this omission. This estimate reflects time spent by the Department by subject matter experts, lawyers, and other reviewers informing the retrospective analysis and providing feedback on draft analyses. It also reflects time spent by economists and other analysts developing the retrospective analysis to respond to this feedback, and time spent reading and incorporating evidence from other

sources, including public comments. Table D2 summarizes the assumptions in the SUNSET RIA and our revised assumptions for the proposed withdrawal rule of the time per assessment and time per review performed under the baseline scenario of the SUNSET final rule. Combining the time spent on retrospective analysis and on other related activities, we estimate that each review will take between 500 and 1,000 hours to complete.

TABLE D2—HOURS PER ASSESSMENT AND REVIEW

Baseline requirement	Sunset RIA		Proposed withdrawal rule	
	Low	High	Low	High
Assessment .....	3	10	40	100
Review: Retrospective Analysis, pre-RFA regulation .....	250	500	250	500
Review: Retrospective Analysis, post-RFA regulation .....	40	100	250	500
Review: Retrospective Analysis, Not Specified .....	40	100	250	500
Review: Other Activities .....	0	0	250	500

Time Spent by the Public To Monitor and Comment

Under the SUNSET final rule, the Department would create a docket on *www.Regulations.gov* for each assessment or review that the Department is conducting. The public would then be able to submit comments to the dockets of each rulemaking being assessed or reviewed. The SUNSET RIA includes a discussion of the costs to the stakeholders to monitor and comment on regulations as they are undergoing assessment and review; however, the analysis assigns no costs to the Department associated with setting up these dockets or engaging with the comments. The analysis also does not monetize any other costs associated with operationalization of the SUNSET final rule, which also requires developing a schedule for activities associated with the SUNSET final rule, publishing monthly updates, and establishing a website dashboard to help the public monitor the Department’s progress.

When estimating the impact on the public, the SUNSET RIA first estimates that 53 rulemakings will be rescinded and another 159 rulemakings amended as a result of the retrospective analyses initiated as a result of the SUNSET final rule, monetizing the time spent by the public responding to those 212 rulemakings. The SUNSET RIA assumes that, for each of the 53 rulemakings rescinded following a review completed

under the SUNSET final rule, the public will submit 243 comments; and for each of the 159 rulemakings amended, the public will submit 486 comments. This will result in an estimated 90,153 comments, for which the SUNSET RIA assumes that each commenter will spend between 5 and 15 hours. Presumably, this estimate is inclusive of finding out that the rulemaking is likely to be rescinded or amended, reading and understanding the rulemaking, completing further research, communicating with other stakeholders, identifying concerns, and drafting and submitting comments. The Preamble to the SUNSET final rule anticipates that the Department will create on its website a dashboard that shows its progress on its Assessments and Reviews. Therefore, we assume that any reduction in the time spent by the public attributable to this dashboard is accounted for in these time estimates. For the purposes of this analysis, we adopt the SUNSET RIA’s assumption about the time spent per comment.

The SUNSET RIA’s discussion of the timing assumptions suggests the public will wait until the retrospective is complete and an Agency has announced it intends to rescind or amend a rulemaking before commenting. Furthermore, for the remaining 3,388 rulemakings subject to the SUNSET final rule that will be available for public comment prior to an Agency assessment or review, the SUNSET RIA

assumes the public will offer no comments. These assumptions appear at odds with the decision to invite public comment during both the assessment and review processes. Furthermore, as discussed by the SBA,<sup>37</sup> “[i]nsights about an existing regulation received from regulated entities and other interested parties should be a key component of a retrospective rule review. By making the review process transparent and accessible, agencies are more likely to identify improvements that will benefit all parties at the conclusion of the review.”

Upon further consideration, the Department finds it more likely that the public will comment on rulemakings undergoing assessment and review rather than wait until learning the specific rulemakings that will be rescinded or amended as a result of these assessment and reviews. We adopt the SUNSET RIA’s estimate of 486 comments per rulemaking, but instead apply this to the 570 rulemakings that, following a threshold analysis in an assessment, an Agency will begin to review. We believe that the public will submit fewer comments for rulemakings undergoing an assessment, and adopt an assumption of 25 comments per assessment. Table D3 summarizes a comparison of the assumptions in the SUNSET RIA and in the baseline analysis of this proposed withdrawal rule of the comments per assessment and review, and for the subsequent

<sup>37</sup> Available at <https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf> pg. 83.

regulatory actions to rescind or amend rulemakings.

