**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**

# Withdrawing Rule on Securing Updated and Necessary Statutory Evaluations Timely

**AGENCY:** Department of Health and Human Services.

**ACTION:** Final rule; withdrawal.

**SUMMARY:** The Department of Health and Human Services (HHS or Department) is issuing a final rule withdrawing a rule entitled ''Securing Updated and Necessary Statutory Evaluations Timely'' (SUNSET final rule), which 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 extended the effective date of the SUNSET final rule until September 22, 2022. HHS is now withdrawing the SUNSET final rule.

**DATES:** As of July 26, 2022, the final rule published on January 19, 2021 (86 FR 5694), which was delayed on March 23, 2021 (86 FR 15404), and March 4, 2022 (87 FR 12399), is withdrawn.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Daniel J. Barry, Acting General Counsel, 200 Independence Avenue SW, Washington, DC 20201; or by email at *SunsetRepeal@hhs.gov*; or by telephone at 1–877–696–6775.

**SUPPLEMENTARY INFORMATION:**

**Table of Contents**



## I. Executive Summary

### *A. Purpose of the Final Withdrawal 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.[1] 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 (Administrative Delay). 86 FR 15404 (Mar. 23, 2021). HHS subsequently extended the effective date of the SUNSET final rule until September 22, 2022. 87 FR 12399 (Mar. 4, 2022).

The Department undertook to reexamine the SUNSET final rule in light of the allegations in the lawsuit, the many substantive comments submitted on the SUNSET proposed rule, and the different policy views held by the Biden-Harris Administration as compared to the previous administration which issued the SUNSET final rule. That review considered the processes followed in issuing the SUNSET final 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. Based on that reevaluation, HHS published a notice of proposed rulemaking to withdraw or repeal the SUNSET final rule (Withdrawal NPRM). 86 FR 59906 (Oct. 29, 2021).

HHS has reviewed the comments on the Withdrawal NPRM and now issues this final rule to withdraw the SUNSET final rule in its entirety.

### *B. Summary of Major Provisions*

We are withdrawing the SUNSET final rule in its entirety.

### *C. Legal Authority*

The primary statutory authorities supporting this rulemaking 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.

[1] The terms ''Section,'' ''Assess,'' and ''Review'' were capitalized in the preamble to the SUNSET final rule where those terms have the definitions ascribed to them in the text of that final rule. For ease of readability, these terms are not capitalized in the following discussion of this withdrawal final rule unless directly quoting or paraphrasing the SUNSET final rule.

*D. Costs and Benefits*

This regulatory action will reduce the time spent by the Department performing retrospective assessments and reviews of its regulations that would have been 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. The impact of the withdrawal is analyzed in the final Regulatory Impact Analysis (RIA) for this final rule. *See* Section VI below. In that section, 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 in Section VI reports these primary estimates alongside a range of estimates that capture uncertainty in the amount of time it would have taken the Department to perform each regulatory assessment and review, and uncertainty in the amount of time the public would have spent on comments.

## 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. |
| AI/ANs | American Indian and Alaska Native people. |
| AI | Artificial intelligence. |
| APA | Administrative Procedure Act. |
| CDC | Centers for Disease Control and Prevention. |
| CFR | Code of Federal Regulations. |
| CHIP | Children's Health Insurance Program. |
| CMS | Centers for Medicare & Medicaid Services. |
| COVID–19 | Coronavirus Disease 2019. |
| E.O. | 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. |
| RIA | Regulatory Impact Analysis. |
| SAMHSA | 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. |
| SSA | Social Security Act. |
| SUNSET | Securing Updated and Necessary Statutory Evaluations Timely. |
| Unified Agenda | Unified Agenda of Regulatory and Deregulatory Actions. |

## III. Background

The SUNSET final rule, if implemented, would have significantly altered the operations of HHS with considerable negative repercussions for a diverse array of stakeholders. We now conclude that these significant repercussions were not adequately considered in issuing the SUNSET final rule in part because the process to promulgate the rule was extremely unusual, if not unprecedented. We note a few of the key considerations here.

The SUNSET final 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. In issuing the Withdrawal NPRM, we explained that, given the lack of a public health or welfare reason to expedite the rulemaking and other procedural shortcomings, we were reconsidering the commenters' significant objections to the SUNSET proposed rule. As summarized and discussed in the Withdrawal NPRM, we found that those comments raised compelling concerns that the SUNSET final rule would harm the public health and welfare, but were given insufficient weight in issuing the SUNSET final rule. Many of those same concerns have been further confirmed in the comments on the Withdrawal NPRM.

We also conducted a reanalysis of the regulatory impact of the SUNSET final rule, and found that the rule rested on flawed assumptions and analysis.[2] We now conclude that the SUNSET final rule likely underestimated to a significant degree the resources needed for the required undertaking. In particular, because the implementation of the SUNSET final rule would have required a significant expenditure of

[2] The initial draft of the RIA for the SUNSET final rule was prepared by an outside economist. *See* 86 FR 5737 n. 210. As far as the Department is currently aware, no Department economist participated in considering, drafting, or revising the economic evaluation of the SUNSET proposed or final rule. These deviations from usual practice in developing the original SUNSET rule may help explain why our current RIA differs so greatly from the previous RIA.

We also note that the Department, in developing the original SUNSET rule, did not follow other routine internal review procedures, such as distributing the draft proposed and final rules to the relevant HHS agencies to solicit their review, comments, and concurrences. These irregularities may have also contributed to the flawed execution and analysis in the original SUNSET rule.

resources, the Department would have been forced to make resource allocation decisions that would have impeded the Department's routine operations and hampered its ability to carry out other key priorities and goals.

We have also reconsidered the impact of the expiration provision in the SUNSET final rule and, upon further examination of the comments and the relevant legal standards, we have determined that the provision is unsound and in our view unlawful. The expiration provision was a key element of the SUNSET final rule (as its name suggests); however, the final rule erred in misjudging the likelihood that HHS regulations would expire if the SUNSET final rule were to go into effect and be implemented. As a result, the final rule failed to examine the instability, uncertainty, and confusion that could be generated by automatically expiring regulations. Further, we now believe that amending thousands of regulations to schedule their expiration based on the Department's purported failure to conduct a small-entity analysis, without any corresponding notice regarding or evaluation of the public health importance of the individual regulations or the public's reliance on them, violates the Administrative Procedure Act (APA) and is inconsistent with the purpose and intent of the Regulatory Flexibility Act (RFA). The policy ramifications and legal defects of the expiration provision call the entire rulemaking into question.

In addition to our reconsideration of the expiration provision, we have reconsidered more broadly the public comments, the stated legal bases for the rule, and its RIA, including a consideration of the impacts that are not quantified or monetized. We have determined that the SUNSET final rule prioritized regulatory review over other Department operations to a degree that would negatively impact many stakeholders and the general public in a variety of ways. We no longer agree with our previous decision-making in promulgating the SUNSET final rule, because that decision-making was predicated on: (1) An inaccurate assessment of the effects of this rule, as indicated in the comments on both the SUNSET proposed rule and Withdrawal NPRM, and as discussed in the current RIA; (2) errors of law; and (3) a different set of policy priorities. We therefore have decided to withdraw the SUNSET final 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 a Department-managed 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 Code of Federal Regulations (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. All of the commenters, which included industry/trade organizations, medical organizations, and public interest organizations, criticized the proposed rule in its substance, the rulemaking process, or both. *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).

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 SUNSET proposed rule, and two of those comments were submitted by an individual who, under an agreement with HHS, also provided a draft RIA 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 (OMB) 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 provided that all regulations issued by the Secretary or their delegates or sub-delegates in titles 21, 42, and 45 of the 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 contained the same basic expiration framework as the proposed rule, but extended the timeframe for assessment and any applicable review of most existing regulations from two calendar years to five calendar years. The final rule also provided for a one-time ''continuation'' of a regulation 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 contained 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 maintained the timeframe for amendment or rescission of regulations, and included a new **Federal Register** publication requirement in addition to the publication requirements proposed in the SUNSET proposed rule.

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 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, the Administrative Delay, which extended the effective date of the SUNSET final rule until March 22, 2022. 86 FR 15404. On March 3, 2022, the Secretary further extended the effective date of the SUNSET final rule until September 22, 2022. 87 FR 12399 (Mar. 4, 2022). At the parties' joint request, the *Santa Clara* litigation has thus far been stayed.

3. The Withdrawal NPRM

HHS published the Withdrawal NPRM on October 29, 2021, in which it proposed to withdraw or repeal the SUNSET final rule in its entirety. 86 FR 59906. In the Withdrawal NPRM, the Department explained that—in issuing the SUNSET final rule—it should have engaged in a more robust consideration of the comments, and should have given greater weight to the potential harms to stakeholders and the public health. Therefore, before issuing the Withdrawal NPRM, the Department reexamined the SUNSET final rule in light of the allegations in the *Santa Clara* complaint, the many substantive comments submitted to the SUNSET proposed rule docket and raised at the Public Hearing, and the changed policy views in the current Administration. That review considered the processes followed in issuing the SUNSET final 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.

The comment period on the Withdrawal NPRM closed on December 28, 2021, and HHS received approximately 80 comments. A substantial majority of comments from a wide range of stakeholders supported the repeal or withdrawal of the SUNSET final rule. These commenters included health care and medical organizations; Federally Qualified Health Centers and advocates for beneficiaries of Federal health care programs; State attorneys general and other state and local government representatives; Tribal governments and Tribal organizations; large industry associations and trade associations; insurance plans and organizations; and consumer and public interest groups. Most of the comments that supported retention of the SUNSET final rule and opposed its withdrawal came from policy advocacy groups, including one business association and one submission from the individual who, as previously noted, provided a draft RIA for the SUNSET final rule. *See* 86 FR 5737 n.210. One comment that supported retention of the original rule was submitted by a group of state legislators led by a former HHS official who presented the overview of the SUNSET proposed rule at the Public Hearing, and another comment was submitted by a different HHS official from the previous administration. There were also several identical anonymous comments that supported the original rule and opposed its repeal or withdrawal.

*B. The Department's Review*

As described above, before issuing the Withdrawal NPRM, the Department reexamined the SUNSET final rule in light of the allegations in the *Santa Clara* complaint, the many comments submitted to the SUNSET proposed rule docket and raised at the Public Hearing, and changed policy views in the current Administration. This review 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 recognizes the importance of retrospective review, already conducts retrospective reviews, and intends to continue to consider how to improve these existing processes. *See* Section V.C.2. The purpose of this review, however, was 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 and that is consistent with applicable law.

We have now carefully considered the comments submitted on the Withdrawal NPRM. As described further below, our consideration of the comments has confirmed our tentative conclusions described in the Withdrawal NPRM and our decision to withdraw the SUNSET final rule. In this section, we summarize the key considerations, addressed in greater detail throughout the preamble, that have led us to conclude, as proposed in the Withdrawal NPRM, that the SUNSET final rule should be withdrawn in its entirety. Many of these considerations, including the burdens of implementing the rule, the harms of expiration, and the various legal infirmities, each provide independent and sufficient reasons for this withdrawal.

First, to be consistent with the Department's usual practices when engaging in rulemaking, the Department should have engaged in a more thorough consideration of the comments, and should have given greater weight to the potential harms to stakeholders and the public health. We have found that there were several procedural shortcuts taken in issuing the SUNSET final rule which may have impeded full consideration of the commenters' significant objections to the proposal as well as the care and meticulousness devoted to the final product. The SUNSET final rule was issued on a timeline of less than three months, which is unusually expedited for a rule of this significance, particularly given the 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 remarkably expansive in scope, requiring review and possibly regulatory or deregulatory activity across a variety of distinct substantive statutes within the jurisdiction of several operating divisions (*e.g.,* CMS, FDA, CDC, Substance Abuse and Mental Health Services Administration (SAMHSA), the Office for Civil Rights (OCR), and the Administration for Children and Families (ACF)). However, 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.[3]

Second, the Department should have more thoroughly examined the factual basis of the SUNSET final rule before issuing it. Our thinking is informed by a reevaluation of the factual premises and conclusions in the SUNSET final rule that are central to the analysis of the rule's implications and effects. In particular, based on a reanalysis of the regulatory impact of the rule, we have now concluded that the rule rested on a flawed understanding of the resources required for implementing the SUNSET final rule, which implicates the likelihood that HHS regulations would have expired, and which would have required the Department to make resource allocation decisions which could have impeded the Department's ability to carry out other key priorities.

In particular, 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: announce on a Department-managed website and in the **Federal Register** the commencement of an assessment or review; open and publicize public dockets for each assessment or review that the Department conducts; collect data to conduct the relevant evaluation (which may require time for additional public notice and comment, and 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, as appropriate; consider any comments to the public docket related to the evaluation; participate in interagency review, as appropriate; 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 the Department could not complete this extensive process within the final rule's timeframes, the regulations would then automatically expire. The original RIA for the SUNSET final rule had erroneously assumed, for example, that an assessment—which requires each of the steps previously discussed—would take between 3 and 10 hours. We have now revised that estimate to between 40 and 100 hours.

Beyond assessments and reviews, the SUNSET final rule would demand other significant resources, including the resources required to implement the overall framework, such as determining which regulations are exempt, and to amend or repeal regulations within a two-year time period (unless an extension is granted). These proceedings to amend or rescind the regulations would require an additional investment of HHS agencies' resources and public input. In addition, after those processes, the Department would likely then need to revise guidance documents and/or forms associated with both expiring regulations and regulations still in effect. Overall, we have determined that the SUNSET final rule miscalculated the extent of the resources needed for this undertaking and likely underestimated the costs of complying with the rule at least by a factor of four.

This reanalysis shows the SUNSET final rule, if implemented, would harm the public health and welfare and diminish the Department's ability to protect and advance the public health and welfare. The diversion of resources to implement the SUNSET final rule processes, the potential for automatic expiration of rules, and the actual expiration of regulations could undermine the operation of existing programs and otherwise harm the public health in numerous ways, discussed in greater detail below. For example, the resulting regulatory uncertainty could have several negative repercussions for stakeholders, by interfering with planning, contracting, and product development. The actual expiration of regulations could lead to confusion among stakeholders and undermine predictability and confidence in many sectors regulated by the Department.

Third, upon review, HHS has determined that the SUNSET final rule is contrary to several policy goals of the current Administration. The SUNSET final rule cited for support an Executive order (E.O.) 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 E.O. entitled ''Revocation of Certain Executive Orders Concerning Federal Regulation,'' which revoked E.O. 13771.[4] 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.*

The Biden-Harris Administration has further committed to using available tools of Federal administrative agencies to, among other things: 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; make respect for Tribal sovereignty, self-governance, and regular, meaningful, and robust consultation with Tribal Nations cornerstones of Federal policy pertaining to American Indian and Alaska Native people (AI/ANs); and protect and strengthen Medicaid and the Affordable Care Act (ACA) and make high-quality healthcare accessible and affordable for every American.[5]

If implemented, the SUNSET final rule would 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 in Section V.A of this preamble, 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

[3] *See* E.O. 13175, ''Consultation and Coordination With Indian Tribal Governments,'' 65 FR 67249 (Nov. 6, 2000).

[4] The SUNSET final rule also cited ''Regulatory Relief To Support Economic Recovery,'' (85 FR 31353, May 22, 2020) (E.O. 13924 of May 19, 2020), which was revoked in E.O. 14018. 86 FR 11855 (Feb. 24, 2021).

[5] *See* ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' 86 FR 7009 (Jan. 25, 2021) (E.O. 13985 of Jan. 20, 2021); ''Tribal Consultation and Strengthening Nation-to-Nation Relationships,'' 86 FR 7491 (Jan. 29, 2021) (Memorandum of Jan. 26, 2021); ''Strengthening Medicaid and the Affordable Care Act,'' 86 FR 7793 (Feb. 2, 2021) (E.O. 14009 of Jan. 28, 2021); ''Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage,'' 87 FR 20689 (April 8, 2022) (E.O. 14070 of April 5, 2022).

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.[6] 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. We further note, however, that attempting to address the lack of adequate notice of expiring regulations would not resolve more fundamental problems with the SUNSET framework for tribal and other stakeholders.

Fourth, the Department should have more carefully considered the legal basis for the SUNSET final rule, including the expiration provision, which is a cornerstone of the rule. Commenters on the SUNSET proposed rule had asserted that the Department did not adequately consider the legal questions raised by the automatic expiration provisions, which would potentially eliminate regulations without due notice and consideration of the implications of that specific expiration. After further review, we have concluded that the legal reasoning offered in support of the expiration provision did not address foundational Supreme Court case law requiring agencies to consider, among other things, the factual bases for a regulation before eliminating that regulation.[7]

The SUNSET final rule dismissed these concerns regarding the public health and legal repercussions of the SUNSET final rule in part by assuming that regulations would not 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''). The Department failed to consider, however, that public health and legal problems with the SUNSET final rule exist even if no expiration occurs. For example, the resources diverted from other key programs would still undermine the Department's public health mission and even the *possibility* of expiration would create serious instability. The SUNSET final rule did not provide an adequate justification for, or even acknowledge, either of these likely consequences.

Moreover, we no longer agree with the Department's previous assumption that no regulations would expire. Preventing the automatic expiration of regulations would require prioritizing retrospective review above many other Department programs and missions. 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 necessary 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 constrain HHS's 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 medical innovation and health sciences. On the other hand, the automatic expiration of regulations could also undermine mission-critical objectives. Based on our reconsideration and expert judgment, we no longer consider prioritizing resources to avoid expiration to be in the best interests of the public health and welfare. Therefore, we believe that this assumption—that no regulations would expire—was not well founded. The Department's previous reliance on this unsupported assumption, together with the miscalculation regarding the resources necessary to comply with the rule, are in themselves detrimental to the viability of the SUNSET final rule.

Upon review, we now conclude 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 its statutory mandates and the policies expressed in EOs 13992, 13985, 14009, and 14070. As further described below, *see* Section V.C, the Department already has a longstanding retrospective review plan in place, and each year publishes in the **Federal Register** a list of the rules that it is reviewing, has reviewed, or intends to review under section 610 of the RFA. And although the Department is committed to exploring additional ways to improve its processes for conducting retrospective reviews under the RFA and identify and retire obsolete rules, the approach in the SUNSET final rule imposes requirements that are far more onerous than what is needed to meet those objectives and that would undermine essential Department priorities. In essence, implementation of the SUNSET final rule would likely have led to a sharply diminished ability of the Department to provide Federal leadership in public health and human services. On full consideration, the Department believes that implementation of the SUNSET final rule fundamentally conflicts with our policies and ability to achieve our statutory missions.

## IV. Legal Authority

The primary statutory authorities supporting this final 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 (SSA), 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 SSA, 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;''

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

[7] The Department is not questioning the legality of the well-considered establishment of sunsetting provisions in other, more-targeted circumstances, such as the inclusion of a sunset provision in a single rule. In such a case, the agency would have provided notice and the opportunity for comment on, and given due consideration of, the potential sunset of that particular regulation. In contrast, the SUNSET final rule was unusually sweeping and superficial, in that it established automatic expiration for a large swath of diverse regulations without due consideration of the substance of each regulation and the impact of the added sunset provision on affected entities under that regulation. See Section V.D.1 (discussing, *e.g., Dep't of Homeland Sec.* v. *Regents of the Univ. of Cal.,* 140 S. Ct. 1891, 1913 (2020)).

• 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 AI/ANs];'' 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's 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). In addition, ''[t]he power to reconsider is inherent in the power to decide,'' *Albertson* v. *FCC,* 182 F.2d 397, 399 (1950), and, thus, ''[a]dministrative agencies have an inherent authority to reconsider their own decisions.'' *Trujillo* v. *Gen. Elec. Co.,* 621 F.2d 1084, 1086 (10th Cir. 1980).

## V. Analysis of and Responses to Public Comments on the Withdrawal NPRM

During the 60-day public comment period, we received approximately 80 public comments. The majority of commenters expressed support for the Withdrawal NPRM, and in general these comments closely aligned with comments received in opposition to the SUNSET proposed rule. A substantial number of these commenters had submitted comments on the SUNSET proposed rule and either restated, submitted, or referenced their earlier comments in explaining their support for the Withdrawal NPRM. In the Withdrawal NPRM, we discussed the substantial number of comments on the SUNSET proposed rule, and we incorporate the comments on the SUNSET proposed rule and the discussion of the underlying issues and comments in the Withdrawal NPRM by reference as part of the basis for this final rule. Below we summarize and respond to the comments on the Withdrawal NPRM.

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

In issuing the Withdrawal NPRM, the Department explained that it was concerned that implementation of the SUNSET final rule would create burdens on the Department and on stakeholders that would divert resources from pressing public health matters and thus harm the public. 89 FR 59911. Below we respond to the comments on the Withdrawal NPRM on this subject.

1. Burden on the Department

*Comment:* The Department received numerous comments agreeing with HHS's explanation in the Withdrawal NPRM that the SUNSET final rule rested on a significantly flawed understanding of the time and resources that would have been needed to carry out the scope and pace of assessments and reviews required under the rule. In general, these commenters asserted that there are simply not enough HHS staff or resources to undertake such a sweeping process and simultaneously evaluate thousands of regulations in a short period of time. Several of the commenters further explained that the SUNSET final rule would create more burdens than it would ease and would be unlikely to benefit industry and consumers. In contrast, one commenter asserted that the SUNSET rule can and should be implemented and that concern regarding the enormous scope of the task and pace of reviews that would be required under the SUNSET final rule is not a valid reason to withdraw or rescind the rule. The commenter explained that, without the SUNSET framework, the quantity of regulatory reviews that the Department should undertake will grow ever more daunting as time passes and rulemaking persists.

*Response:* We agree with the commenters who stated that the framework set forth in the SUNSET final rule would create a tremendous economic and workload burden on the Department and would require pursuing the objective of regulatory review at great expense to the public and to the small business community it purports to benefit. Our current RIA, revised from the SUNSET final rule, provides ample support for these assertions. *See* Section VI. The assessments and reviews required by the SUNSET final rule would be a colossal undertaking with significant resource implications. Among other things, approximately 12,400 of the Department's estimated 18,000 sections in the CFR are over ten years old and would be subject to review during the initial five-year period. Assessing more than two-thirds of all HHS regulations simultaneously in a compressed 5-year timeframe, and assessing them again on a recurring basis ten years after conclusion of the prior assessment, is infeasible. Many of these comments underscored that the SUNSET final rule failed to appreciate the scope of its effects on the Department, including that the rule could compromise some of the Department's most important public health and public safety initiatives. As stated in the Withdrawal NPRM, HHS continues to conclude that the SUNSET final 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.'' 86 FR 59911.

We disagree with one commenter's suggestion that we should disregard these concerns because we should prioritize retrospective review as provided under the SUNSET final rule. First, we disagree that the framework that would have been established by the SUNSET final rule is an appropriate model for engaging in retrospective review. As discussed in further detail in Sections V.C. and D. of this preamble, the framework that would have been implemented under the SUNSET final rule is inconsistent with the requirements and objectives of the RFA; does not fulfill the directives of EOs related to retrospective review, such as E.O. 13563 on ''Improving Regulation and Regulatory Review;'' and likely violates the APA. Second, the disruption to the Department's normal operations that would have been caused by the implementation of the SUNSET final rule is too sizable to disregard and is an entirely valid reason to reject these self-imposed procedures. As discussed in Section V.C below, the Department intends to continue to engage in retrospective review and to explore ways to improve those processes in a manner that is consistent with applicable law and does not undermine its core missions.

*Comment:* A number of commenters supporting the Withdrawal NPRM highlighted the concern that the SUNSET final rule would shift the Department's focus away from its public health mission. Several of these commenters particularly focused on concerns that the SUNSET final rule would divert resources and attention from the urgent COVID–19 pandemic response and impact the Department's ability to develop policy and

promulgate regulations implementing new Federal laws and programs to address pandemic relief. In describing the need for the Department to remain flexible and have the capacity to respond quickly to crises and changing circumstances, one commenter gave the example of CMS needing to take action during the pandemic to swiftly approve hundreds of waivers and state plan amendments so people with disabilities could remain safely in their home. The commenter concluded that, if the SUNSET final rule had been in effect and CMS staff were hamstrung by assessments and reviews, they may not have been able to pivot quickly and review and approve states' crucial changes. Some commenters also expressed concern that the SUNSET final rule would divert resources and attention from other public health emergencies like the opioid epidemic.

Commenters also expressed concern that the volume of assessments and reviews would detract from the Department's overarching work to address the needs of vulnerable populations including children, the elderly, the disabled, those living in poverty, the LGBTQ community, patients living with HIV/AIDS, tribal members, and communities of color. Commenters stated that the SUNSET final rule would frustrate the objectives articulated in E.O. 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' 86 FR 7009, by burdening the programs that serve vulnerable populations and communities of color.

In addition, commenters asserted that implementation of the SUNSET final rule would detract from public health and innovation in the health sector by diverting FDA staff time from regulatory science, engagement with sponsors to support product development, communication of standards to stakeholders on new therapeutic areas such as gene editing, and the conduct of timely reviews of new drug applications. Other commenters expressed concern that the SUNSET final rule would undermine FDA's ability to ensure the safety of food and medicines because the burden of assessments and reviews could divert resources from the implementation and enforcement of existing regulations impacting public safety, patient safety, and public health.

*Response:* We agree that redirecting significant resources from core HHS functions and priorities to undertake assessments and reviews and preserve regulations from automatic expiration under the SUNSET final rule would be contrary to the Department's role as the 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. The Department's ongoing experience with the current pandemic reinforces the need for the Department to remain flexible and focused on the management and utilization of HHS resources. The SUNSET final rule, however, would require HHS to redirect subject matter experts, including program analysts and administrators, economists, and counsel, to perform assessments and reviews. The SUNSET framework would require prioritizing retrospective review above many other Department programs and missions, including both ongoing program operations and the development of new policies and regulations (often necessitated by new statutory requirements) to address public health needs such as the needs of vulnerable populations and advances in health care products and services. Because of these effects, the SUNSET final rule poses a significant risk of future harm.

Moreover, as described in the Withdrawal NPRM, the SUNSET final rule provides no good cause exception to avert the expiration of a regulation, such as in the event of a pandemic, a public health emergency, or another declared national emergency. 86 FR 59912. Although the SUNSET final rule added a provision to permit the Secretary to extend the period for assessments and reviews, the extension could only be applied one time, for up to one year, per each section of regulation, and the extension could 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 2 years plus duration of the COVID–19 pandemic), the Department has determined that the SUNSET final rule was 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. Even if a broader good cause exception were included, the option of employing an exceptional process for emergencies would not begin to address the substantial burdens imposed by, and fundamental policy and legal problems with, the SUNSET final rule, with its application to virtually all of HHS regulations.

2. Burden on Stakeholders

*Comment:* Commenters representing industry and public interest groups supported withdrawing or repealing the SUNSET final rule because of the expected burden on the general public and entities with an interest in the underlying regulations. These stakeholders explained that the rule failed to adequately consider the burden imposed on regulated industry and others to both track HHS regulations for potential expiration and submit comments related to the assessments and reviews. For example, one commenter expressed concern that if the SUNSET final rule is not withdrawn, their advocacy organization would need to redirect resources to monitor the status of the approximately 2,000 FDA regulations and then, if needed, invest at least 40 to 100 hours per rule to provide comments. Another coalition estimated that over 1,000 CMS regulations would require their immediate attention if the SUNSET final rule was not withdrawn or repealed. Among industry stakeholders, one commenter stated that, rather than having a deregulatory impact, the SUNSET final rule would require near constant vigilance as relatively stable regulatory schemes like Medicaid programs would become subject to constant change.

*Response:* The Department believes that any retrospective review process should not impose an undue burden on the public and agrees that the SUNSET final rule would be extremely burdensome on stakeholders to monitor and provide input on both assessments and reviews. As noted in the Withdrawal NPRM, approximately 12,400 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 if the rule were implemented. 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. 86 FR 59912. These numbers indicate that the burden of public participation is significant. In addition, HHS no longer agrees with its previous approach of putting the onus on the public to monitor the Department's progress under the rule to prevent expiration.

The SUNSET final rule stated that a ''safeguard'' to mitigate the risk of inadvertent expiration was for the public to perform this monitoring function and submit comments requesting that the Department commence an assessment or review. 86 FR 5714. We no longer believe it is appropriate to set up a system that depends on stakeholders, including non-profits and state, tribal, and local governments, to ensure that a Department performs an administrative function properly, due to the significant resources it would require those stakeholders to invest in such an effort.

*Comment:* Several commenters expressing support for the Withdrawal NPRM stated that it would be difficult, if not impossible, for the public to accurately determine whether and when a regulation would be subject to review under the SUNSET final rule, and if so, the deadline for informing the Department and commenting. Many of these commenters noted, in response to similar comments on the SUNSET proposed rule, the Department had attempted to mitigate those concerns in the SUNSET final rule by providing that the Department would (1) publish a monthly list of new assessment or review that have commenced and (2) establish a general docket where the public could alert the Department when a regulation may be at risk of expiration because of an approaching deadline for assessment or review. 86 FR 5702. However, the commenters explained that these mitigation efforts are insufficient to address the difficulty of continuously monitoring the pace of assessments and reviews and the burden on stakeholders to alert the Department regarding potentially expiring rules. Another commenter disagreed and stated that, if a section of a regulation were to inadvertently expire under the SUNSET final rule, HHS could follow the APA's flexible rulemaking procedure to readopt it.

*Response:* The Department agrees that the overall framework of the SUNSET final rule would make it difficult and confusing for the Department to implement and for stakeholders to follow. For example, the SUNSET final rule would require each section of the CFR to be assessed and, if applicable, reviewed in the context of the final rule under which it was promulgated. However, final rules often cross-reference or amend previously promulgated sections of the CFR. Given this complication, it would be difficult for the HHS to accurately and comprehensively develop and maintain a list for stakeholders regarding regulations that could expire under the SUNSET final rule framework. Moreover, the Department agrees that it is unreasonable to expect stakeholders to navigate such a process. We conclude it is inappropriate for the SUNSET final rule to rely in part on the public submitting comments requesting that the Department assess or review a regulation in order to operationalize the final rule.

The Department also has determined that addressing the inadvertent expiration of a regulation under the SUNSET final rule by reissuing the implicated regulation would be inefficient, costly, wasteful, and confusing—with insufficient, and in many cases, no countervailing benefit. Such an effort would require a full notice and comment process, as well as a full economic assessment, for a proposed and final rule during which stakeholders and programs would experience the legal and regulatory uncertainty of an expired regulation.

3. Comments on Economic Evaluation of Burdens

*Comment:* A few commenters disagreed with the Department's assessment in the Withdrawal NPRM of the burden of the SUNSET final rule and asserted that the Withdrawal NPRM's RIA overstated the cost estimated for implementing the SUNSET final rule. More specifically, some commenters questioned the estimates for burdens on stakeholders to comment on assessments and reviews based on these commenters' prediction that most members of the public have little incentive to take an interest in the assessment and review of individual HHS policies. One comment suggested the costs were overstated because the regulations that were the subject of stakeholder comments would be eliminating costs on these (and other) commenters. The comment also asserted that any uncertainty created by the SUNSET final rule is a ''short-term cost[]'' that ''will be resolved as the schedules for expiration are discovered'' and may be offset by the reduction in uncertainty associated with diverting HHS resources away from other actions.

Another comment asserted that HHS ignored the concept of ''rent-seeking'' when it considered the costs of HHS regulatory actions and the ''likely unrepresentative nature of the comments received by HHS'' on the SUNSET proposed rule. The commenter further stated that ''rent-seeking costs'' may also affect the Department's cost estimates. The commenter concluded that ''[i]f the entities that submit comments to the department while it is undergoing retrospective reviews would have been rent-seeking in absence of having to write comments, then the private costs to these individuals and groups from writing comments could well constitute social benefits to society writ large.''

In addition, one comment questioned the estimates for burdens on the Department. The commenter stated that the Withdrawal NPRM's RIA used cost estimates for burdens on the Department that were inconsistent with guidance in OMB Circular A–4 and HHS Guidelines for Regulatory Impact Analysis.[8] In the commenter's view, the RIA incorrectly projected ''accounting costs'' from hiring new personnel to perform these tasks. The commenter asserted that, instead, the RIA should have assessed the real opportunity costs to the Department and taxpayers from the forgone activities such staff would have performed in the absence of the process required by the SUNSET final rule. The commenter also questioned the Department's assumption in the RIA for the Withdrawal NPRM that HHS would follow Small Business Administration (SBA) guidance in conducting reviews, and asserted that the costs of conducting reviews would lessen over time.

*Response:* We disagree with these commenters concerning the cost estimates in the Withdrawal NPRM RIA and continue to believe that the RIA in the SUNSET final rule likely underestimated the costs of implementing that rule to a significant degree. With regard to the estimated burden on stakeholders, as discussed in greater detail in Section VI, the SUNSET final rule likely underestimated the time and resource commitment of a credible assessment and review process. The Department acknowledges that there is uncertainty in the amount of time the public would spend commenting on assessments and reviews under the SUNSET final rule. We have appropriately incorporated this uncertainty into the estimates of the burden to stakeholders by incorporating a range of estimates of the time spent per comment into our current evaluation of the burden of the SUNSET final rule. To the extent that the commenters indicate that the public would submit fewer, rather than zero, comments prior to the assessments, we have incorporated this into the Withdrawal NPRM's preliminary RIA by incorporating a lower estimate of 25

[8] *See* OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*); HHS Guidelines for Regulatory Impact Analysis (2016) (available at *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//171981/HHS_RIAGuidance.pdf*).

comments per assessment into our current evaluation of the burden of the SUNSET final rule. This estimate is about five percent of the comments anticipated in the SUNSET final rule's RIA for regulations that the Department announces would be rescinded following a review.

In contrast, the SUNSET final rule's RIA incorrectly based its burden estimates on an assumption that the public would forego commenting until the retrospective analysis was complete and the Department announced its intent to rescind or amend a rulemaking. We now find this assumption puzzling: It would not make sense to require a comment process for assessments if the Department thought no one would be interested in commenting. In any event, we disagree with the assumption that stakeholders will forego commenting until late in the process because it is illogical, lacks any evidentiary basis, and is contrary to the weight of the comments. Indeed, stakeholders have already demonstrated a high level of interest in the subject of this rulemaking.[9] We understand that these stakeholders would be motivated to comment because they would want to ensure that HHS has up-to-date information to correctly evaluate both the impacts of a rulemaking and potential changes to the regulations. We also note that Congress, in drafting the RFA, appeared to believe the public would be interested in commenting on reviews because it required agencies to provide an opportunity for public participation in the review process.

We also do not agree that uncertainty is a short term cost. The SUNSET final rule creates a continuing threat of expiration because, regardless of the ''schedules for expiration,'' the public cannot know what public health exigencies may arise in the future and what decisions the Department will make to serve its mission. The same uncertainty does not exist with more typical rulemakings because they have built-in safeguards, such as notice and opportunity for comment.

With regard to the comment about ''rent-seeking,'' this comment appears to confuse several economic concepts, including ''rent-seeking,'' ''rent-seeking costs,'' and economic rent, which makes the comment difficult to parse and understand. Additionally, we do not unambiguously attribute to the SUNSET final rule the impacts of regulations that would be rescinded or amended following a review under the SUNSET final rule. It is also not clear why the commenter anticipates that the SUNSET final rule, which would invite public comment on about 18,000 regulations over ten years, would result in public comments that are more representative of the views of the general public than the notice-and-comment rulemaking process the Department follows under the APA in this rulemaking. As such, it is not clear how the SUNSET final rule would provide a superior approach to addressing economic rents attributable to existing regulations.

With respect to the comment on the Withdrawal NPRM preliminary RIA's estimated burden on the Department, we agree with the commenter that there would be real opportunity costs to the Department and taxpayers attributable to forgone activities that would have been performed in the absence of the process required by the SUNSET final rule. While we cannot predict all of the likely forgone activities, they could include, for example, actions to address urgent public health matters such as COVID–19 pandemic relief efforts or similar efforts to respond to future emergent threats, FDA review of applications and the fulfillment of user fee commitments, work to ameliorate the opioid crisis, stem outbreaks of foodborne illness, and conduct inspections, recalls and other public health priorities. To the extent that Department would need to defend challenges related to expired regulations, such effort would further require the Department to divert resources from other public health priorities. To measure these opportunity costs, we adopt the standard approach recommended in the *HHS Guidelines for Regulatory Impact Analysis* of a ''default assumption'' ''that the value of activities conducted during paid work time can be best approximated by the cost of labor to the employer. The standard economic model assumes that employers are willing to incur labor costs equal to the value of workers' marginal product. Conceptually, this amount represents the value of what the employee would have otherwise produced in the absence of the regulation. Thus, the opportunity cost of paid work time can be approximated based on the employer costs, including pay, benefits, taxes, and associated overhead.'' [10]

However, the commenter is incorrect that the assessments and reviews would be achieved solely through the reallocation of existing staff resources. As described in Section VI, implementation of the SUNSET final rule would require contributions from current and new Department subject matter experts, lawyers, and other reviewers informing the retrospective analysis and providing feedback on draft analyses, time spent by economists and other analysts developing the retrospective analysis to respond to this feedback, time spent reading and incorporating evidence from other sources, including public comments, and other activities. The SUNSET final rule RIA did not explicitly include these important activities in its estimates of the time per review. The consequence of excluding these activities in its analysis is that the SUNSET final rule likely underestimated the total costs to the Department of the SUNSET final rule to a significant degree. Our current evaluation of these costs indicates that the Department would incur additional costs to hire, train, and transfer personnel with technical expertise.