TABLE D3—BASELINE COMMENTS PER ACTION

Baseline requirement	SUNSET RIA	Proposed withdrawal rule
Assessment .....	0	25
Review .....	0	486
Rescission .....	486	N/A
Amendment .....	243	N/A

Considerations Related to Rescissions and Amendments

As described earlier, the SUNSET RIA envisions the Department identifying and rescinding 53 rulemakings and amending 159 rulemakings following completed reviews under the SUNSET final rule. Upon further reflection, the Department no longer believes it was appropriate to unambiguously attribute to the SUNSET rulemaking subsequent regulatory actions of this nature in the context of a regulatory impact analysis. Even if the challenging attribution questions could be resolved, we believe that the SUNSET RIA understates the impact of the SUNSET rule since it implicitly assumes that the Department would not have to spend any time to develop and publish subsequent regulatory actions to rescind or amend existing regulations. This unstated

assumption is difficult to justify. Since these anticipated regulatory actions relate to regulations that have a significant economic impact on a substantial number of small entities, we expect that these actions will need to involve subject matter experts, legal review, policy coordination, Departmental clearance, and a communications strategy to bring transparency to the process. For certain regulatory actions, we anticipate the need for review by the Office of Management and Budget. We have not attempted to estimate the time associated with developing these regulatory actions.

Baseline Effect of the SUNSET Rule

To quantify the likely effect of the SUNSET final rule on the Department, we multiply the number of assessments

and number of reviews from Table D1 by the assumptions relating to the time per assessment and time per review described in Table D2. To quantify the likely effect of the SUNSET final rule on the public, we multiply the figures in Table D1 by the assumptions relating to the comments per assessment and comments per review described in Table D3. This gives us estimates for the number of comments, which we then multiply by the time estimates per comment, described above, to estimate the total time spent by the public. Table D4 presents yearly estimates of hours spent related to assessments performed under the SUNSET final rule to the Department and the public. Table D5 presents comparable figures related to reviews. Table D6 presents the total time anticipated under the SUNSET rule related to assessments and reviews.

TABLE D4—HOURS RELATED TO ASSESSMENTS UNDER THE SUNSET RULE

Year	Assessments	Department		Public	
		Low	High	Low	High
2022 .....	683	27,320	68,300	85,375	256,125
2023 .....	683	27,320	68,300	85,375	256,125
2024 .....	683	27,320	68,300	85,375	256,125
2025 .....	683	27,320	68,300	85,375	256,125
2026 .....	683	27,320	68,300	85,375	256,125
2027 .....	32	1,272	3,180	3,975	11,925
2028 .....	32	1,272	3,180	3,975	11,925
2029 .....	32	1,272	3,180	3,975	11,925
2030 .....	32	1,272	3,180	3,975	11,925
2031 .....	32	1,272	3,180	3,975	11,925

TABLE D5—HOURS RELATED TO REVIEWS UNDER THE SUNSET RULE

Year	Reviews	Department		Public	
		Low	High	Low	High
2022 .....	101	50,600	101,200	245,916	737,748
2023 .....	101	50,600	101,200	245,916	737,748
2024 .....	101	50,600	101,200	245,916	737,748
2025 .....	101	50,600	101,200	245,916	737,748
2026 .....	101	50,600	101,200	245,916	737,748
2027 .....	5	2,400	4,800	11,664	34,992
2028 .....	5	2,400	4,800	11,664	34,992
2029 .....	5	2,400	4,800	11,664	34,992
2030 .....	5	2,400	4,800	11,664	34,992
2031 .....	5	2,400	4,800	11,664	34,992

TABLE D6—TOTAL HOURS RELATED TO THE SUNSET RULE

Year	Department		Public	
	Low	High	Low	High
2022	77,920	169,500	331,291	993,873
2023	77,920	169,500	331,291	993,873
2024	77,920	169,500	331,291	993,873
2025	77,920	169,500	331,291	993,873
2026	77,920	169,500	331,291	993,873
2027	3,672	7,980	15,639	46,917
2028	3,672	7,980	15,639	46,917
2029	3,672	7,980	15,639	46,917
2030	3,672	7,980	15,639	46,917
2031	3,672	7,980	15,639	46,917

While these time estimates are significant, they are not inclusive of all costs expected under the SUNSET final rule. In addition to the quantified estimates above, we expect that the Department will experience other costs related to the requirements of the SUNSET rule under the baseline scenario. For example, the estimates above do not include time spent reviewing guidance documents related to rulemaking undergoing assessment and review. They also do not include the time associated with developing SECGs for the 160 rulemakings newly found to have a significant impact on a substantial number of small entities, or the time associated with updating existing guides for other rulemakings. The figures above also omit the monetary costs to purchase data and data subscriptions that we anticipate will serve as critical inputs for the assessments and reviews, and costs associated with conducting formal evaluations to understand the impact of the rules.