One comment argued that the Department's cost estimates in the Withdrawal NPRM are likely to be inaccurate because the comment disagreed with our assumption that the Department would follow the recommendations in the SBA guidance.[11] The commenter cited an analysis of regulatory impact analyses performed between 2008 and 2013 as support. This analysis, which predates the SBA Guidance published in August 2017, does not reference ''Regulatory Flexibility Act,'' ''regulatory flexibility analysis,'' ''Section 610 reviews,'' ''small business,'' ''small entity,'' or otherwise contain any evidence that the Department does not currently follow the recommendations in the SBA guidance, or any evidence that the Department would not follow these

[9] As noted above, a wide range of stakeholders submitted over 500 comments on the SUNSET proposed rule, almost all in opposition, and several stakeholders filed the *Santa Clara* lawsuit seeking to overturn the SUNSET final rule. As discussed in the Withdrawal NPRM and in Sections IV.A.2 and IV.B.1. of this preamble, many stakeholders opposed the SUNSET final rule because the threat of regulations automatically expiring would increase cost and confusion, impede competition, and harm the public health in numerous ways. Moreover, if the SUNSET final rule were to be implemented, many of these stakeholders have indicated that they would expect to expend considerable resources tracking HHS regulations for potential expiration and submitting comments. *See* Section V.A.2.

[10] HHS Guidelines for Regulatory Impact Analysis at 27 (2016) (available at *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//171981/HHS_RIAGuidance.pdf*). This default assumption is discussed in greater detail in Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices'' (Sept. 17, 2017) (available at *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework*).

[11] ''A Guide for Government Agencies: How to Comply with The Regulatory Flexibility Act,'' (Aug. 2017) (available at *https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf*).

recommendations for assessments or reviews performed under the SUNSET final rule.

The commenter also discussed the potential that the costs of conducting reviews will lessen over time. We are not able to fully evaluate the merits of comment since it does not provide any guide for when the Department would begin to experience these lower costs, and because it does not include a quantification of the reduction in time per assessment or review resulting in lower costs over time. *See* Section VI.

*B. Comments on Potential Harms From the Possible and Actual Expiration of Regulations*

In issuing the Withdrawal NPRM, the Department explained that it was concerned that, if the SUNSET final rule were implemented, both the possibility of automatic expiration of HHS regulations, and the actual expiration of HHS regulations, could harm the public. 89 FR 59914. Below we respond to the comments on the Withdrawal NPRM on this subject.

1. Impact on Stakeholders in General

*Comment:* A number of commenters, including health care providers, public interest groups, and private sector entities, urged HHS to withdraw the SUNSET final rule because it would create unpredictability for industry and consumers. These commenters noted that the lack of predictability concerning the potential automatic expiration of regulations could result in the haphazard vacating of numerous existing rules without appropriate communication to regulated entities, and potentially upend long-standing foundational rules with provisions that are inter-related with other rules. The commenters expressed concern that such unpredictability regarding large swathes of the rules governing public health and welfare could lead to adverse impacts for stakeholders.

Several of these comments expressed concern that the SUNSET final rule would introduce uncertainty regarding the validity and enforceability of regulations and wreak havoc on HHS programs. Commenters noted that there would be uncertainty and confusion regarding the current and future regulatory status of rules slated for review and assessment, and that expiring regulations could leave vast, gaping holes in the regulatory framework implementing HHS programs and policies and introduce confusion and sudden shifts in regulatory requirements. Commenters further noted that if the intent of the SUNSET final rule was to ease burdens upon small businesses, it would more likely have the opposite effect. All businesses, but most especially small ones, benefit from transparent regulation that can be planned for, budgeted for, and implemented.

Among these commenters, several representatives of industry coalitions whose membership includes small entities also warned that, if not withdrawn or repealed, the SUNSET final rule could engender chaos and harm to both industry and consumers. Several commenters discussed the time, resources, and capital investments made by the food industry because of reliance on durable public standards that have been codified in regulation. The commenters expressed significant concerns about the expansive and accelerated approach taken in the SUNSET final rule and the disproportionate burden and uncertainty small entities would face should the final rule lead to the expiration of regulations that have been in place for years and are essential to a level playing field within the industry.

Commenters also described the impacts of regulatory uncertainty on public health. One commenter described the potential damaging effects the SUNSET final rule would have on the drug development process, where drug sponsors rely on a predictable regulatory environment to plan their development programs. The commenter stated that an environment in which FDA or other HHS regulations may be capriciously eliminated could hamper progress on much needed therapies in the drug development pipeline. One commenter specifically referenced the consequences of a lack of public confidence in food labeling, including the rules that inform consumers about the ingredients and nutrient content of their food, and safety rules concerning Salmonella, Shiga toxin-producing E. coli, and other potentially deadly foodborne pathogens. Other commenters provided examples of harms of uncertainty to the HHS programs such as Temporary Assistance for Needy Families (TANF) and the Child Care and Development Fund (CCDF), where a strong regulatory framework provides the clarity needed to run these programs on a day-to-day basis, gives providers guidance on their obligations, and explains to beneficiaries what their benefits mean.

*Response:* We agree with these comments about the importance of a relatively steady and predictable regulatory environment and appreciate the examples of the ways the SUNSET final rule would introduce unpredictability regarding HHS regulations and the associated harms. Given the complicated resource allocation decisions necessary to implement the review framework prescribed in the SUNSET final rule, HHS is unable to forecast the number of or identify specific regulations that may expire without a completed assessment and, if applicable, review. It therefore may be difficult for stakeholders to know which regulations would remain in place because that would depend on whether the Department could actually complete each regulation's assessment and/or review by the assessment or review deadline. We concur that the potential automatic expiration of large swathes of rules, or even one complex rule, without notice of the reasoned justification for retiring that rule or set of rules, could create uncertainty and unpredictability regarding regulatory programs going forward.

Although the SUNSET final rule stated 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 concludes that this reasoning was flawed. The rule's automatic expiration of regulations is very different from amendment or rescission through notice and comment rulemaking, because there is no built-in safeguard of prior notice for automatic expiration, and no process for obtaining stakeholder input on the implications of losing the regulation. Therefore, expiration could be haphazard and unpredictable and without appropriate notice to and input from stakeholders. This outcome would be far 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, policy, or other circumstances. Moreover, the Department generally uses mechanisms such as the Unified Agenda of Regulatory and Deregulatory Actions (Unified Agenda) and the HHS Regulatory Agenda, which are published in the **Federal Register**, to provide advance notice and predictability to affected stakeholders about specific regulations that may be amended or rescinded.[12]

We have now determined that the mechanisms described in the SUNSET final rule, which include a dashboard on the HHS website that shows the

[12] *See, e.g.,* Regulatory Information Service Center, ''Introduction to the Unified Agenda of Regulatory and Deregulatory Actions—Fall 2021'', 87 FR 5002, 5009 (Jan. 31, 2022).

progress of Assessments and Reviews and when HHS expects them to be completed, are insufficient to provide adequate clarity concerning regulations that may be subject to automatic expiration. As discussed in greater detail in Section V.E, the rule includes a number of vague and confusing provisions that would make it difficult to determine when any given section of the CFR is subject to expiration. For example, a section may need to be reviewed multiple times as part of multiple rulemakings to avoid expiration, or it may require no review at all because it has been determined to fall within an exception. The public could not necessarily predict, from looking at the dashboard, the fate of that particular section. Moreover, rulemakings could be added or deleted from the dashboard at HHS's discretion, so the fact that a particular rulemaking is absent would not necessarily mean that the public could draw conclusions regarding the rule's expiration status until the expiration date is near. For these reasons, a dashboard indicating the progress of assessments and reviews would not adequately alleviate public uncertainty about the loss of regulations. These uncertainties could have several adverse repercussions as discussed in the Withdrawal NPRM, comments to the SUNSET proposed rule and Withdrawal NPRM, and below, for example, in the following comment and response.

*Comment:* A variety of commenters including states, tribes, municipalities, hospital systems, insurers, healthcare providers, and patient advocacy organizations expressed support for the Withdrawal NPRM, citing the potential consequences of the SUNSET final rule creating uncertainty about the stability and predictability of HHS regulations and causing harm if HHS regulations were to actually expire. A number of commenters described the risk of such uncertainty for the Modified Adjusted Gross Income (MAGI) regulations, which are relied upon by states and state agencies to determine who is eligible for certain Medicare and Medicaid programs, Medicare Advantage, the Children's Health Insurance Program (CHIP), and insurance affordability programs through the Health Insurance Marketplace, as well as the consequences of such uncertainty for individuals in trying to ascertain their likely eligibility for these programs. Commenters underscored that Medicaid and CHIP are large, complex, Federal-state health insurance programs that affect not only all of the states and territories, but also millions of beneficiaries, tens of thousands of providers, and hundreds of managed care plans. They stated that these stakeholders have a legitimate expectation of stability in the Federal regulatory guidelines for these programs and that predictable and reliable Federal regulations are essential to facilitate their effective implementation, so that providers understand what their obligations are, and beneficiaries can understand what they are entitled to receive. Commenters emphasized the significance of these and other HHS administered healthcare programs for seniors, children, the disabled, low-income and rural communities, and other vulnerable segments of the population including people of color, members of the LGBTQ+ community, and others who suffer health disparities, and the dire consequences they would suffer if regulations were to expire under the SUNSET final rule and safety net programs were disrupted. Commenters noted that the SUNSET final rule is at odds with the policy goals of E.O. 14009, ''Strengthening Medicaid and the Affordable Care Act'', 86 FR 7793, by weakening the strong regulatory framework necessary for states to implement these complex programs that provide health care access to millions of otherwise uninsured Americans.

Other commenters described the potential impact of expiration on stakeholders in the food industry and on consumer confidence in the safety of food and medical products. They provided examples of harms that would result in the event FDA regulations concerning false and misleading medical product labeling and advertising, nutrition labeling, food safety, or food standards of identity were to expire. Comments on the SUNSET proposed rule provided numerous additional examples related to HHS programs, as discussed in the Withdrawal NPRM. 86 FR 59915–59917.

*Response:* We thank the commenters for illustrating the many ways participants across the health care system and other Department programs would be harmed if they could not depend on the integrity and reliability of HHS regulations. We agree that, beyond the harm of regulatory uncertainty, the damage from actual expiration of regulations could be severe. As explained in the Withdrawal NPRM and in Section III.B., we have determined that regulations are likely to expire under the SUNSET final rule. Expiration could cause serious harm to millions of stakeholders who rely on HHS programs, including underserved populations; upend established understandings across the public health spectrum as to how to comply with statutory requirements; and disrupt established industry standards that advance public health, create a level playing field for businesses, and boost consumer confidence. Because of these potential harms, we now conclude that the automatic expiration provision is contrary to the Department's mission to protect the health of all Americans and provide essential human services, especially for those who are least able to help themselves.

States, non-state government entities, hospitals and other health providers, insurers and managed care plans, and other key stakeholders in our country's health care system structure their programmatic and business operations to satisfy the current Federal regulations. These rules help beneficiaries and potential applicants to understand the coverage they are or may be entitled to receive, patients to understand their rights in accessing and receiving care, and providers to understand their patients' coverage. As discussed in the Withdrawal NPRM, the expiration of these regulations could mean that these and other 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. *See* 86 FR 59915–59917. Likewise, we now recognize, as discussed in Section V.D of this preamble, that the SUNSET final rule could result in rescinding rules in their entirety without a rule-specific justification or an opportunity for the public to comment on that justification, including identifying potential harms associated with the expiration.

2. Impacts on State, Local, and Tribal Governments

*Comment:* Several tribal organizations explained that the SUNSET final rule would undermine crucial regulatory protections for AI/ANs in accessing healthcare, including HHS regulations that are based in statute and developed through years of government-to-government consultation between Tribal Leaders and HHS Leadership. Tribal commenters expressed support for HHS's Withdrawal NPRM because the SUNSET final rule threatens the regulations intended to protect AI/ANs. These commenters also opposed the SUNSET final rule because they said the Department failed to abide by the HHS Tribal Consultation Policy and conduct tribal consultation to minimize the implications of this rule on tribal governments. One tribal commenter

expressed appreciation for the change of direction on the SUNSET final rule and hoped that the Department continues in this spirit of accounting for the impact of such decisions on Tribal Nations.

*Response:* HHS respects and appreciates the leadership and partnership of Tribal Nations in protecting the health of AI/ANs. The Department is committed to strengthening the Nation-to-Nation relationship between the United States and federally recognized Indian Tribes.

As discussed in the Withdrawal NPRM, HHS acknowledges that consultation with Tribal governments on the SUNSET proposed rule was not adequate. The Department also recognizes that it previously stated that the SUNSET final rule ''would have no direct impact on Indian Tribes, beyond their costs of participation in the monitoring, Assessment, and Review processes,'' based on an assumption that regulations would not expire. 86 FR 5711. However, we have now determined, and explained in detail throughout this preamble, that the Department's prior assumption that regulations would not expire was not well-founded. Therefore, HHS has revised its view of the impacts of the SUNSET final rule on Tribal Nations.

The IHS serves over 2.6 million AI/ANs and the Department recognizes that there are stark health disparities that persist in Tribal communities. The COVID–19 pandemic's devastating impact on Tribal communities has demonstrated the real human toll of these disparities. HHS concludes that the SUNSET final rule would only make it harder to expand access to high-quality health care across Indian Country, because it is likely to divert resources from HHS programs serving Tribes and introduce uncertainty and a threat of expiration for regulations that support HHS programs serving tribal communities. Likewise, the SUNSET final rule does not provide for advance notice of regulations that might automatically expire which would make it difficult for the Department or Tribes to initiate consultation. Moreover, even if these significant deficiencies could be improved, it would still not resolve more fundamental problems the SUNSET framework presents for tribal stakeholders, such as the burdens imposed on and uncertainties created for many stakeholders.

As discussed in the Withdrawal NPRM, HHS now acknowledges the SUNSET final rule conflicts with the Department's policy to engage in meaningful consultation. *See* 86 FR 55911. HHS believes finalizing the Withdrawal NPRM is consistent with the objectives of the January 26, 2021, Presidential memorandum on ''Tribal Consultation and Strengthening Nation-to-Nation Relationships,'' which reaffirmed the tribal consultation policy outlined in E.O. 13175, and announced that the Biden-Harris administration priority to make respect for Tribal sovereignty, self-governance, and regular, meaningful, and robust consultation with Tribal Nations cornerstones of Federal Indian policy. 86 FR 7491.

*Comment:* A number of states, municipalities, and State attorneys general expressed concern that the SUNSET final rule would pose a direct threat to state health care systems and the health and safety of their residents. The commenters indicated that states are directly threatened by the SUNSET final rule because they depend on HHS to administer trillions of dollars in Federal funding, governed by an intricate web of regulations and requirements. A comment from State attorneys general explained that, by permitting complex regulatory systems to automatically expire, the SUNSET final rule could have dire consequences for those who stand to lose health benefits or services but have no recourse to prevent that loss. One commenter stated that the SUNSET final rule stands to undermine the operations of state partners, such as state Medicaid agencies, and would impede their ability to provide services for Medicaid beneficiaries.

*Response:* We agree that many diverse stakeholders throughout the country, including states, state Medicaid and other program agencies, and tribal governments, as well as health care providers, program beneficiaries, and others who rely on the legal framework established by the Department's regulations and their implementation of the relevant statutes, could experience undue disruption as a result of the SUNSET final rule. As discussed in the Withdrawal NPRM, the automatic, potentially haphazard and unpredictable expiration of regulations could result in significant disruption, based on the sudden and unexamined removal of the prior regulatory framework without accompanying explanation or replacement. We appreciate the comments highlighting challenges that this scenario could present for many stakeholders, including state and tribal governments.

3. Other Comments on Expiration

*Comment:* A few commenters expressed doubt that accidental and unintended expiration of regulations would occur and pointed to the experience of North Carolina and Missouri. Each of those states has an established process for the review of state regulations that features a sunset mechanism. One commenter stated that North Carolina's process resulted in no reports of accidental expirations. The commenter suggested that, because the quantity of HHS regulations is similar to the number of all regulations promulgated in North Carolina, the process should not be difficult for HHS to implement and avoid any expiration of a regulation. A second comment stated that Missouri connects a sunset provision to a five-year periodic review requirement in a manner similar to the SUNSET rule. The commenter shared a quote from the Missouri attorney general stating that they were not aware of any regulations that had expired as a result of Missouri's sunset provision and that state agencies review every regulation under their control.

*Response:* We address in greater detail in Section V.C the many significant differences between the SUNSET final rule and these and other state sunset laws—here we address only the specific points regarding the potential expiration of regulations. We disagree with these commenters in their assertions that we should extrapolate from these state examples to conclude that regulations would not expire under the SUNSET final rule because there are too many substantial differences to make a direct comparison helpful or appropriate. North Carolina's reviews are less burdensome overall because North Carolina's experience does not entail the multi-factor review and assessment required by the SUNSET final rule. We similarly find that Missouri's experience does not match the scale and scope of the SUNSET final rule's assessment and review scheme. For example, the most recent reports of the Missouri State Auditor responsible for assessing state agency compliance with periodic rule review found that the Missouri Department of Health and Human Services reviewed 759 rules and received no comments on its review and that the Department of Mental Health reviewed 156 rules and received 14 comments.[13] These rules represent a small fraction of the number of HHS regulations covering all of the HHS agencies and divisions, and the comment offers no analysis as to whether individual Missouri rules are

[13] *See* Nicole Galloway, Missouri State Auditor Report No. 2019–126 (Dec. 19, 2019) (available at *https://app.auditor.mo.gov/Repository/Press/2019126349658.pdf*); Nicole Galloway, Missouri State Auditor Report No. 2017–152 (Dec. 19, 2017) (available at *https://app.auditor.mo.gov/Repository/Press/2017152319255.pdf*).

comparable to HHS regulations in terms of length and complexity. Furthermore, HHS regulations are national in scope, have an impact on a much greater number of programs and persons, and cover more diverse circumstances than state regulations. In issuing its regulations, HHS also follows Federal procedures and policies as set forth in statutes, EOs, and Department memoranda, which are not applicable to states. Accordingly, the review of HHS regulations is likely to entail greater complexities and the level of public interest in the HHS rules is likely to be much higher, which would result in significantly more comments. Thus, the pace and resources required to review North Carolina's and Missouri's inventory of regulations are not indicative of what HHS would experience under the SUNSET final rule, including the likelihood of expiring regulations.

Moreover, as explained in Section III.B., implementation of the SUNSET final rule would require the Department to choose how to prioritize its resources as between (1) addressing existing and new priorities, including promulgating new congressionally directed regulations, and (2) preserving regulations from expiration. The fact that certain states with ''sunset'' programs can, and have chosen to, allocate resources in a way that preserves their regulations from expiration does not in any way imply that HHS would or could make the same choices in confronting this question. As explained above, we have considered the overall burdens and the ways in which full implementation of the SUNSET program would undermine other Department objectives, and we have concluded that prioritizing resources on SUNSET compliance, in order to avoid regulatory expiration, is not in the best interests of the public health and welfare. Therefore, we think regulations will expire. Whether states have made different choices does not determine the Department's analysis regarding its obligations and priorities.