As an additional consideration, we estimate that assessing and reviewing

regulations will require the equivalent of 67 and 146 full-time employees in each of the first five years of the analysis, adopting the SUNSET RIA’s estimate of 1,160 hours of work per year per employee. Given current staffing and other Departmental needs and priorities, we anticipate the need to hire non-government experts to perform a share of the retrospective work. This approach will likely result in additional overhead costs that we have not quantified. We also anticipate the need to spend Departmental resources to find, hire, train, and transfer personnel with technical expertise to conduct the analyses, which have not been quantified in this analysis.

*E. Benefits of the Proposed Withdrawal or Repeal Rule*

The monetized benefits of this regulatory action to withdraw or repeal the SUNSET final rule are the cost savings to the Department from not completing the assessments and reviews required under the baseline scenario, and the cost savings to the public from not commenting on these assessments

and reviews. To monetize these cost savings, we multiply the hours related to the SUNSET final rule in Table D6 by the cost per hour of these activities. We adopt the SUNSET RIA’s estimates of 244.98 per hour developing assessments and reviews and 143.20 per hour spent submitting comments. Table E1 presents the yearly cost savings to the Department and the public expected under the proposed withdrawal or repeal rule compared to the baseline scenario. We combine the low estimates for the Department and the public to generate an overall low estimate, and similarly combine the high estimates for the Department and the public to generate an overall high estimate. We also report an overall primary estimate, which is the midpoint between the low and high estimates. Finally, we report the present discounted value (PDV) and annualized cost savings under the proposed withdrawal or repeal rule for both a 3% and 7% discount rate. All figures are reported in 2020 dollars, in millions.

TABLE E1—COST SAVINGS UNDER THE PROPOSED WITHDRAWAL RULE  
[Millions of \$]

Year	Department		Public		Overall		
	Low	High	Low	High	Low	Central	High
2022	\$19.1	\$41.5	\$47.4	\$142.3	\$66.5	\$125.2	\$183.8
2023	19.1	41.5	47.4	142.3	66.5	125.2	183.8
2024	19.1	41.5	47.4	142.3	66.5	125.2	183.8
2025	19.1	41.5	47.4	142.3	66.5	125.2	183.8
2026	19.1	41.5	47.4	142.3	66.5	125.2	183.8
2027	0.9	2.0	2.2	6.7	3.1	5.9	8.7
2028	0.9	2.0	2.2	6.7	3.1	5.9	8.7
2029	0.9	2.0	2.2	6.7	3.1	5.9	8.7
2030	0.9	2.0	2.2	6.7	3.1	5.9	8.7
2031	0.9	2.0	2.2	6.7	3.1	5.9	8.7
PDV, 3%	91.0	197.9	226.1	678.3	317.1	596.7	876.2
PDV, 7%	80.9	176.0	201.1	603.2	282.0	530.6	779.2
Annualized, 3%	10.7	23.2	26.5	79.5	37.2	69.9	102.7
Annualized, 7%	11.5	25.1	28.6	85.9	40.1	75.5	110.9

For comparison, in present value terms, these estimates of annualized cost savings are more than four times the size of the annualized cost estimates included in the SUNSET RIA. This reflects what the Department has now concluded are more reasonable assumptions about the effect of the SUNSET final rule rather than a claim that the combination of these two regulatory actions would generate net cost savings. These cost savings estimates are consistent with a scenario that the Department returns to its approach to Section 610 reviews that immediately predate the publication of the SUNSET final rule on January 19, 2021. We believe that this represents a credible and appropriate approach for estimating the likely cost savings that would be attributable to the proposed withdrawal or repeal rule, if it is finalized. Other considerations relating to the appropriate frequency or nature of retrospective economic analyses of existing Departmental regulations are beyond the scope of this preliminary regulatory impact analysis.

In the previous section, we discussed concerns about potential costs of the SUNSET final rule that were overlooked in the SUNSET RIA. To the extent that we are unable to quantify or monetize these costs, such as the purchase of data, conducting studies to evaluate the impacts of rules, additional overhead costs associated with contracting with non-government entities to perform a share of the retrospective work, and other personnel costs, the cost savings anticipated under the proposed withdrawal or repeal rule would be equally underestimated.