### *C. Comments on the RFA and Retrospective Review*

In the Withdrawal NPRM, we tentatively concluded that the final rule may be harmful to small entities, inconsistent with Congress's intent in enacting the RFA, and unnecessary to achieve the RFA's objectives or to incentivize the Department to engage in retrospective review. 86 FR 59917. In this section, we respond to the comments submitted both on policy issues related to retrospective review and on compliance with the RFA.

#### 1. SUNSET Final Rule's Degree of Consistency With the RFA

*Comment:* Numerous commenters supported withdrawal of the SUNSET final rule as inconsistent with the RFA. Many of these commenters agreed with HHS's assertion in the Withdrawal NPRM that the SUNSET final rule imposes requirements beyond the requirements of the RFA. Several of these commenters noted that the RFA focuses on review of only those rules that have or will have a ''Significant Economic Impact Upon a Substantial Number of Small Entities'' (SEISNOSE), and the SUNSET rule exceeds that scope because it requires assessment of all agency rules regardless of whether they have a SEISNOSE. One commenter noted that the majority of the regulations to which the SUNSET final rule applies do not actually fall within the scope of the RFA, citing the SUNSET final rule's assumptions, which estimate that only 15% of the Department's regulations have a SEISNOSE. Commenters also questioned HHS's authority to impose the SUNSET rule's requirements for the scale and speed of assessments and reviews in the absence of express authorization in the RFA. One commenter noted that courts have uniformly recognized the limited scope of the RFA and that the SUNSET final rule's expansion of the RFA's requirements finds no support in the text or purpose of the statute. Several commenters also noted that the RFA does not authorize agencies to retroactively impose a blanket expiration date to rescind regulations.

*Response:* The Department agrees with these commenters that the SUNSET final rule's requirements exceed the RFA's requirements. Specifically, the Department agrees with the commenters who noted that the rule's requirement that the Department ''assess'' all HHS regulations within certain timeframes, to determine whether the regulations have or will have a SEISNOSE, exceeds the express requirements of section 610 of the RFA, which contemplates periodic review of only ''rules . . . which have or will have a [SEISNOSE].'' Nothing in the express language of that section requires agencies to identify such rules by conducting ''assessments'' of every rule issued by the agency and to comply with the SUNSET final rule's notice and comment requirements for such assessments. Indeed, section 610 does not specify any means of identifying rules that have or will have a SEISNOSE. Section 610(a)'s silence with respect to identifying rules that have or will have a SEISNOSE, when contrasted with other provisions of that section explicitly imposing specific requirements on agencies' retrospective reviews, *see, e.g.,* 5 U.S.C. 610(b) (requiring agencies to consider specific enumerated factors when conducting reviews), indicates that Congress intended to leave such determinations to agencies' discretion. *See Fisher* v. *Pension Benefit Guar. Corp.,* 994 F.3d 664, 671 (D.C. Cir. 2021) (''In an administrative setting, . . . 'the contrast between Congress' mandate in one context with its silence in another suggests . . . a decision *not to mandate* any solution in the second context, *i.e.,* to leave the question to agency discretion.' '').

Judicial decisions have reinforced agencies' discretion under the RFA. As the D.C. Circuit has explained, ''the Act in and of itself imposes no substantive constraint on agency decisionmaking,'' *Nat'l Tel. Co-op Ass'n* v. *FCC,* 563 F.3d 536, 540 (D.C. Cir. 2009), but instead is limited to ''setting out precise, specific steps an agency must take,'' *Aeronautical Repair Station Ass'n, Inc.* v. *FAA,* 494 F.3d 161, 178 (D.C. Cir. 2007). Courts have therefore instructed that the RFA ''requires nothing more than that the agency . . . demonstrate[e] a reasonable, good faith effort to carry out'' those steps. *U.S. Cellular Corp.* v. *FCC,* 254 F.3d 78, 88 (D.C. Cir. 2001); *Aeronautical Repair Station,* 494 F.3d at 178 (''[Section 604 of] the Act requires agencies to publish analyses that address certain legally delineated topics. Because the analysis at issue here undoubtedly addressed all of the legally mandated subject areas, it complies with the Act.''); *see also Montgomery Cty., Maryland* v. *Fed. Commc'ns Comm'n,* 863 F.3d 485, 495 (6th Cir. 2017) (upholding agency's final regulatory flexibility analysis as ''procedurally adequate''); *Zero Zone, Inc.* v. *United States Dep't of Energy,* 832 F.3d 654, 683 (7th Cir. 2016) (citing *U.S. Cellular Corp.,* 254 F.3d at 88); *Alenco Commc'ns, Inc.* v. *FCC,* 201 F.3d 608, 625 (5th Cir. 2000) (citing *Assoc. Fisheries of Me., Inc.* v. *Daley,* 127 F.3d 104, 114 (1st Cir. 1997)).

In addition to not being mandated by the RFA, the assessment process in the SUNSET final rule is an overly burdensome and unnecessary means of identifying rules that have or will have a SEISNOSE. In fact, as discussed in more detail below, we now question whether the assessment process is a reasonable exercise of the Department's discretion in light of the purpose and language of the RFA. As noted by one commenter, based on the Department's assumptions in the RIA of the SUNSET

final rule, which are adopted in the RIA of this final rule, only 530, or approximately 15%, of the Department's rulemakings impose a SEISNOSE, whereas the SUNSET rule estimates the Department would need to assess a total of 3,574 rulemakings in order to identify those rules. The Department continues to believe that, had Congress intended for section 610 to mandate such a burdensome process for identifying a minority of rulemakings that have or will have a SEISNOSE, it would have said so explicitly. *See Whitman* v. *Am. Trucking Ass'ns,* 531 U.S. 457, 468 (2001) (Congress ''does not[ ] . . . hide elephants in mouse holes''). Moreover, as explained in Section V.C.2 of this rule and the Withdrawal NPRM, conducting assessments of all HHS rules is not the only available means of identifying rules with a SEISNOSE, as commenters have identified numerous more targeted, efficient, and effective alternatives for identifying regulations that have or will have a SEISNOSE. We further note that, although the RFA applies across numerous government agencies, HHS is not aware of any department or agency issuing a similar sunset regulation or any litigation asserting that any department or agency, including HHS, has violated the RFA by failing to implement a rule like the SUNSET final rule.

Moreover, as explained in the Withdrawal NPRM, principles of statutory construction do not support broadly interpreting section 610 to require agencies to simultaneously consider all regulations and do so on a recurring basis to determine whether they have or will have a SEISNOSE. Section 610(a) mandates that agencies publish a plan providing for a one-time simultaneous reexamination of regulations that have or will have a SEISNOSE. Had Congress intended for this plan to provide for simultaneous review that applies more broadly to all regulations and on a recurring basis, it would have said so. *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.'')).

The Department also agrees with commenters that the SUNSET final rule's automatic expiration provision—providing for the automatic expiration of any rule issued by the Department if it is not timely assessed or, as applicable, reviewed—exceeds the express requirements of the RFA. As explained in the Withdrawal NPRM, section 610 neither provides for automatic expiration of rules nor presumptively applies automatic expiration dates to regulations. Rather, it merely contemplates rescission or revision of rules, through the standard notice and comment rulemaking processes, only if they have or will have a SEISNOSE and if the Department has determined, based on its review of the factors set forth in section 610, that such rules should be rescinded or revised to minimize any SEISNOSE. We also note that section 608(b) of the RFA explicitly provides: ''If the agency has not prepared a final regulatory analysis pursuant to section 604 of this title within one hundred and eighty days from the date of publication of the final, such rule shall lapse and have no effect.'' The absence of any similar language in the RFA requiring rules to automatically lapse if an agency fails to comply with section 610 suggests that Congress did not intend for noncompliance with section 610 to have such an effect. *See, e.g., Salinas,* 141 S. Ct. at 698.

The Department also notes that other requirements in the SUNSET final rule extend beyond the express requirements in the RFA. For example, the SUNSET final rule's requirements for public notice and comment procedures with respect to assessments—such as publishing in the **Federal Register** a notice within a month of commencing an assessment as well as a notice of the results of all assessments—extend beyond section 610's notice and comment requirements. Although section 610 requires notice and comment procedures for retrospective review of rules which have or will have SEISNOSE,[14] it does not require notice and comment procedures for the Department's determinations of which regulations have or will have a SEISNOSE. Additionally, the SUNSET final rule's expedited five-year timeline for the completion of certain reviews and two-year timeline for amending or rescinding regulations following such reviews go beyond the express requirements of section 610(a), which contemplate only that reviews of rules under that section be conducted ''within ten years'' of specific dates.[15]

Additionally, the Department agrees with commenters that the automatic expiration provision and other requirements imposed by the SUNSET rule otherwise lack support in the language and purpose of the RFA. For the reasons already explained, the RFA does not explicitly impose or authorize these requirements. Moreover, as explained in the Withdrawal NPRM, these requirements appear to be inconsistent with the intent and purpose of the RFA as expressed in the statute's language and legislative history. Specifically, the automatic expiration provision—by providing for the automatic expiration of rules without consideration of the impact of the rules on small entities or the statutory objectives the rule implements—appears to be inconsistent with the RFA's intent to balance the objectives of the RFA with the objectives of statutes critical to public health. Congress expressed this intent in the language of section 610(a) itself, which contemplates the rescission of rules only if ''consistent with the stated objectives of applicable statutes'' and if the agency has determined that that the rule should be rescinded ''to minimize any significant economic impact of the rules upon a substantial number of . . . small entities.'' The RFA's legislative history further expresses this intent, stating 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) (statement of Sen. Culver, sponsor of S. 299, which was ultimately enacted as amended as the RFA); *see also* S. Rep. 96–878 (1980) (''The Committee is emphatically opposed to any weakening of the legislatively mandated goals of federal regulation in the name of cost reduction. The bill clearly stipulates that there is to be no loss of regulatory goals. The language states that agencies shall seek and consider alternative proposals to the proposed rule 'consistent with the stated objectives of applicable statutes.''). Rather, Congress intended that ''agencies . . . continue to enforce [substantive] laws in a fully effective fashion,'' *id.,* and that ''environmental, health or safety catastrophes must never be made more likely because of flexible regulations,'' *id.* at 21,455 (Description of Major Issues and Section-by-Section Analysis of Substitute for S. 299).

In addition to the automatic expiration provision, other SUNSET final rule requirements exceeding the express requirements of section 610

[14] *See* 5 U.S.C. 610(c) (requiring agencies to publish in the **Federal Register** a list of rules to be reviewed during the succeeding twelve months as well as invite public comment on rules to be reviewed).

[15] We note that, as discussed in Section V.D, expanding these timeframes would not resolve the myriad of problems with the SUNSET final rule discussed throughout this preamble, such as the burdens, confusion, and uncertainty imposed on stakeholders.

appear inconsistent with the RFA's intent. As explained previously in this preamble and in the Withdrawal NPRM, compliance with the SUNSET final rule's requirement to assess thousands of regulations within certain timeframes would require the agency to divert resources from the Department's significant public health objectives and potentially impair its ability to achieve those objectives. The RFA's legislative history indicates that such a burden imposed by assessments would be contrary to Congress's intent that ''regulatory flexibility legislation [not] undermine . . . important [regulatory] achievements.'' 126 Cong. Rec. 21,451 (statement of Sen. Culver); *see also id.* at 21,455 (Description of Major Issues and Section-by-Section Analysis of Substitute for S. 299) (addressing concerns that the RFA ''might require agencies to significantly compromise the objectives of underlying statutes authorizing rulemaking''). Such burdens on the Department's ability to achieve important statutory objectives related to public health also appear inconsistent with the RFA's intent to enhance administrative efficiency in the achievement of such objectives. *See* 126 Cong. Rec. 21,456 (Description of Major Issues and Section-by-Section Analysis of Substitute for S. 299) (emphasizing 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''); *see also* S. Rep. 96–878 (stating that S. 299's findings include ''that reasonable alternative rules and regulations could be developed . . . without a significant loss of regulatory efficiency'').

Furthermore, the SUNSET final rule's requirements exceeding the express requirements of section 610 also appear to be inconsistent with the RFA's purpose of alleviating the regulatory burden on small entities. *See, e.g.,* 126 Cong. Rec. 21,449 (Description of Major Issues and Section-by-Section Analysis of Substitute for S. 299) (explaining that the RFA seeks to address the ''unnecessary and disproportionately burdensome demands . . . [of uniform regulatory requirements] upon small [entities] . . . with limited resources''). As discussed in Section V.A and V.B of this preamble, the regulatory uncertainty created by the sudden expiration and threat of sudden expiration of regulations would disproportionately burden small entities who rely on regulations to level the playing field and lack the resources to successfully navigate a confusing regulatory landscape. *See* 126 Cong. Rec. 21,453 (Description of Major Issues and Section-by-Section Analysis of Substitute for S. 299) (finding that small entities often have limited access to regulatory expertise and capital as compared to larger businesses). Additionally, the scope of and compressed timelines for the assessments required by the SUNSET final rule would undermine small entities' ability to provide input and data and otherwise participate in the assessment and review process, as well as undermine the Department's ability to meaningfully consider such information. Such a result would be 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 (statement of Sen. Culver). This result would also undermine the quality of the Department's reviews and, therefore, the Department's ability to accomplish the purpose of retrospective reviews as stated in section 610(a), which is ''to minimize any significant economic impact of the rules upon a substantial number of such small entities.''

For these reasons, the Department agrees with the commenters that the SUNSET final rule's requirements exceed the express requirements of the RFA and appear to be inconsistent with the intent and purpose of the RFA as expressed in the statute's language and legislative history, as well as case law interpreting the statute. We recognize that we previously took the position, in the SUNSET final rule, that the ''rule does not impose any additional burden on the Department beyond what was already called for in the RFA,'' 86 FR 5705, but after further considering the RFA and its legislative history, we now consider that prior position erroneous.

*Comment:* Several commenters asserted that the SUNSET final rule, including its automatic expiration provision, is consistent with section 610 of the RFA. One commenter stated that the SUNSET rule accomplishes nothing new, different from, or contrary to the RFA because the RFA expressly contemplates rule rescission as one of the outcomes of retrospective review, and the SUNSET rule's automatic expiration provision preserves rule rescission as one of the options available to HHS upon completion (or not) of retrospective review under the RFA. Another commenter claimed that a 10-year automatic expiration provision seems entirely appropriate and consistent with the RFA's Congressional intent based on the view that the RFA already requires HHS to conduct 10-year reviews under section 610. Another commenter stated that the SUNSET rule is consistent with section 610 because it simply establishes an enforcement mechanism for that section. One commenter questioned the Department's conclusion that the SUNSET final rule's assessment requirement goes beyond the requirements of section 610 and states that the Department must assess rules to determine whether a rule has or will have a SEISNOSE under section 610. The commenter also noted that assessments of rules not previously identified as having a SEISNOSE would impose a ''minimal burden'' because ''[i]t is likely that most of th[ose] . . . regulations would remain'' without a SEISNOSE and therefore ''only a simple assessment of these rules would be necessary.''

*Response:* The Department disagrees with the commenters that the SUNSET final rule, including the automatic expiration provision, is no different from and consistent with the RFA, for the reasons already explained in the prior comment response.

Specifically, with respect to the automatic expiration provision, the RFA contains no explicit or implicit authority for an automatic expiration provision, and such a provision is inconsistent with the RFA's intent and purpose. Thus, the Department disagrees with the commenter that the automatic expiration provision is not different from or inconsistent with the requirements in the RFA. Although section 610 of the RFA does contemplate rule rescission as a potential outcome of retrospective review, it contemplates rescission of rules only through the standard notice-and-comment process. Furthermore, that outcome would apply only to rules that have or will have a SEISNOSE and for which the agency has conducted a review considering the factors set forth in section 610 and has determined, in its discretion and based on the results of the review, whether the rule at issue ''should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities.'' 5 U.S.C. 610(a). In contrast, the automatic expiration provision explicitly mandates automatic rescission of any rule, regardless of whether it has or will have a SEISNOSE, not based on the agency's consideration of the relevant statutory factors or the potential for rescission to minimize SEISNOSE, but simply based on the agency's failure to conduct an assessment or review of the rule within certain timeframes. Therefore, the

commenter is incorrect that the automatic expiration provision can be equated to or is consistent with the rescission of rules under the RFA. Furthermore, as explained above, section 608(b) of the RFA explicitly requires rules to automatically ''lapse and have no effect'' if the agency fails to timely prepare a final regulatory analysis pursuant to section 604, and the absence of any similar language in the RFA requiring rules to automatically lapse if an agency fails to comply with section 610 suggests that Congress did not intend for noncompliance with section 610 to have such an effect. *See, e.g., Salinas,* 141 S. Ct. at 698.

The Department also disagrees with commenters that the SUNSET final rule's automatic expiration provision is consistent with section 610 because that section already requires agencies to conduct 10-year reviews or because the rule simply provides an enforcement mechanism for section 610's review requirements. As already explained in the prior comment response, the SUNSET final rule's requirement that agencies assess thousands of rules without a SEISNOSE, in some cases within an expedited five-year timeframe, exceeds the express requirements of section 610. Therefore, by mandating automatic expiration of rules without a SEISNOSE when the Department fails to timely assess them, the rule's automatic expiration provision does not seek to enforce only the requirements of section 610 but also requirements not expressly imposed by that section. Moreover, the Department notes that section 611(a) of the RFA already provides a remedy for agency noncompliance with section 610: Judicial review of such noncompliance and any relief deemed appropriate by the reviewing court.

Additionally, the Department disagrees with the comment that the SUNSET final rule's assessment requirement is necessary under or consistent with section 610. Indeed, HHS is not aware of any other Federal department or agency implementing a rule similar to the SUNSET final rule. As explained in the previous comment response, although section 610 implicitly contemplates that agencies have some means of identifying rules with a SEISNOSE for retrospective review, it does not require agencies to conduct ''assessments'' of every rule and comply with the notice and comment requirements for such assessments. Rather, it is silent with respect to how agencies identify rules with SEISNOSE for review. This indicates that Congress intended to leave these determinations to agencies' discretion, *see Fisher,* 994 F.3d at 671, and the Department, in its discretion, has now determined that the assessment process in the SUNSET final rule is overly burdensome and unnecessary for making such determinations.

Moreover, the commenter's suggestion that assessments would impose a ''minimal burden'' is not persuasive. The only support the commenter cited for this assertion is its speculation that assessments of rules previously identified as not having a SEISNOSE would be ''simple'' because ''[i]t is likely that most of th[ose] . . . regulations would remain'' without a SEISNOSE. However, even if the commenter is correct that such rules are likely to remain without a SEISNOSE, the SUNSET final rule would still require the Department to assess them to determine whether that is the case, and in doing so, the Department would need to examine any relevant experience with the rule since its promulgation. Furthermore, the commenter failed to acknowledge that even assessments that are potentially more straightforward than others would still be subject to the extensive requirements the SUNSET final rule imposes on every assessment, including requirements for announcing the assessment on the website and in the **Federal Register**, opening a public docket, considering comments to the docket, and publishing the full results in the **Federal Register**. Given these requirements, the Department does not agree with the commenter that any assessment under the SUNSET final rule would be ''simple'' or that the assessment process as a whole would impose a ''minimal burden.''

2. HHS Compliance With the RFA

*Comment:* Several commenters contended that withdrawal of the SUNSET final rule violates the RFA because, without the rule, the Department would not comply with section 610. These commenters asserted that HHS historically has not complied with section 610, and withdrawal of the rule would allow the Department to continue its noncompliance. Some of these commenters maintained that the SUNSET final rule is HHS's current ''plan'' for periodic review under section 610(a), and therefore repealing it will leave HHS without the required plan. One commenter asserted that HHS cannot repeal the SUNSET final rule because section 610 allows agencies only to ''amend'' their plans for retrospective review. Another commenter asserted that HHS has failed each year to ''publish in the **Federal Register** a list of the rules . . . which are to be reviewed pursuant to . . . section [610] during the succeeding twelve months'' under section 610(c). The commenters also claimed that the RFA requires (''shall provide for'') that HHS conduct the retrospective reviews identified in section 610 on the timelines provided for in that section, and that HHS has not adequately conducted such reviews.

*Response:* We disagree with these commenters' assessments of the history of the Department's compliance with the RFA and predictions about the Department's future plans with respect to the RFA. As noted by commenters, section 610 requires agencies to: Publish in the **Federal Register** a plan for the periodic review of the rules issued by the agency which have or will have a SEISNOSE; and each year publish in the **Federal Register** a list of the rules which have a SEISNOSE and are to be reviewed pursuant to section 610 during the succeeding twelve months. HHS has complied with these requirements.

First, following the enactment of the RFA, on July 14, 1981, the Department published in the **Federal Register** its plan for periodic review as required by section 610(a).[16] That plan provides for, among other things, the Department's review of regulations that have or will have a SEISNOSE and identifies processes and principles that guide such reviews, including principles for prioritizing those reviews.[17] Accordingly, the Department has had a plan in place since shortly after the enactment of the RFA. Second, in accordance with that plan and section 610(c), the Department each year publishes in the **Federal Register** a list of the rules with a SEISNOSE that it is reviewing, has reviewed, or intends to review under section 610, along with a discussion of the Department's

[16] *See* Notice of Plan for Periodic Review of Rules, 46 FR 36332 (July 14, 1981). We note that FDA simultaneously published in the **Federal Register** its own plan for periodic review of its rules as a supplement to the Department's plan. *See* Notice, 46 FR 36333 (July 14, 1981) (''This notice supplements the Department plan with additional information about FDA procedures for reviewing existing rules.'').

[17] *See, e.g.,* 46 FR 36332 (''[T]he Department and those staff divisions which administer rules will inventory and review all regulations for the purpose of selecting those regulations that should receive early, in depth review and revision, where necessary, to reduce regulatory burdens'' and identifying principles to guide prioritization of review of existing regulations); *id.* (''[A]gencies and offices of the Department will seek to identify for earliest review those regulations for which revision will most advance [certain] principles,'' including ''[m]inimiz[ing] Federal, State, local, and private costs'' and ''[p]revent[ing] fraud, abuse, waste, and inefficiency''); *id.* (''The Department's semiannual agenda will advise the public of regulations selected for review''); *id.* at 36333 (''[I]t is important that to the extent possible the more costly and burdensome rules by reviewed first'').

commitment to compliance with the requirements and intent of section 610.[18] As required by section 610(c), this document includes for each such rule a brief description of the rule, its legal basis, and the opportunity for public comment.[19] Therefore, the commenters are incorrect that withdrawal of the SUNSET final rule would leave the Department without a plan for the periodic review of rules as required by section 610(a), or that HHS does not comply with section 610(c). The commenters have not cited any authority that either of these sections requires more.[20]

The Department also disagrees with the commenter that it cannot repeal the SUNSET final rule because section 610 permits agencies to only ''amend[]'' their plans for retrospective review. However, the language the commenter cites—''[s]uch plan may be amended by the agency at any time,'' 5 U.S.C. 610(a)—is a broad grant of authority to agencies with respect to amending their plans for retrospective review, not a limitation. *See, e.g., Adirondack Med. Ctr.* v. *Sebelius,* 740 F.3d 692, 698 (D.C. Cir. 2014) (''Congress generally knows how to use the word 'only' when drafting laws.''). This interpretation of section 610(a) is also consistent with Congress's intent as expressed in the remaining language of that provision, which sets forth the general requirement that agencies publish plans for retrospective review but does not further specify how agencies develop and implement those plans. Such language stands in stark contrast to section 610(b), which explicitly imposes specific requirements on agencies' retrospective reviews. *See Fisher,* 994 F.3d at 671 (''In an administrative setting, . . . 'the contrast between Congress' mandate in one context with its silence in another suggests not a prohibition but simply a decision *not to mandate* any solution in the second context, *i.e.,* to leave the question to agency discretion.' '').

We also disagree with the assertion in the comments that the SUNSET final rule is HHS's current ''plan.'' As described above, HHS has had a retrospective review plan in place since 1981, which was unacknowledged in the SUNSET final rule. Under that plan, among other things, the Department reviews regulations that have or will have a SEISNOSE and identifies processes and principles that guide such reviews, including principles for prioritizing those reviews. Because the SUNSET final rule never became effective, the Department has never implemented the SUNSET final rule as its retrospective review plan. Instead, HHS's longstanding plan remains operative.

Furthermore, as discussed in the Withdrawal NPRM and as noted by the commenters to that proposal, the Department has a meaningful track record of retrospective regulatory review. HHS conducts retrospective reviews of its regulations with impacts on small entities and publishes notice of the reviews in the **Federal Register**. Additionally, as acknowledged in the SUNSET final rule, the Department in 2016 and 2019 issued final rules resulting from section 610 reviews updating the requirements of participation in the Medicare and Medicaid programs for hospitals and critical access hospitals [21] and long-term care facilities.[22] These rulemakings, among other things, allowed these entities greater flexibility in meeting the requirements and eliminated unnecessary, obsolete, or overly burdensome requirements.[23]

As described in the Withdrawal NPRM and as noted by commenters to that proposal, the Department also has undertaken several other recent and significant retrospective regulatory review efforts. Several commenters noted the 2015 CMS initiative to modernize Medicaid Managed Care regulations for Medicaid and CHIP beneficiaries, and we also noted in the Withdrawal NPRM that the CMS Office of Burden Reduction and Health Informatics works to eliminate over-burdensome and unnecessary regulations. Commenters additionally noted that the Department's 2011 Plan for Retrospective Review of Existing Rules,[24] an initiative developed in accordance with E.O. 13563 and E.O. 13610, and plans the Department subsequently published from Fiscal Year 2012 through 2016, have served as a framework for its retrospective review of existing regulations. Under these plans, the Department identified rules that could be potentially eliminated as obsolete, unnecessary, burdensome, or counterproductive or that could be modified to be more effective, efficient, flexible, and streamlined. Additionally, as noted in the Withdrawal NPRM, the Department, in response to E.O. 13771, ''Enforcing the Regulatory Reform Agenda,'' 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. While this E.O. has since been revoked, the published summary reports of these reviews for Fiscal Years 2018–2020 are available on the HHS website.[25]

Also noted in the Withdrawal NPRM, numerous additional regulatory efforts by HHS routinely involve the review of regulations. The Department provides technical assistance to Congress on proposed legislation, which quite often requires an assessment of the proposal's impact on current regulations. FDA also reviews regulations in responding to certain citizen petitions submitted

[18] *See, e.g.,* Semiannual Regulatory Agenda, 86 FR 16892 (Mar. 31, 2021) (publishing under the RFA and E.O. 12866 the Department's ''semiannual . . . inventory of rulemaking actions under development throughout,'' including ''as required by the [RFA] . . . , those prospective HHS rulemakings likely to have a [SEISNOSE],'' ''offering for public review summarized information about forthcoming regulatory actions the Department,'' and describing and identifying examples of the Department's ''agency-wide effort to support the [Regulatory] Agenda's purpose of encouraging more effective public participation in the regulatory process'').

[19] *See, e.g., id.* The Department also submits this information regarding rules it has identified for periodic review under section 610 in its submissions to the Unified Agenda. One commenter maintained that these Unified Agenda submissions cannot satisfy section 610 because they are not published in the **Federal Register** and they are not contained in a single document. However, as explained above, the Department publishes information satisfying section 610 in the **Federal Register** as a single document. *See, e.g.,* Regulatory Information Service Center, Introduction to the Unified Agenda of Regulatory and Deregulatory Actions—Fall 2021, 87 FR 5002, 5009 (Jan. 31. 2022).

[20] Congress considered and rejected a provision included in an earlier version of the bill that would have supported the commenter's position. *See* 46 FR 21449 (section 5(a) of S. 299, which was amended before being enacted as the RFA, included the following: ''Each agency shall periodically review its rules and regulations in accordance with the schedule and criteria set forth in its published plan.'').

[21] *See* Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care, 84 FR 51732 (Sept. 30, 2019) (RIN 0938–AT23); *see also* Semiannual Regulatory Agenda, 84 FR 29633 (June 24, 2019) (merged with 0938–AT23).

[22] *See* Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 FR 68688 (Oct. 4, 2016); *see also* Regulatory Agenda, 81 FR 94754 (Dec. 23, 2016) (0938–AR61).

[23] *See, e.g.,* Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, andImprovement in Patient Care, 84 FR 51732 (Sept. 30, 2019).

[24] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011).

[25] FY 2021 Annual Performance Plan and Report—Regulatory Reform, HHS, *https://www.hhs.gov/about/budget/fy2021/performance/regulatory-reform/index.html.*

under 21 CFR 10.30, requesting changes in FDA regulations. Additionally, it is 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 entails review of these sections.[26] As another example, regulations are reviewed to determine if guidance documents are needed to provide recommendations for complying with the regulation, which 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.

All of these initiatives demonstrate HHS's commitment to reviewing its regulations. Thus, the suggestion in the comments that HHS will not adequately conduct periodic review under section 610 of the RFA moving forward absent the rule is groundless and speculative. HHS is committed to effective and appropriate retrospective review of its regulations and looks forward to exploring ways to improve its processes through means other than binding regulations.

Accordingly, the Department believes that the SUNSET rule is not necessary to ensure its compliance with section 610 and that its ability to undertake regulatory review efforts in the future would be undermined by complying with the unnecessary and burdensome requirements of the SUNSET final rule.

*Comment:* Several comments asserted that HHS has essentially admitted in the SUNSET final rule that, absent the rule, it does not otherwise comply with the RFA. One comment asserted that HHS admitted in the SUNSET final rule that ''all prior plans'' for retrospective review did not meet the requirement to publish a plan under section 610 ''because each prior plan hopelessly failed to provide for any review of each regulation within ten years, if ever.'' The comment also cited the following statements in the SUNSET final rule: HHS has had ''limited success in performing retrospective regulatory review,'' 86 FR 5738; ''the Department's efforts to comply with 5 U.S.C. 610 have at times been lacking,'' *id.* at 5696; and ''The Department's experience over the last forty years is that, absent a strong incentive such as the potential expiration of a regulation, the Department will not review an adequate number of its regulations,'' *id.* at 5739. Another comment asserted that HHS admitted that many of its rules have remained untouched for years. Two of these comments questioned the Withdrawal NPRM's assertion that many rules have remained untouched because they work as intended, asserting that the Withdrawal NPRM does not provide evidence to support this assertion. One comment asserted that if a rule finalized in the 1980s or 1990s is working as intended, that means it is likely out of date because rule's drafters could not have envisioned the technological and informational improvements that have taken place since the rule's promulgation.

*Response:* The Department disagrees with the comments that the SUNSET final rule concluded or demonstrated that HHS does not comply with the RFA absent that rule, but, to the extent that the SUNSET final rule is understood to convey that conclusion, we now think that conclusion is wrong. First, the SUNSET final rule does not state that ''all prior plans'' for the Department's retrospective review do not satisfy section 610(a), nor could it. For example, as explained in a prior comment response, the Department in 1981 published in the **Federal Register** a plan for retrospective review that directly responds to the requirements under the RFA and provides for the Department's periodic review of regulations that have or will have a SEISNOSE.[27] Thus, HHS fulfilled section 610(a)'s ''plan'' requirement long before the promulgation of the SUNSET final rule. Notably, the SUNSET final rule does not even refer to this plan, let alone assert that it does not satisfy section 610(a)'s requirements.

Second, neither the statements from the SUNSET final rule cited by the comments, nor the evidence cited for those statements, establish noncompliance or support the comments' conclusion that HHS does not otherwise comply with the RFA. For example, the SUNSET final rule's statement that the Department has had ''limited success in performing retrospective regulatory review'' does not assert that the Department does not comply with section 610 specifically. As the SUNSET final rule shows, the Department under the previous administration expressed the policy position that extensive retrospective review, across the Department's entire regulatory portfolio, was appropriate and should be prioritized above other Department priorities; its statements of ''limited success,'' ''lacking'' efforts, and ''adequate'' review must be understood in the context of these prior expectations and priorities rather than compliance with the RFA. Furthermore, the evidence the Department cited as support also does not specifically pertain to the Department's section 610 reviews or necessarily reveal anything about them. Specifically, this evidence includes: (1) An artificial intelligence (AI) data analysis of HHS regulations identifying that ''85% of Department regulations created before 1990 have not been edited; the Department has nearly 300 broken citation references in the CFR; and there are more than 50 instances of HHS regulatory requirements to submit paper documents in triplicate or quadruplicate''; and (2) a 2018 study estimating that 68% of Federal regulations have never been updated. 86 FR 5710. The SUNSET final rule does not assert that the HHS regulations identified in this analysis are regulations with a SEISNOSE subject to section 610, and there appears to be no reason to assume that is the case. *See* 86 FR 5710 (acknowledging that AI ''cannot at this time easily determine if a regulation satisfies the criteria listed in 5 U.S.C. 610''). Indeed, based on the SUNSET final rule's estimate that only 15% of the Department's regulations have or will have a SEISNOSE, it is possible that none of the regulations identified in either study are rules that have or will have a SEISNOSE. Thus, there appears to be no reason to conclude that the rules identified as unedited or flawed are rules with SEISNOSE that should be reviewed under section 610.[28]

Another HHS statement cited by the comment—that ''the Department's efforts to comply with 5 U.S.C. 610 have at times been lacking,'' 86 FR 5696—also does not assert or establish that the Department does not comply with section 610. The statement merely suggests a belief that, ''at times,'' the Department could have improved its processes for retrospective review under section 610. It does not explicitly assert that the Department, then or now, fails to comply with the RFA. Additionally, like the data discussed above, the data the statement cites as support does not

[26] For example, the regulations FDA issued to implement FSMA included both the addition of new sections of regulation and revisions and modifications to existing sections. *See* FSMA Rules & Guidance for Industry (available at *https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry#Rules*).

[27] *See* Notice of Plan for Periodic Review of Rules, 46 FR 36332 (July 14, 1981).

[28] Commenters to the SUNSET proposed rule also expressed concern that the methodology of the AI review was never made public, and the SUNSET final rule confirmed that the ''Department did not notify the public about this research project.'' 86 FR 5710.

pertain specifically to reviews conducted under section 610. Specifically, the statement cites the number of retrospective analyses the Department has conducted in response to E.O. 13563. 86 FR 5696. However, E.O. 13563, unlike section 610, does not contemplate periodic review of only rules with a SEISNOSE for the purpose of minimizing SEISNOSE but instead applies to ''existing significant regulations'' for the purpose of assessing a far broader set of factors not focused on small entities, including ''whether any such regulations should be modified, streamlined, expanded, or repealed . . . to make [an] agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.'' *See* Improving Regulation and Regulatory Review, 76 FR 3821, 3822 (Jan. 18, 2011). Therefore, the Department's reviews conducted in response to that E.O. do not necessarily indicate anything about the number of reviews the Department has conducted or should consider conducting under section 610. The SUNSET final rule itself appears to recognize the limited value of these data by concluding only that ''[t]hese findings *are consistent with* government assessments that the Department's efforts to comply with 5 U.S.C. 610 have at times been lacking.'' 86 FR 5696 (emphasis added).

The final HHS statement cited by the commenter—''The Department's experience over the last forty years is that, absent a strong incentive such as the potential expiration of a regulation, the Department will not review an adequate number of its regulations''—is equally flawed. Again, this statement does not explicitly address the adequacy of the Department's reviews of regulations under section 610 but only generally refers to ''review . . . of [ ] regulations.'' Moreover, as explained above, the statement's implication that the Department has not conducted an ''adequate'' number of reviews must be understood in the context of the Department's policy position under the previous administration that extensive retrospective review across its entire regulatory portfolio was appropriate and should be prioritized above other agency priorities.

Third, the SUNSET final rule's discussion of the Department's section 610 compliance and record of retrospective review contains errors and misstatements. In relying on studies purporting to demonstrate that HHS's regulations have not been edited or are otherwise flawed, the SUNSET final rule appears to incorrectly assume that the age of a regulation and the fact that it has not been edited for some period of time suggests that the regulation should be and has not been reviewed under section 610 or pursuant to any of the Department's numerous regulatory review efforts. *See* 86 FR 5710 (concluding the AI data ''suggested that large numbers of Department regulations would benefit from retrospective review''); *id.* at 5738 (''These findings suggest regulations are not being updated to reflect evolving economic conditions and technology, even though this is a goal of the RFA.''). As the Withdrawal NPRM explained, numerous agency efforts involving the review of regulations do not result in a change in the regulation. Moreover, section 610(a) explicitly contemplates unchanged regulations, stating that ''[t]he purpose of the review shall be to determine *whether such rules should be continued without change,* or should be amended or rescinded'' (emphasis added). Also, as noted in the Withdrawal NPRM, the broken links and other typographical errors identified through the AI review 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.[29]

The assumption that unedited rules have not been reviewed is incorrect for the additional reason that many rules setting industry standards have remained untouched for years, not from neglect, but because they work as intended. The OMB memo offering guidance to heads of executive departments and agencies on implementation of E.O. 13563 explicitly states that, in conducting retrospective analysis of existing rules: ''Agency plans should not, of course, call into question the value of longstanding agency rules simply because they are longstanding. Many important rules have been in place for some time.'' [30] The Withdrawal NPRM points to numerous longstanding regulations that bring efficiencies to industry by clarifying applicable statutory obligations, such as food regulations involving nutrition, food labeling, standards of identity, food ingredients, and color additives. Furthermore, the Withdrawal NPRM cited comments to the SUNSET proposed rule confirming that these longstanding regulations create important efficiencies for regulated industry. By contrast, the commenter offered no support for its assumption that the age of a rule and the fact that it has not been edited must mean that it is out of date with respect to its technological and informational requirements. Moreover, even if certain of such requirements could be updated to reflect technological advances, the commenter does not explain why that would necessarily mean that the rule has or will have a SEISNOSE and should be reviewed under section 610. To have a SEISNOSE, a rule must have a *significant* economic impact on a *substantial* number of small entities, and the Department considers a rule to have a SEISNOSE if it has at least a three percent impact on revenue on at least five percent of small entities. *See, e.g.,* 86 FR 5749. Again, based on the SUNSET final rule's estimates, only 15% of the Department's regulations have a SEISNOSE, 86 FR 5737, which suggests that many, or potentially all, of the regulations the commenter claims have outdated technological requirements are not regulations with SEISNOSE subject to section 610 review.