In addition to cost savings, the proposed withdrawal or repeal rule would generate non-quantified benefits

from reduced regulatory uncertainty. Although we calculate the cost savings estimates in this analysis by adopting an assumption that the Department will fulfill the requirements of the SUNSET final rule rather than to let any regulation expire automatically, it is highly likely that some regulations will automatically expire without substantive review. Revoking the SUNSET final rule would remove the expiration provisions, which would also remove the likelihood of any automatic expiration of regulatory requirements. The proposed rule would also eliminate the potential for regulatory confusion among stakeholders, and harm to the public health related to the actuality of having regulations expire automatically.

*F. Costs of the Proposed Withdrawal or Repeal Rule*

The costs of the proposed withdrawal or repeal rule would be the forgone benefits of the information learned from the assessments and reviews completed under the baseline scenario. We adopt the approach taken in the SUNSET RIA and make no attempt to quantify or monetize the value of this information. The SUNSET RIA also describes potential benefits from subsequent regulatory actions to rescind or amend existing regulations as a result of the SUNSET final rule; however, the Department now believes that any effects associated with future regulatory actions raise challenging questions of attribution (entirely to those regulatory actions themselves, or at least partially to the SUNSET final rule). We therefore do not unambiguously identify these as a source of foregone benefits under the proposed withdrawal rule.

*G. Analysis of Regulatory Alternatives to the Proposed Withdrawal or Repeal Rule*

We analyze two alternative options to the proposed withdrawal rule. First, we consider an option to maintain the general approach of the SUNSET final rule, but adopt a two-year period following the effective date to assess and review all regulations older than ten years. This option, Alternative 1, follows the timeline envisioned under the November 4, 2020, proposed rule.<sup>38</sup> Second, we consider an option to maintain the general approach of the SUNSET rule, but adopt an initial ten-year period following the effective date to assess and review all regulations, regardless of when they were first published. This option, Alternative 2, evenly distributes the time spent by the Department assessing and reviewing existing regulations.

Table G1 presents the primary estimates of yearly cost savings under the proposed withdrawal rule and under the two policy alternatives described above. All three policy options are compared to the common baseline scenario described in section D. We report the PDV and annualized cost savings under the proposed withdrawal or repeal rule and two policy alternatives for both a 3% and 7% discount rate. All figures are reported in 2020 dollars, in millions. In addition to the monetized estimates below, Alternative 1 would increase the likelihood that the Department would need to hire non-government experts to perform a share of the retrospective work, resulting in additional overhead costs that we have not monetized. Compared to the baseline scenario, Alternative 2 reduces this likelihood and thus reduces these overhead costs.

TABLE G1—PRIMARY ESTIMATE OF COST SAVINGS UNDER THE PROPOSED WITHDRAWAL RULE AND ALTERNATIVES  
[Millions of \$]

Year	Proposed withdrawal rule	Alternative 1	Alternative 2
2022	\$125.2	-\$187.8	\$59.6
2023	125.2	-187.8	59.6
2024	125.2	121.5	59.6
2025	125.2	121.5	59.6
2026	125.2	121.5	59.6
2027	5.9	2.2	-59.6
2028	5.9	2.2	-59.6
2029	5.9	2.2	-59.6
2030	5.9	2.2	-59.6
2031	5.9	2.2	-59.6
PDV, 3%	596.7	-26.6	37.5
PDV, 7%	530.6	-54.5	70.2
Annualized, 3%	69.9	-3.1	4.4
Annualized, 7%	75.5	-7.8	10.0

<sup>38</sup> 85 FR 70096.

### H. Initial Small Entity Analysis

The Department has examined the economic implications of this proposed withdrawal or repeal rule as required by the Regulatory Flexibility Act. This analysis, as well as other sections in this Regulatory Impact Analysis, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

#### 1. Description and Number of Affected Small Entities

The U.S. Small Business Administration (SBA) maintains a Table of Small Business Size Standards Matched to North American Industry Classification System Codes (NAICS).<sup>39</sup> We replicate the SBA's description of this table:

This table lists small business size standards matched to industries described in the North American Industry Classification System (NAICS), as modified by the Office of Management and Budget, effective January 1, 2017. The latest NAICS codes are referred to as NAICS 2017.

The size standards are for the most part expressed in either millions of dollars (those preceded by "\$") or number of employees (those without the "\$"). A size standard is the largest that a concern can be and still qualify as a small business for Federal Government programs. For the most part, size standards are the average annual receipts or the average employment of a firm.

The SUNSET rule will potentially impact small entities across at least NAICS industry sectors 11 (Agriculture, Forestry, Fishing and Hunting), 31–33 (Manufacturing), 42 (Wholesale Trade), 44–45 (Retail Trade), 48–49 (Transportation and Warehousing), 52 (Finance and Insurance), 54 (Professional, Scientific, and Technical Services), 62 (Health Care and Social Assistance), 81 (Other Services (except Public Administration)), and 92 (Public Administration). Given the wide range of entities affected, and various sources of uncertainty described in this section, it is not practical to directly estimate the number of small entities that would potentially be impacted under the baseline scenario of the SUNSET rule. Similarly, it is impractical to identify the small entities that would be impacted by the proposed withdrawal or repeal rule, if it is finalized. The Congressional Research Service observes that "about 97% of all employer firms qualify as small under the SBA's size standards. These firms represent about 30% of industry

receipts."<sup>40</sup> For practicality, we assume that the bulk of the potential impacts of the proposed withdrawal or repeal rule to private sector regulated entities are small entities.

#### 2. Description of the Potential Impacts of the Rule on Small Entities

##### Impacts to Small Entities Related to Rescissions and Amendments

When estimating the impact on the public, the SUNSET RIA first estimates that 53 regulations will be rescinded and another 159 regulations will be amended as a result of the retrospective analyses initiated as a result of the SUNSET rule. Since the particular regulations impacted are unknowable prior to conducting the retrospectives, this results in uncertainty over the types of small entities that will be affected under the baseline scenario of the SUNSET rule. The nature of this uncertainty means it is infeasible to estimate the number of small entities affected by these potential rescinded or amended regulations without first completing the retrospectives.

As described earlier, the Department no longer believes it was appropriate to unambiguously attribute to the SUNSET rulemaking subsequent regulatory actions of this nature in the context of a regulatory impact analysis. We therefore do not attribute any impacts of this nature to the proposed withdrawal or repeal rule, nor do we identify any impacts to small entities.

##### Impacts to Small Entities Related to the Automatic Expiration of Regulations

When identifying the potential benefits of the proposed withdrawal or repeal rule, we note that, while the Department will seek to fulfill the requirements of the SUNSET rule rather than to let any regulation expire automatically, it is highly likely that some regulations will automatically expire without substantive review. This potential impact under the SUNSET rule does not introduce similar questions of attribution; however, there remains uncertainty over the particular regulations that will be impacted. The nature of this uncertainty means we cannot identify the small entities that are most likely to be affected by regulations that automatically expire without substantive review.

Revoking the SUNSET rule would remove the expiration provisions, which would also remove the likelihood of any

automatic expiration of regulatory requirements. The proposed withdrawal or repeal rule would also eliminate the potential for regulatory confusion among stakeholders, including small entities. We anticipate that a large share of these non-quantified benefits would accrue to small entities.

##### Impacts to Small Entities Related to Commenting on Assessments and Reviews

When identifying the potential benefits of the proposed withdrawal or repeal rule, we estimate the cost savings to the public from not commenting on these assessments and reviews that would be performed under the baseline scenario of the SUNSET rule. Table E1 summarizes these estimates, including a range of cost-savings to the public sector between \$26.5 million and \$79.5 million in annualized terms under a 3% discount rate. Under a 7% discount rate, the comparable range of cost savings is \$28.6 million and \$85.9 million. Although these represent substantial cost savings in the aggregate, these include comments not just from small entities but also the general public, larger businesses, Tribes, States, non-governmental organizations, and other regulated entities and stakeholders.

To evaluate the likely magnitude of the impact to a single small entity, we consider an illustrative scenario of a full-time sole proprietor that submits 1 or fewer comment per year. As described earlier, we estimate that each comment takes between 5 and 15 hours to prepare and submit. If the proposed withdrawal or repeal rule is finalized, this would reduce the time spent on comments for this small entity by 5 to 15 hours per year. This represents between 0.2% to 0.7% of annual labor time saved, computed using an assumption that the individual works 2,087 hours per year. As an additional sensitivity analysis, we computed the number of comments that a sole proprietor would need to submit in one year such that the time spent on comments would exceed 3% of total time spent on labor. Assuming 2,087 hours of labor time per year, the total time spent on comments to meet this threshold is about 63 hours. Using a central estimate of 10 hours to prepare and submit each comment, the sole proprietor could prepare up to 6 comments per year without exceeding the 3% threshold. We expect that fewer than 5 percent of small entities will share more than 6 comments per year on regulations undergoing a retrospective analysis under the SUNSET rule. This indicates that the potential cost savings to small entities under the proposed

<sup>39</sup> U.S. Small Business Administration (2019). "Table of Size Standards." August 19, 2019. <https://www.sba.gov/document/support-table-size-standards>.