The SUNSET final rule made similar errors with respect to other data it cited in its discussion of the Department's RFA compliance and record of retrospective review. Specifically, the SUNSET final rule cited a review of HHS's entries in the semiannual Unified Agenda over the last ten years, which identified three entries for final rulemakings resulting from section 610 reviews. *See* 86 FR 5737. Based on these data, the SUNSET final rule suggested that, during that ten-year time period, the Department conducted section 610 reviews of only 26 of its 370 rulemakings previously determined to have a SEISNOSE. *See id.* at 5737–38 (referring to ''lax compliance with periodic review requirements under the . . . [ ]RFA[ ]''). However, in drawing this conclusion, the SUNSET final rule appears to improperly assume that the three final rulemakings resulting in section 610 reviews (which it estimated

[29] ''Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify that Paper Copies To Be Required in Electronic Format,'' 84 FR 68334 (Dec. 16, 2019).

[30] OMB Memorandum M–11–10, ''Executive Order 13563, 'Improving Regulation and Regulatory Review' '' (Feb. 2, 2011) (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2011/m11-10.pdf*).

amended CFR sections equivalent to approximately 26 rulemakings) represented the only section 610 reviews conducted by the Department during this ten-year time period. *See id.* at 5737 n.213. In so concluding, the SUNSET final rule again relied on the flawed assumption that a section 610 review must result in the amendment of a rule or a new rule, and thus excluded all other section 610 reviews indicated in the Unified Agenda during that time period. As a result of that exclusion, the Department incorrectly assessed the scope of rulemakings the Department reviewed under section 610 during the last ten years.

The SUNSET final rule's discussion of the Department's RFA compliance also contains misstatements and other errors. The SUNSET final rule cited three ''examples of regulations that [commenters] and/or Congress have requested the Department to review, but that the commenters claimed were not reviewed.'' 86 FR 5696. Although the SUNSET final rule did not take a firm position on the status of these examples, the implication that these matters are inactive is factually incorrect. For example, the Fall 2021 Unified Agenda includes planned action to harmonize the differences between the Basic HHS Policy for the Protection of Human Research Subjects (45 CFR part 46, subpart A) and the FDA regulations for the protection of human subjects (21 CFR parts 50 and 56).[31] The Fall 2021 Unified Agenda also includes several planned regulatory actions by FDA's Center for Veterinary Medicine (CVM) to revise [32] and in certain instances withdraw several regulations based, in part, on the comments received in dockets issued in 2017 seeking comments and information from interested parties to help FDA identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing us to achieve our public health mission and fulfill statutory obligations. In addition, CMS revised the Medicare Beneficiary Program Manual (MBPM), in accordance with the national settlement agreement in the *Jimmo* v. *Sebelius* litigation.[33] Moreover, the SUNSET final rule did not assert that these regulations have or will have a SEISNOSE, or even that the commenters or Congress asserted that they do, and thus, the rule failed to demonstrate how, if at all, these examples implicate the Department's retrospective review efforts under section 610.

The remaining data cited in the SUNSET final rule's discussion of the Department's RFA compliance lacks relevance to that discussion. For example, the SUNSET final rule asserted that good governance stewardship actions were deprioritized and relegated to ''rainy day'' activities the Department operating divisions would get to when they could, citing a review conducted in 2019 that entailed an AI data analysis of HHS regulations. 86 FR 5697. As already discussed in this response, the AI review results do not indicate whether any of the rules it identified as not updated or otherwise flawed have or will have a SEISNOSE, and thus the rule fails to demonstrate how, if at all, this review implicates the Department's activities under section 610. Furthermore, as noted above, the broken links and other typographical errors identified through the AI review process were successfully addressed as part of the HHS ''Regulatory Clean-Up Initiative.'' As another example, the SUNSET final rule also cited ''government assessments that the Department's efforts to comply with 5 U.S.C. 610 have at times been lacking,'' 86 FR 5696; however, these sources at most indicate at times in the past the Department could have reviewed more rules under section 610, and therefore, these sources do not demonstrate that the Department does not currently comply.[34]

The SUNSET final rule's discussion of ''[m]achine-learning tools . . . [that] demonstrate the complexity of Department rules'' similarly lacks relevance to the Department's compliance with section 610. The rule cites data showing that the Department's regulations in 2019, ''based on the amount of information contained in text,'' were ''more complex than a typical Shakespeare play,'' and notes that ''reducing complexity is another goal of the RFA.'' 86 FR 5738. However, as with much of the data already discussed, these data do not purport to relate specifically to rules that have or will have a SEISNOSE, and thus, again do not necessarily implicate the Department's efforts under section 610. Moreover, even if these data were specific to regulations with a SEISNOSE, the Department does not agree with the SUNSET final rule that these data demonstrate that its regulations are overly complicated. As the SUNSET final rule itself acknowledges, complexity in the Department's regulations ''is not . . . surprising given that the regulations often involve science, engineering, or highly technical material.'' 86 FR 5738.

Moreover, the Department disagrees that ''the amount of information in text'' is a reliable proxy for complexity that is unnecessary or undesirable given that, in the Department's experience, providing more information in a regulation can often enhance clarity. For example, in FDA's experience, often in response to a proposed rule, commenters will request that the agency provide examples in the codified text which can lengthen the text but clarify the requirements. For example, a good manufacturing practices rule may require that ''qualified personnel handle x.'' So, to better explain what constitutes ''qualified personnel,'' the codified text may include examples such as education, years of work experience, etc. The examples are general and not prescriptive so that the regulated entity can exercise flexibility in determining what is applicable to their industry and their unique

[31] *See* Protection of Human Subjects and Institutional Review Boards, RIN 0910–A107 (Fall 2021) (available at *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0910-AI07*).

[32] *See, e.g.,* Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, RIN 0910–AI24 (Fall 2021) (available at *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0910-AI24*); Phased Review of New Animal Drug Applications, Electronic Submission, and Master Files, RIN 0910–A135 (Fall 2021) (available at *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0910-AI35*); Revision of Requirements for the Establishment and Maintenance of Records Related to Medicated Animal Feed and Veterinary Feed Directive Drugs Office of Information and Regulatory Affairs, RIN: 0190–AI67 (Fall 2021) (available at *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0910-AI67*).

[33] *See Medicare Beneficiary Policy Manual,* Chapters 7 (Home Health), 8 (Skilled Nursing Facilities) and 15 (Outpatient Therapy) (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS012673*). We note that the SUNSET final rule referred to a comment stating that *regulations* covering access to skilled therapy services had not been updated to reflect the national settlement in *Jimmo* v. *Sebelius. See* 86 FR 5696. However, the settlement agreement requires HHS to amend the *Medicare Benefit Policy Manual* to clarify the coverage standards, not to amend Medicare regulations. *See* ''IX. Injunctive Provisions'' in Settlement Agreement, at 8–14 (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Jimmo-Settlement-Agreement.pdf*).

[34] *See, e.g.,* Curtis W. Copeland, Cong. Rsch. Serv., RL32801, Reexamining Rules: Section 610 of the Regulatory Flexibility Act 8 (2008) (''[I]t would be reasonable to expect that, since [certain departments] indicated that they intended to issue a large number of rules each year with a significant effect on small entities, those same agencies would need to reexamine a large number of rules each year under Section 610.''); U.S. Accountability Off., GAO/GGD–94–105, Regulatory Flexibility Act: Status of Agencies' Compliance (1994) (citing an SBA report from 1983 suggesting potential for improving the Department's review plan).

manufacturing processes. Thus, while the codified text may be longer, it is not inherently more complex or burdensome.

3. Policy Considerations Related to Retrospective Review

*Comment:* Some commenters opposed finalizing the Withdrawal NPRM because, in their view, there is a need for HHS to conduct more retrospective review. Several commenters asserted that HHS regulations are outdated. One comment stated that greater retrospective review is needed because ''the costs of regulations frequently exceed what was projected at the time of promulgation,'' citing information from the preamble to the SUNSET final rule. Another comment stated that there is an ''overall lack of an evidentiary basis for many of [HHS's] regulations'' and cited a working paper [35] criticizing the Department's retrospective review and HHS regulations' identification of a problem that would be solved by the regulation. Several comments stated that widespread retrospective review is appropriate because, if the public must comply with HHS regulations, HHS should have to review them. Approximately ten identical anonymous comments stated that the Withdrawal NPRM should not be finalized because withdrawal or repeal of the SUNSET final rule would ensure Americans continue to be subject to costly, burdensome regulations and, before adding additional burdens on the American people, HHS should determine if its existing regulations are helping or harming them.

*Response:* HHS does not agree that the SUNSET final rule should be retained for any of the reasons cited by commenters. First, even assuming that HHS would benefit from more retrospective review, none of these comments explain why the onerous procedures and compressed timeframes of the SUNSET final rule are necessary or desirable to achieve that goal. Upon review, HHS believes that the procedures set forth in the SUNSET final rule would be a poor method for achieving the goal of improved regulations through retrospective review because the pressure created by the SUNSET final rule process would undermine the quality of the Department's reviews. The SUNSET final rule's focus on small-entity impacts also does not seem directly responsive to these calls for large-scale reconsideration of HHS regulations.

Second, HHS does not agree that the commenters have demonstrated a need for widespread retrospective review. For example, HHS disagrees with the general proposition that its regulations are outdated. The only evidence offered to support these assertions is the evidence presented in the SUNSET final rule, which is discussed in the previous comment response. For example, commenters cited the fact that many HHS regulations issued prior to 1990 have not been edited. But that fact does not show that edits are *needed,* and it certainly does not show that the underlying policies of those regulations are flawed or that the regulations have impacts that should be reassessed. Similarly, the fact that broken links or typographical errors may exist in HHS regulations does not stand for a broader proposition that the underlying policies or impact analyses in the regulations are outdated. Nor is automatic expiration of a regulation an appropriate response to broken links or typographical errors in that regulation. Overall, HHS rejects the conclusion that our regulations are generally ''outdated'' because, as discussed throughout this preamble, we review regulations under many processes, regularly engage with stakeholders regarding the effects of our regulations, and craft regulations to be flexible and to account for technological advancement and changed circumstances over time.

HHS has also reconsidered the evidence presented in the SUNSET final rule concerning cost-benefit projections at the time of promulgation, and we now determine that it is of limited, if any, relevance to HHS. In particular, in order to reach the conclusion that limitations in ''government projections'' counsel in favor of widespread retrospective regulatory review specifically for HHS, the SUNSET final rule relied on a 2005 OMB report that compared pre- and post-regulation cost-benefit calculations for 47 regulations at five agencies. However, the report did not include HHS or any HHS regulations.[36] Moreover, the 2005 OMB report looked at rules dating back from 1975 to 1996.[37] The SUNSET final rule also relied upon another study that evaluated OMB's 2005 report to Congress on the benefits and costs of Federal regulations and a 2005 analysis sponsored by the SBA, but this study did not evaluate any HHS regulations.[38] In addition, the SUNSET final rule presented, as evidence of inaccuracies in regulatory cost-benefit analysis, a publication that looked at eight regulations and included only one HHS regulation, an FDA rule related to food safety.[39] One single FDA regulation is not a sufficiently representative sample from which any generalizable conclusions may be drawn regarding HHS regulations. Finally, another study relied upon in the SUNSET final rule pertained to only one regulation promulgated by the Environmental Protection Agency (EPA) to address arsenic in drinking water.[40] It is not possible to draw any conclusions about HHS regulations from a study looking at just one EPA regulation.

The Department also strongly disagrees that there is a lack of an evidentiary basis for many of its regulations. At the most basic level, the Department relies on evidence to guide it in its public health mission, including its rulemaking efforts. The economic analyses for rulemakings include qualitative and quantitative consideration of the impacts. Evidence, data, and analyses are considered to the extent available and are reflected in the RIAs for the regulations. The analyses and supporting data are included and made publicly available when the rulemaking is published. The same principles apply to the entire rulemaking.

We are also not persuaded that the working paper cited by the commenter supports the proposition that HHS's regulations lack an evidentiary basis. Critically, the paper limited its assessment to preliminary regulatory impact analyses accompanying proposed economically significant regulations. This approach discounts any additional evidence gathered between a notice of proposed rulemaking and publication of a final rule, including evidence from public

[35] Ellig, Jerry, ''Evaluating the Quality and Use of Regulatory Impact Analysis: The Mercatus Center's Regulatory Report Card 2008–2013'' Mercatus Center at George Mason University (July 2016) (available at *https://www.mercatus.org/publications/regulation/evaluating-quality-and-use-regulatory-impact-analysis*).

[36] OMB, Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities (2005), at 42 (available at *https://perma.cc/R8LX-BQMJ*) (comparing pre- and post-regulation cost-benefit data for regulations promulgated by the Occupational Safety and Health Administration, the National Highway Traffic Safety Administration, the Environmental Protection Agency, the Department of Energy, and the Nuclear Regulatory Commission).

[37] *Id.*

[38] *See* 86 FR5697 (citing Winston Harrington, Grading Estimates of the Benefits and Costs of Federal Regulation, Res. for the Future, Discussion Paper 06–39 (2006)).

[39] *See* 86 FR 5698 (citing Richard Morgenstern, Retrospective Analysis of U.S. Federal Environmental Regulation, 9 J. of Benefit Cost Anal., no. 2., 285–304 (2018)).

[40] *See* 86 FR 5698 (citing Cynthia Morgan & Nathalie B. Simon, National primary drinking water regulation for arsenic: A retrospective assessment of costs, 5 J. Benefit Cost Anal. no. 2 (2014)).

comment incorporated into the final regulatory impact analysis. Thus, the commenter likely errs when transferring the findings of the report to finalized regulations, since HHS is more likely to publish final rules of actions that are justified. As an additional concern, the underlying report adopts several assessment criteria that do not speak to the quality of evidence presented in the preliminary regulatory impact analyses. For example, the paper awards points based on writing style, including whether the RIA is ''written in plain English (light on technical jargon and acronyms, well organized, grammatically correct, direct language used),'' and on how well a non-specialist reader would understand the analysis, results, and conclusion. Although these factors may represent desirable practices, they do not relate to the evidentiary basis of a regulation. The commenter highlights the paper's findings related to retrospective review; however, this score relates to whether a preliminary regulatory impact analysis discusses whether ''the proposed rule establish[es] measures and goals that can be used to track the regulation's results in the future'' and whether it ''indicate[s] the data it will use to assess the regulation's performance in the future and establish[es] provisions for doing so?'' [41] Similarly, although these may represent desirable practices, they do not speak to the evidence contained in regulatory impact analysis of HHS regulations. Finally, we note that the paper covers proposed rules published between 2008 and 2013. It is quite likely that a more recent assessment would yield higher scores for HHS as regards some of the scoring criteria. For example, the paper assigned points based on accessibility, including whether an agency publishes proposed rules and RIAs on its website. FDA now maintains a website containing Economic Impact Analyses of FDA regulations, which contains links to at least 170 regulatory impact analyses the agency has developed since 2012.[42] Other HHS agencies currently routinely publish preliminary RIAs in the same document as notices of proposed rulemaking in the **Federal Register**, which is also available online.[43] Thus, we anticipate that a more recent assessment of the availability of RIAs online would yield higher scores in this category. The report also assigned points based on the verifiability of the models and assumptions used in the analysis, including whether the RIAs include citations to sources that justify the models or assumptions. Since the time of the paper, HHS has updated its approach to valuing reductions in mortality risks in benefit-cost analysis by commissioning a criteria-driven review of the empirical literature on the value per statistical life (VSL),[44] and has published subsequent documentation of the Department's approach to updating the VSL to account for income growth and inflation.[45] HHS also commissioned research on the approaches used to value changes in time use and research on estimating impacts related to medical costs in RIAs, publishing conceptual frameworks and best practices on each of these topics.[46] [47] HHS also published Guidelines for Regulatory Impact Analysis in 2016, which includes best practices for conducting prospective and retrospective analysis.[48] Since HHS RIAs routinely reference these documents, as well as the models and assumptions contained in these documents, we anticipate that a more recent assessment of the verifiability of the models and assumptions used in RIAs would also yield higher scores in this category.

The Department also does not agree that the fact that regulated entities must comply with HHS regulations is a reason to retain the SUNSET final rule. The commenters appear to suggest that widespread review of regulations is needed as a sort of *quid pro quo* for regulated entities to comply with those regulations. But to the extent that these comments are purporting to protect the interests of regulated entities, HHS does not agree that the SUNSET final rule protects those interests. We have now determined, as discussed in Section VI, that the quantified costs of the rule far outstrip the quantified benefits, and the expiration provision threatens the basic regulatory frameworks on which regulated entities rely. Furthermore, the Department has finite resources, and we seriously doubt that deploying those resources for roving review under the SUNSET final rule, rather than other initiatives important to regulated entities, is in these entities' interest. We note that almost no regulated entities submitted comments in support of the SUNSET final rule.

Although some commenters stated that HHS regulations generally are burdensome, these commenters did not identify any specific regulations or offer support for their assertions. In any event, we disagree with the assertion. HHS regulations enhance public health, safety, and welfare and provide significant cost savings by, for example: Facilitating the implementation of programs to benefit millions of stakeholders, including underserved populations; preventing serious harm to the public; providing clarity and consistency across the public health spectrum to streamline compliance with statutory requirements; creating a level playing field for businesses; and boosting consumer confidence.

In general, HHS agrees that there is value in retrospective review, but it must weigh that value against the value of other competing regulatory objectives that may be of equal or greater importance. Weighing those considerations, the Department has determined that the SUNSET final rule is not an appropriate way to achieve the goals of retrospective review.

*Comment:* Some commenters stated that the SUNSET final rule should be retained because it provides benefits to the public. These commenters stated, for example, that the rule: allows HHS to consider new developments in science and medicine, better respect legal rights of conscience and religion, and perform more accurate cost-benefit analyses; gives ''recurring departmental attention to the impact of HHS regulations on small and independent businesses;'' increases accountability to real-world impacts; and makes sure that regulations ''do not unnecessarily burden the American public through sheer inertia.'' Some commenters stated that the rule would ''eliminate red tape,'' lead to ''faster economic growth'' and ''significant economic benefits,'' and ''save lives.'' Certain policy advocacy groups suggested that the

[41] *https://www.mercatus.org/system/files/Ellig-Reg-Report-Card-Eval-v1.pdf.* Quotes are located on pages 14 and 94.