<sup>40</sup> Robert Jay Dilger (2021). "Small Business Size Standards: A Historical Analysis of Contemporary Issues." Congressional Research Service Report R40860. Updated May 28, 2021. Page 2. <https://crsreports.congress.gov/product/pdf/R/R40860>.

withdrawal or repeal rule, if it is finalized, are unlikely to be significant for a substantial number of small entities. The Department considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue on at least five percent of small entities. This cost-saving benefit is well below this threshold.

## VII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. We have determined that because the SUNSET final rule has not become effective, this proposal to withdraw the final rule, if finalized, will continue the status quo, and therefore does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

## VIII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. Multiple comments from representatives of several Tribes and related groups expressed concern that the SUNSET final rule would have significant tribal implications, if implemented, and that consultation with Tribal governments on the SUNSET proposed rule was not adequate. We agree.<sup>41</sup> HHS remains committed to holding meaningful tribal consultation consistent with the HHS Tribal Consultation Policy. However, this proposed rule to withdraw or repeal the final rule, if finalized, will continue the status quo, and therefore does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Based on this status, as well as the comments already received on this issue, we do not believe tribal consultation is required. We plan to provide notice to Tribes of this

<sup>41</sup> As explained in greater detail in the Administrative Delay Order, Tribes should have been “afforded an opportunity to comment meaningfully on the rule’s impact,” but “HHS failed to consult with Tribal governments (or even notify them regarding the proposal).” 86 FR 15407.

proposed rule, acknowledging tribal concerns with the lack of tribal consultation on the earlier rulemaking and encouraging them to share any additional feedback by providing written comments on this proposed withdrawal or repeal.

## IX. Analysis of Environmental Impacts

HHS had determined that the proposed rule will not have a significant impact on the environment.

## X. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, 44 U.S.C. 3501–3521; 5 CFR part 1320, appendix A.1, the Department has reviewed this proposed rule and has tentatively determined that it proposes no new collections of information.

## XI. References

1. OIRA dashboard screenshot (Dec. 18, 2020).
2. Complaint, *County of Santa Clara v. HHS*, Case No. 5:21-cv-01655-BLF (N.D. Cal. Mar. 9, 2021).

**Xavier Becerra,**

*Secretary.*

[FR Doc. 2021–23472 Filed 10–28–21; 8:45 am]

BILLING CODE 4150–26–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Chapter I

[EPA–HQ–OPPT–2021–0599; FRL–8949–01–OCSP]

### TSCA Section 21 Petition for Rulemaking Under TSCA Section 6; Reasons for Agency Response; Denial of Requested Rulemaking

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Petition; reasons for Agency response.

**SUMMARY:** This action announces the availability of EPA’s response to a petition received on August 2, 2021, from William D. Bush. The petition requests that EPA determine “that the chemical mixtures contained within cigarettes present an unreasonable risk of injury to health and the environment.” The petitioner also seeks issuance of a rule or order to “eliminate the hazardous chemicals used in a mixture with tobacco,” and to “develop material techniques of biodegradation to counter or reduce” environmental risk from current disposal methods of cigarettes under section 6(a) of the Toxic Substances Control Act (TSCA). After

careful consideration, EPA has denied the TSCA section 21 petition for the reasons set forth in this document.

**DATES:** EPA’s response to this TSCA section 21 petition was signed October 25, 2021.

**ADDRESSES:** The docket for this TSCA section 21 petition, identified by docket identification (ID) number EPA–HQ–OPPT–2021–0599, is available at <https://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Public Reading Room is by appointment only. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** For technical information contact: Amy Shuman, Existing Chemicals Risk Management Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–2978; email address: [shuman.amy@epa.gov](mailto:shuman.amy@epa.gov).

For general information contact: The TSCA–Hotline, ABVI–Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

## SUPPLEMENTARY INFORMATION:

### I. General Information

#### A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those persons who manufacture (including import), distribute in commerce, process, use, or dispose of cigarettes. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

#### B. What is EPA’s authority for taking this action?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a proceeding for the issuance,