[42] *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

[43] *https://www.federalregister.gov/.*

[44] Robinson, L.A., & Hammitt, J.K., ''Valuing reductions in fatal illness risks: Implications of recent research,'' 25(8) Health Economics 1039–52 (2016).

[45] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, ''Appendix D: Updating Value per Statistical Life (VSL) Estimates for Inflation and Changes in Real Income'' (June 2021) (available at *https://aspe.hhs.gov/reports/updating-vsl-estimates*).

[46] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices'' (June 2017) (available at *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework*).

[47] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, ''Estimating Medical Costs for Regulatory Benefit-Cost Analysis: Conceptual Framework and Best Practices'' (June 2017) (available at *https://aspe.hhs.gov/reports/estimating-medical-costs-regulatory-benefit-cost-analysis-conceptual-framework-best-practices*).

[48] *https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis.*

SUNSET final rule benefits individuals because it provides a mechanism for every American to have their voice heard.

*Response:* HHS does not agree that the SUNSET final rule should be retained based on these purported benefits. First, HHS considers matters of conscience and religion as relevant and appropriate as a matter of course, and has an Office for Civil Rights to address such issues as they arise. We do not see how conducting retrospective reviews under SUNSET final rule is necessary or even helpful to better respect legal rights of conscience and religion.

Second, for the purported benefits of eliminating red tape, faster economic growth, significant cost savings and other types of broad economic benefits, and saved lives, HHS considers these speculative and not obviously attributable to the SUNSET final rule. The commenters make a number of leaps in their analysis to assert these benefits. For example, they assume that (1) regulations would be amended or rescinded following review under the SUNSET final rule; (2) these amendments and rescissions would have overall economic and/or life-saving benefits; and (3) no other Department processes would result in these same amendments or rescissions. We disagree both with these assumptions and the chain of reasoning leading to the conclusion that the SUNSET final rule would necessarily have these benefits. As discussed in more detail in our preliminary and final regulatory impact analyses, *see* 86 FR 59922 and Section VI, the benefit attributable to the SUNSET final rule is the benefit of any information learned from completing the assessments and reviews. We note that the SUNSET final rule's regulatory impact analysis, similarly, contained very little discussion of benefits and did not quantify any benefits of the rule. 86 FR 5749.

Third, for the purported benefit of helping individuals—for example, by making it easier for them to participate in the process of regulatory review and have their voices heard—we do not agree that the SUNSET final rule would provide that benefit. Our view, which is informed by many comments on this subject as discussed in detail above, is that the SUNSET final rule generally harms individuals. The rule poses harm through, among other things, Department and stakeholder diversion of resources away from other important initiatives, uncertainty, and loss of regulatory programs through expiration. And, with respect to regulations that automatically expire, there will have been no notice and comment process for the expiration of those specific regulations. Even considering in a vacuum the purported benefit of increased stakeholder participation, our regulatory impact analysis recognizes that the approach of the SUNSET final rule creates greater costs for stakeholders. Furthermore, the sheer volume of rulemakings under assessment and review risks overwhelming individual commenters and preventing their participation.

Fourth, for the remaining benefits asserted by commenters, such as incorporating new scientific information and updating impact analyses, HHS recognizes that these could be potential benefits of an appropriately targeted and manageable retrospective review scheme. Thus, the RIA notes that the final withdrawal rule will result in forgone information as a result of not performing the SUNSET final rule's assessments and reviews. See Section VI below. However, we disagree that the SUNSET final rule would have generated significant benefits in these areas that outweigh the costs. Among other things, the pace and scope of assessments and reviews, combined with the threat of expiration, would likely curtail the careful and thorough deliberation needed to produce these types of benefits and could reduce the quality of regulatory reviews. Moreover, because HHS already undertakes regulatory review under the RFA and otherwise, benefits in these areas, if any, would only be incremental over the ones already produced.

In light of the limited nature of the potential benefits, and balancing those potential benefits against the significant harms of the rule (which include, for example, resource diversion from other key programs, uncertainty, and the potential loss of regulations through the expiration mechanism), the Department has determined that the SUNSET final rule should be withdrawn. The Department recognizes that it previously concluded, in the SUNSET final rule, that the value of the rule's retrospective review program outweighed any harms associated with the rule. However, the Department has since identified multiple flaws in its prior analysis that have led it to reconsider and reverse this conclusion. Among other things, finalization of the SUNSET final rule was premised on a miscalculation of the resources needed to comply with the rule. Because of that error, the analysis in the SUNSET final rule failed to recognize the effects the rule would have on other key programs and initiatives and the likelihood of expiration. The Department also previously miscalculated the substantial burdens the rule would place on stakeholders. Overall, HHS now recognizes that any informational benefits of the rule are greatly outweighed by its harms, and that the rule is irreconcilable with the Department's public health mission. Thus, HHS is withdrawing this rule.

*Comment:* Several commenters referred to various E.O.s issued over the years related to retrospective review. One of these commenters stated that HHS, in withdrawing the SUNSET final rule, must consider compliance with the E.O.s identified in the preamble to that rule.

*Response:* First, we note that many of the E.O.s referred to in these comments or identified in the SUNSET final rule have been revoked, including E.O. 12044, E.O. 12291, E.O. 12498, E.O. 13771, and E.O. 13924. Thus, there is no requirement or expectation of ''compliance'' with these E.O.s.

Second, HHS has considered these E.O.s and does not agree that they provide support for retaining the SUNSET final rule. Most of these E.O.s direct agencies to develop plans for the periodic review of existing significant regulations to determine whether any such regulations should be modified or repealed so as to make the agency's regulatory program more effective or less burdensome. One E.O. focuses on public engagement and OMB reporting with respect to the same scope of retrospective review. HHS already took various actions in response to these E.O.s, including publishing a plan and soliciting comments.[49] Moreover, the E.O.s have a different purpose and focus than the SUNSET final rule, which purports to focus on minimizing the impacts of regulations on small entities. *See, e.g.,* 86 FR 5751 (defining ''Review'' as ''a process . . . the purpose of which shall be to determine whether Sections [of the CFR] . . . should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.'').

Thus, we disagree that the E.O.s constitute a reason to retain the SUNSET final rule.

*Comment:* In the Withdrawal NPRM, the Department invited comment on the experience of states and foreign governments implementing laws requiring ''sunset reviews.'' A few

[49] More information about HHS's actions, including HHS's plan, progress on the plan, and public engagement, is available here: *https://www.hhs.gov/open/retrospective-review/index.html.*

commenters provided an assessment of the positive experience some states and foreign governments have had with implementing their own sunset laws. These commenters opposed the Withdrawal NPRM and pointed to the experience of North Carolina, Missouri, and Texas, whose state legislatures have each established a sunset law and a process for the review of state regulations that feature a sunset mechanism. One commenter stated that North Carolina's process, under which all agency rules are slated for automatic repeal in 10 years unless reviewed, resulted in the repeal of about one state rule out of every ten reviewed. A second comment described the cost savings attributed to the Texas Sunset Advisory Commission. A third comment noted that Missouri connects a sunset provision to a five-year periodic review requirement in a manner very similar to the SUNSET final rule. In contrast, a comment submitted by the North Carolina attorney general, together with 19 other State attorneys general, expressed support for withdrawing the SUNSET final rule, noting that the SUNSET final rule posed a direct threat to their states' health care systems and the health and safety of their residents.

*Response:* We appreciate that the commenters provided information in response to our request. The SUNSET final rule cited the experience of states and foreign governments as a justification for the rule, noting that the mechanism of retrospective review being implemented by the SUNSET final rule was informed by the experience of states and other jurisdictions that allow for the automatic expiration of regulations subject to review. *See* 86 FR 5700 (''experience in the States suggests that sunset provisions can be an important tool to ensure reviews take place''). However, the SUNSET final rule did not account for myriad ways in which those state and international frameworks cited are considerably different from each other, nor did it account for their considerable differences with the SUNSET final rule.[50]

The Department has given further consideration to differences between state sunset laws, such as those of North Carolina, Missouri, and Texas, and the HHS SUNSET final rule. These differences include the legislative origins, implementation, operations, governing administrative law requirements, and the scope, breadth and volume of regulations. More specifically, the states' experience with their sunset laws is of limited relevance to HHS because of the vastly greater scope of national regulations that impact tribal, state and local governments, and international stakeholders; the corresponding greater extent of the economic and public health impacts of the regulations; the amount of Department and stakeholder resources consumed by that larger scope; and differences in governing law, including the APA. We now conclude that the differences are so stark the states' experiences have limited relevance for the Department and do not support retention of the SUNSET final rule.

For example, with respect to North Carolina, the initial assessment outlined in its sunset law does not entail the multi-factor review and assessment required by the SUNSET final rule to evaluate whether a regulation has significant economic impact on a substantial number of small entities. Rather, the North Carolina law enacted by the General Assembly entails periodic review and expiration based on whether the rule is ''necessary with substantive public interest,'' ''necessary without substantive public interest,'' or ''unnecessary.'' [51] Given that this framework is starkly different from the framework in the SUNSET final rule, and given the differences in the breadth and complexity of the underlying HHS regulations as compared to state regulations, the state experience implementing its own law does not shed much light on how implementation of the SUNSET final rule would impact the Department and its stakeholders. For example, the state experience does not inform the extent of Federal resources which would be diverted from addressing public health goals to undertake the scale and pace of reviews required by the SUNSET final rule, and potentially defend against challenges to each of those actions.

The commenter also contended that continuing to create regulations without revisiting them is irresponsible because, with decades passing by without review, it is reasonable and likely to expect some portion, possibly sizeable, of HHS rules to be obsolete. The commenter asserted that North Carolina's experience with regulatory review supports this assertion. We disagree. The commenter's characterization of HHS regulations was conclusory and not grounded in any actual evaluation of current HHS regulations. In particular, it failed to take into account the regulatory reviews that have taken place and it assumes without evidence that the passage of time alone makes regulations obsolete. However, as discussed in greater detail elsewhere in this section, many regulations remain unchanged because they work as intended. For example, regulations that establish product standards or public service programs may not need periodic updates and their automatic expiration would cause public harm.

Under the Texas Sunset Law, the Texas Legislature sets an expiration date in an agency's authorizing statute and a review cycle to determine whether the Agency should be automatically abolished on this date or continued. As part of a review cycle, the Agency must submit a self-evaluation report, the public is invited to submit comments, and then the Texas Sunset Advisory Commission, a legislative advisory body, reviews the information and makes a recommendation whether to abolish or continue the agency. If the recommendation is for the Agency to continue, the Legislature must pass a bill to continue the Agency. As explained by Sunset Advisory Commission, in the self-evaluation report agencies describe their mission, functions, and programs, provide operational and performance data, and identify potential issues and opportunities for change through the Sunset process.[52] Thus, the Texas agencies are not required to provide an assessment or review of their regulations. Because this scheme differs so vastly from the SUNSET final rule, Texas is not an appropriate model or comparator for the SUNSET final rule.

With respect to Missouri, we already explained that the quantity of regulations subject to review in that state represents a small fraction of HHS regulations, and their substantive scope is far more limited. *See* Section V.B.3. We also note that it was the Missouri General Assembly that enacted

[50] *See, e.g.,* N.D. Cent. Code 28–32–18.1 (permitting amendment or repeal of rules without complying with the other requirements of North Dakota's Administrative Agencies Practice Act relating to adoption of rules); 75 OK Stat section 75–307.1 (2014) (directing the Oklahoma House and Senate to conduct rule review); Tenn. Code Ann. section 4–56–102 (limiting review to procurement rules). One state cited had repealed its sunset provision. Rhode Island created an Office of Regulatory Reform to review proposed and existing rules and regulations, but the statutory provision requiring all agencies to conduct periodic review of rules was repealed. *See* R.I. Gen. Laws Ann. tit. 42, ch. 64.13; *see also* 2016 R.I. Pub. Laws 206 (June 29, 2016) (repealing section 42–35–3.4 of Rhode Island's Administrative Procedures Act).

[51] N.C. Gen. Stat section 150B–21.3A, ''Periodic Review and Expiration of Existing Rules.''

[52] Sunset Advisory Commission, ''Sunset in Texas 2022–2023,'' 88th Legislature (Sept. 2021) (available at *https://www.sunset.texas.gov/public/uploads/files/reports/Sunset%20in%20Texas%202022-23.pdf*).

legislation directing State agencies to conduct periodic review of rules and rendering rules void if the agency fails to timely file a report on their review.[53] Thus, the Missouri example does not show that the relevant agencies themselves view this type of sunset framework as advantageous or beneficial to their missions or that they would choose of their own volition to allocate their resources in this manner. In contrast, Congress has not directed the Department or any other agency, under the RFA or any other statute, to adopt a sunset mechanism for their regulations.

One commenter also cited an Organisation for Economic Cooperation and Development (OECD) [54] report on the ex post review of laws and regulations and reiterated that the SUNSET final rule acknowledges that some countries have sunset provisions. However, no commenters provided substantive information about the experience of foreign governments adopting such laws. Thus, the Department concludes that the resource allocations of foreign governments, and approaches adopted in countries not bound by the U.S. APA, are not instructive for one department of the U.S. Government to adopt unilaterally.

The comment submitted by the North Carolina attorney general and 19 other State attorneys general in favor of withdrawing the SUNSET final rule, reflects that these attorneys general do not share the views of the commenters discussed above. Despite a comment indicating the lack of reports of accidental expirations of regulations encountered, for example, in North Carolina's regulatory reform process, the attorneys general stated that the considerably different process embodied by the SUNSET final rule would threatens their states' health care systems and the health and safety of their residents. We agree with this comment and find it notable that an attorney general from a state with sunset provisions does not find their experience with the sunset law to be beneficial enough to encourage HHS to adopt its own. In sum, as discussed above, we conclude that the states' experience with sunset laws do not support retention of the SUNSET final rule.

[53] Missouri Rev. Stat., Title XXXVI section 536.175.5.

[54] The OECD is forum where 37 democratic governments with market-based economies collaborate to develop policy standards to promote sustainable economic growth. *See https://www.state.gov/the-organization-for-economic-co-operation-and-development-oecd/.*

*D. Other Legal Comments*

In issuing the Withdrawal NPRM, the Department explained that questions had been raised in comments on the SUNSET proposed rule as to whether the SUNSET final rule is consistent with the procedural and substantive requirements of the APA. 86 FR 59921. Commenters on the Withdrawal NPRM discussed these and other legal issues. Below, we respond to the comments on (1) the legal issues with the SUNSET final rule, (2) legal arguments regarding this withdrawal proceeding, (3) proposed modifications to the SUNSET final rule, and (4) other legal issues raised in comments.

1. Legal Objections to the SUNSET Final Rule

*Comment:* Multiple comments stated that the expiration portion of the SUNSET final rule violates the APA because, to amend or repeal a rule under the APA, an agency must conduct a notice-and-comment process specific to the individual rule being amended or repealed. Various comments identified regulations subject to the expiration provision whose elimination would likely cause harm to the public, and stated that HHS was obligated to consider the seriousness of these potential harms. Other comments stated that the expiration provision was unlawful for other reasons, such as that it lacked or was contrary to statutory authority.

One commenter disagreed, arguing that the expiration provision is consistent with the APA because HHS followed the APA's rulemaking procedure in adopting the SUNSET rule and because ''the Sunset Rule merely encoded what the RFA already contemplates.'' Another commenter stated that HHS must ''specifically address the inconsistency between its current view that the SUNSET Rule stands on a legally questionable footing, and its prior conclusion that it was legally sound under the RFA.''

*Response:* The Department agrees with commenters who raised questions about lawfulness of the expiration provision. Specifically, we have serious concerns that the SUNSET final rule's automatic expiration provision, as constructed, was not adequately justified under the APA. Similarly, we also question whether the SUNSET proposed rule was sufficiently detailed to provide adequate notice and an opportunity to comment on the potential expiration of each and every regulation covered under the SUNSET final rule.

''The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained.'' *FCC* v. *Prometheus Radio Project,* 141 S. Ct. 1150, 1158 (2021). An ''agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.' '' *State Farm,* 463 U.S. at 43 (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.* If the agency has ''entirely failed to consider an important aspect of the problem,'' the rule is ''normally . . . arbitrary and capricious.'' *Id.* These principles apply in full force to agency decisions to amend or repeal regulations. *See generally id.* 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, the SUNSET final rule would have amended thousands of regulations to schedule their expiration if the Department failed to conduct assessments and reviews on a certain timetable. In addressing this subject, the Department did not provide any particularized consideration of the regulations subject to expiration. It did not consider the specific ''facts and circumstances that underlay'' these regulations, such as the statutory directives and public health problems that these regulations address and that would be left unaddressed upon expiration.[55] It also did not consider the specific ''facts and circumstances that . . . were engendered'' by these regulations, such as any reliance interests that may have developed based on the regulations. The Department did not even *identify* these specific facts and circumstances for the covered regulations, let alone treat them as

[55] For example, the SUNSET final rule amended an FDA regulation requiring an investigational medical device to disclose that it is ''[l]imited . . . to investigational use.'' 21 CFR 812.5(a). This regulation responds to a legislative directive to establish an investigational device program, the public-health need to establish safeguards for investigational use, and the specific circumstance that investigational devices could be diverted for ordinary patient use. Merely by introducing the possibility of expiration of this regulation without any replacement, the SUNSET final rule undermines these legislative objectives, threatens basic public-health protections, and creates uncertainty in the marketplace about the status of this requirement. But these factors were not considered when this regulation was amended by the SUNSET final rule.

relevant factors and weigh them against any perceived advantages of the SUNSET final rule. In addition, the Department did not address the various statutory purposes that would be undermined by expiration. Congress empowered the Department to act through its grants of authority, but there is no evidence that the Department considered those legislative goals or considered the expiration amendments in light of those goals. The expiration amendments were promulgated on a scale that made it nearly impossible to generate this type of particularized analysis or explanation.

Instead, the Department offered the categorical 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. One commenter asserted that this type of rationale, focusing solely on benefits and importance of retrospective review, meets the satisfactory explanation requirement in the APA. However, the Department now questions that assertion. We doubt that this one-sided explanation, which considers none of the facts, circumstances, or goals of the regulations subject to expiration, would enable a court to conclude that the expiration amendment was reasonable and reasonably explained. Ultimately, the Department failed to genuinely grapple with the potential harms of each amended regulation expiring, and the Department now acknowledges that those harms are unquestionably ''relevant factors.''

The Department recognizes that it previously stated that it was ''considering the important factors'' in the SUNSET final rule, but this bare assertion is belied by the fact that the rule did not elaborate on any factors other than the benefits of retrospective review. 86 FR 5716. The Department also stated that it had ''provide[d] the reasoned explanation that would be required if it were a change in policy,'' but, as previously noted, the Department did not provide any explanation addressing the relevant factors. *Id.* at 5702. In addition, in the final rule, HHS stated that it ''considered each individual Department regulation'' in connection with deciding whether to exempt the regulation from the scope of the SUNSET final rule. *Id.* at 5703. However, courts have found that ''[s]tating that a factor was considered . . . is not a substitute for considering it,'' *Getty* v. *Fed. Sav. & Loan Ins. Corp.,* 805 F.2d 1050, 1055 (D.C. Cir. 1986), and the record does not provide further evidence of Departmental consideration of the individual covered regulations. On the contrary, the SUNSET final rule contains a list of various regulations that commenters had proposed for exemption from the SUNSET final rule and then concludes, without explanation, that the regulations would not be exempt. 86 FR 5736. This bare conclusion appears to be directly at odds with the Department's obligations under the APA to consider the relevant factors and adequately explain its decision.[56]

The legal defects described above concerning the SUNSET final rule's amendments to regulations are the same, only magnified, in the circumstance that the SUNSET final rule results in the automatic expiration of a regulation. As reflected elsewhere in this preamble, the Department has determined that it is likely that at least some amended regulations would expire because of overburdened resources. Even if that were not immediately the case, this framework would allow a future administration with a deregulatory agenda to strategically repeal regulations through inaction. In the event of such expiration, the Department would be reversing course on a policy embodied in a regulation without any specific analysis of, or justification for—and without notice and an opportunity to comment on—the expiration, including the original motivating factors for issuing the regulation and potential relevant reliance interests. The Department likewise appears not to have examined whether expiration—without notice and comment—would be consistent with the HHS agency's decision not to impose a termination date when it promulgated the rule in question. But, as noted above, when an agency changes course, such as by repealing a regulation, ''a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.'' *Fox,* 556 U.S. at 515–16.

The failure to consider reliance interests, in particular, presents a substantial legal concern in light of the Supreme Court's admonition that ''[w]hen an agency changes course, . . . it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.'' *Dep't of Homeland Sec.* v. *Regents of the Univ. of Cal.,* 140 S. Ct. 1891, 1913 (2020) (internal quotations omitted). The Court held that agencies in the midst of policy change are ''required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns.'' *Id.* at 377. The Department's regulations, which affect a significant sector of the American economy, undoubtedly could have engendered varying degrees of reliance, and the expiration of those regulations could undermine any such reliance interests. At the time that a particular regulation expires under the SUNSET final rule, however, the Department would not have considered any of those regulation-specific interests.

In the SUNSET final rule, HHS acknowledged the significant potential for there to be reliance interests in existing HHS regulations. For example, it stated that it had increased the length of time before the first expiration date from two years to five years in order to give ''the regulated community . . . five years to adjust to the changes made by this final rule, so any reliance interests are significantly reduced as compared to the proposed rule.'' 86 FR 5709. The Department has reconsidered this statement and has determined that this additional length of time is unlikely to significantly reduce reliance interests because the public would not know, likely for most of the five-year time period, whether a regulation would actually expire. In any event, the Department did not supply the particularized analysis regarding reliance interests contemplated by the Supreme Court, and the Department now doubts that this approach is lawful under the APA.[57]

[56] The Department also previously justified the SUNSET final rule by comparing it to an amendment to a specific rule to add an expiration date, or an amendment to a defined term that is more widely applicable to a set of regulations. However, those comparisons do not address the underlying concern that the expiration provision lacked adequate justification. Because of the differences in scope, scale, and effect, it is far more likely that HHS could provide appropriate notice, consider the relevant factors, and produce the record needed to support those more targeted amendments, in contrast to the global amendment created by the SUNSET final rule.

[57] The Department also continues to be concerned that the specific exemptions included in the SUNSET final rule were not the product of reasoned decision-making. The Department exempted certain FDA regulations, for example, because they ''simply create product identities'' and because, according to the Department, some subset of those regulations are being reviewed under other processes. 86 FR 5731. However, these regulations do not simply create product identities; instead, they describe the conditions under which certain products can be marketed. The stated reasoning does not appear to support the exemption decision or their scope. In addition, the existing review processes cited by the Department only apply to a subset of the exempted regulations, and some of those review processes are limited to narrow issues, such as whether a device should be exempt from premarket review. *See* 86 FR 5731 nn. 199, 200 (citing 21 U.S.C. 360(l), (m)

HHS also disagrees with the commenter who stated that ''the Sunset Rule merely encoded what the RFA already contemplates.'' As explained elsewhere in this preamble, the RFA neither explicitly nor implicitly provides authority for automatic expiration dates. With respect to the comment that HHS must specifically address the inconsistency between its current view that the SUNSET final rule stands on a legally questionable footing, and its prior conclusion that it was legally sound under the RFA, the Department now has concluded that the SUNSET final rule exceeded the requirements of the RFA and did so in a manner that likely violates the APA.

*Comment:* Multiple comments objected to the length of the comment period for the SUNSET proposed rule. One comment stated that ''HHS did not provide . . . a meaningful opportunity for comment'' under the APA. Another comment stated that the Department ''failed to provide any justification for the unusually short 30-day comment period'' for portions of the proposed rule. The comment stated that the ''ability of the public to meaningfully and thoroughly comment on all aspects of the [SUNSET proposed rule] was compromised by the lack of prior notice and the shortened comment period.''

*Response:* The Department shares the commenters' concerns that the 30-day comment period on the SUNSET proposed rule did not provide a meaningful opportunity for comment in this particular rulemaking. The SUNSET final rule was indisputably complex and vast in scope and impact, affecting thousands of regulations. Given the complexity of this rule, we are no longer confident in the Department's previous conclusion that the comment period during the initial SUNSET rulemaking was adequate. However, because the Withdrawal NPRM provided an opportunity for additional comment on the SUNSET final rule and because the SUNSET final rule is now being withdrawn, this procedural concern about the SUNSET proposed rule is now moot.

2. Legal Objections to Withdrawal of the SUNSET Final Rule

*Comment:* One comment asserted that the proposed withdrawal of the SUNSET final rule would be unlawful under the APA because HHS has not considered the ''relevant factor'' of compliance with the RFA. The comment stated that the SUNSET rule put HHS into compliance with the RFA, and that HHS ''ignored important factors'' when it ''fail[ed] to explain how [it] will, in the alternative to the SUNSET Rule, comply with the RFA.'' The comment also stated that HHS was obligated to explain how ''its actions during the delay [of the SUNSET rule effective date] complied with its RFA obligations.''

*Response:* HHS agrees that it must consider ''relevant factors'' in issuing this withdrawal decision, including the requirements of applicable statutes and the impact of the SUNSET final rule on stakeholders. Thus, the Department's statutory obligations under the RFA is one of the factors we must consider. Elsewhere in this preamble, the Department has discussed in detail how it complies with the RFA's requirements to publish a plan for periodic review and a list of the rules to be reviewed each year and how it completes regular reviews of its regulations under section 610. All of these RFA activities continued during the delay of the effective date for the SUNSET final rule. HHS intends to continue its current practices under the RFA. Thus, HHS has considered the factor of compliance with the RFA and does not believe this factor requires the Department to retain the SUNSET final rule.

*Comment:* One comment identified various factors that, in the commenter's view, are ''important aspects'' that HHS needs to consider under the APA in order to withdraw the SUNSET final rule. The comment stated that these factors include (1) ''the disruption that . . . this repeal rule would have on the agency and on public participation in the review process'' and ''the degree of regulatory uncertainty that [this rule] create[s]''; (2) ''the interests of doctors who would benefit from the on-time implementation of the SUNSET Rule to rules like the gender identity [nondiscrimination] mandate in HHS's Section 1557 rule under the ACA, HHS's gender identity [nondiscrimination] mandate in its grants rule 45 CFR 75.300(c) and (d), and HHS's conscience rule at 45 CFR part 88''; and (3) the public's ''interests in participating in notice and comment procedures to lift regulatory burdens on small entities.''

*Response:* We disagree with this comment's characterization of this rulemaking and its assessment of its impacts. With respect to the first factor identified in the comment, concerning disruption to the agency and the public, HHS has determined that it is the SUNSET final rule, and not withdrawal of the SUNSET final rule, that will disrupt the Department's operations and create regulatory uncertainty. With elimination of the SUNSET final rule, HHS agencies and the public can have confidence that resources will continue to be allocated in the manner that best promotes the Department's mission, and that HHS's regulations will be amended or repealed through the well-established APA rulemaking processes. Because the SUNSET rule never took effect, the Department has not taken any implementation steps that would be disrupted by this withdrawal. Furthermore, because the rule never took effect, HHS has no reason to believe that the public has developed processes or expectations that would be disrupted by this withdrawal. This is particularly true given that the SUNSET final rule was issued on January 19, 2021, and a new administration, with new policies and priorities, entered office on January 20, 2021. Even in the unanticipated circumstance that significant reliance interests have developed, we believe those interests would be outweighed by the important reasons for withdrawal identified in this preamble.

With respect to the second factor, the suggestion that the expiration of regulations under the SUNSET final rule will benefit certain doctors who disagree in conscience with certain HHS rules is entirely speculative, and we do not agree that it is an ''important aspect of the problem'' that must be evaluated in connection with this withdrawal action. Even if this could be considered a relevant factor, the interests of this one subgroup do not outweigh the many important reasons for withdrawing this rule, including differing views on the same regulations as well as the risks the rule poses to a far larger sector of the U.S. population.

With respect to the third factor, concerning the public's interest in participating in a notice and comment process to lift regulatory burdens on small entities, HHS notes that under its current processes, the public already has an opportunity to participate in this type of notice and comment process when the Department conducts reviews under section 610. Indeed, section 610(c) requires HHS to ''invite public comment'' on rules that are being reviewed under the RFA. Furthermore, the Department publishes its semiannual Regulatory Agenda for the express ''purpose of . . . encourag[ing] more effective public participation in the regulatory process.'' [58] In addition,

and 85 FR 21795). Finally, the exemptions are underinclusive: The Department failed to include other regulations that are similar, such as those codifying the standards for human blood and blood products or those codifying animal drug approvals.

[58] *See, e.g.,* Regulatory Agenda, 87 FR 5226 (Jan. 31, 2022).

HHS implements Department-wide initiatives to support that purpose, including the Department's regulatory web page with resources such as links to HHS rules currently open for public comment and an ''HHS Regulations Toolkit'' providing background information on regulations, the commenting process, how public comments influence the development of a rule, and how the public can provide effective comments.[59] Thus, to the extent that this is a relevant factor, HHS has considered this factor and does not agree it justifies retaining the SUNSET final rule.

*Comment:* A few comments asserted that HHS has not adequately considered the benefits of the SUNSET final rule, in violation of the APA. One comment stated that the Withdrawal NPRM was ''inadequately supported'' because HHS has not provided ''any meaningful analysis or balance of the two sides of the issues.'' Another comment asserted that the benefits of the SUNSET final rule were an ''important aspect of the problem'' that HHS had ignored.

*Response:* In Section V.C.3 of this preamble, the Department has considered and addressed the various benefits asserted by commenters to be associated with the SUNSET final rule. Overall, we consider many of these benefits to be speculative, and we question whether they would transpire as a result of the SUNSET final rule. Furthermore, we have confirmed that the SUNSET final rule involves significant costs and legal vulnerabilities. In light of these considerations, we conclude that any benefits of the SUNSET final rule do not justify its costs and do not change the legal analysis of the expiration provision. Because HHS has considered the purported benefits and weighed them against the harms in determining that the rule should be withdrawn, we have fulfilled any applicable obligation under the APA.

*Comment:* One comment asserted that ''HHS has not offered sufficient new reasons to change course'' and withdraw the SUNSET final rule because ''each reason [provided in the Withdrawal NPRM] had been considered and rejected in the SUNSET rule.'' The comment also claimed that the Department did not give the public an adequate opportunity to comment because the Withdrawal NPRM did not ''disclos[e] to the public HHS's reasons for changing its views.''

*Response:* HHS disagrees with the commenter that its reasons for withdrawal, as stated in the Withdrawal NPRM and here, are inadequate or were inadequately communicated to the public. In both documents, HHS identified a number of reasons why this withdrawal is appropriate, and we explained in detail why these reasons are persuasive even in light of the Department's prior analysis. We have been clear that the SUNSET final rule contained significant errors of fact and law and is contrary to the policies of the current Administration.

For example, we explained that in the SUNSET final rule, HHS failed to give sufficient consideration and weight to the many comments opposing the SUNSET proposed rule and grossly miscalculated the resources required to comply with the rule and the manner in which the rule would affect the Department. Because of that, HHS improperly dismissed the many concerns raised about the diversion of HHS's resources from other key initiatives and the harms of expired regulations, among other things. Although HHS may have previously ''considered and rejected'' these considerations, HHS's decision-making relied on a fundamentally flawed premise and therefore was unsound.

In addition, we have explained that, upon review, we believe HHS previously overlooked key legal defects in the justification for the expiration provision, which we now must consider in the context of withdrawal. We have also cited the policy goals of the current Administration, which strongly support a change in course here. It is our view that 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. We have also further considered the evidence HHS previously cited to establish the purported need for or benefits of the SUNSET final rule, and we have explained why we no longer consider that evidence to justify the rule. In light of these and other reasons provided throughout this preamble and in the Withdrawal NPRM, HHS has adequately justified the change in course.

*Comment:* One comment suggested that it is arbitrary and capricious for HHS to consider the harms of expiration in determining whether to withdraw the SUNSET final rule. The comment expressed the view that the SUNSET final rule does not exceed the requirements of the RFA, and because HHS must comply with the RFA, HHS should assume it can also comply with the SUNSET final rule and avoid expiration. The comment posited that, because letting anything expire under the SUNSET rule would violate the RFA, HHS should not consider expiration (and the resulting harms) within the realm of possibility.

*Response:* We disagree. This comment is premised on the incorrect assumption that the RFA requires HHS to conduct assessments and reviews under the processes specified in the SUNSET final rule. As noted elsewhere in this preamble, that is not true: The requirements of the SUNSET final rule far exceed the requirements of the RFA. Because of that, it is entirely reasonable for HHS to predict that it will not be able to conduct the assessments and reviews in the timeframes required under the SUNSET final rule, such that regulations will expire, but that it can, at the same time, fully comply with the RFA. Moreover, HHS believes that the risk of expiration is exactly the type of relevant factor it is required to consider. HHS can and must consider whether its self-imposed retrospective review scheme will consume such resources, and creates such an existential threat, that duly promulgated regulations will disappear for reasons that have nothing to do with their regulatory value.

*Comment:* One comment asserted that withdrawal of the SUNSET final rule will render HHS noncompliant with the RFA's requirements, including the requirement to publish a plan for periodic review, such that withdrawal is unconstitutional under the Take Care Clause, the Supremacy Clause, and the separation-of-powers doctrine. The comment stated that ''[n]either the President nor HHS can render optional a statutory directive that HHS publish a plan to periodically review its code of regulations.''

*Response:* HHS disagrees that maintaining the SUNSET final rule is necessary to prevent non-compliance with the RFA. In Section V.C.2, the Department discussed its compliance with the RFA, including compliance with the ''plan'' requirement under section 610(a). In light of this compliance, to the extent that the Take Care Clause, Supremacy Clause, or separation-of-powers doctrine are implicated here, the President and the Department have fully discharged their responsibilities under those authorities.

3. Proposed Modifications to the SUNSET Final Rule

*Comment:* Some commenters stated that HHS should withdraw the SUNSET final rule in its entirety, citing, for example, the continuing uncertainty the rule would create. Other commenters identified modifications to the SUNSET

[59] *See, e.g.,* Regulatory Agenda, 86 FR 16892 (Mar. 31, 2021).

final rule, short of full withdrawal, that they believed could address the Department's concerns as described in the Withdrawal NPRM. These proposed alternatives included providing a longer period for reviewing existing rules or forgoing the review of existing rules; providing a longer period for undertaking the reviews; reviewing only a subset of existing rules, such as those that have already been designated as having a SEISNOSE, are significant rules, are major rules, have unfunded mandates, or arise out of a particular section of the CFR, subagency, or statute; and narrowing or eliminating the expiration provision. Some of these commenters also suggested that the Withdrawal NPRM conceded that such targeted approaches are desirable. These commenters asserted that the Withdrawal NPRM failed to seriously consider alternatives and asserted that neither of the two alternatives considered in the Withdrawal NPRM's economic analysis offers a targeted approach.

*Response:* The Department agrees with the commenters who supported full withdrawal, but thanks the other commenters for offering these proposed modifications. In evaluating these proposals, we must balance the relevant factors and determine whether the various proposals advance the mission, policies, and priorities of the Department. We must take into account both competing statutory obligations and significant public health and welfare considerations, among other things. *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc.* v. *State Farm Mut. Auto Ins. Co.,* 463 U.S. 29, 43 (1983) (holding agencies must consider each ''important aspect of the problem''). After assessing the benefits and harms of the SUNSET final rule's binding program of retrospective review, the statutory obligations for HHS to follow lawful regulatory processes and establish and maintain programs that serve the public health and welfare, and the Department's basic public health mission, we have concluded that the relevant factors weigh heavily in favor of withdrawing the SUNSET final rule in its entirety. To the extent that there are any issues with HHS's current retrospective review process, those issues should be addressed through other means than this rulemaking. Our reasoning is set forth below.

First, the Department has determined that any version of a retrospective review program established through binding regulations could undermine our mission to advance public health and welfare. Legislative rules impose a legal duty on the Department to conduct retrospective review regardless of other urgent priorities, and they create an avenue for litigation based on non-compliance. While the Department acknowledges that there is value in retrospective review and has a plan for such review, the resources allocated for retrospective review can and should vary depending on the circumstances facing an agency. A prescriptive, binding review framework can improperly skew priorities, forcing the Department to elevate review above other public health initiatives that may be more important. The emergence of a global pandemic, for example, has shown how HHS must have the flexibility to adapt as new public health demands arise.

In the RFA, Congress recognized the importance of this type of flexibility. Importantly, the RFA does not direct agencies to issue rules binding themselves to a prescriptive program of retrospective review. Instead, it directs agencies to ''publish in the **Federal Register** a *plan* for the periodic review of [certain] rules.'' 5 U.S.C. 610(a) (emphasis added). This plan can be ''amended by the agency *at any time* by publishing the revision in the **Federal Register**.'' *Id.* (emphasis added). Congress could have required agencies to proceed through notice-and-comment rulemaking to bind themselves to a review program. It certainly demonstrated awareness of that procedural mechanism, given that the RFA is squarely focused on rules promulgated through notice-and-comment rulemaking. But instead, Congress tasked agencies with establishing a ''plan'' by **Federal Register** publication that can be amended ''at any time''—*i.e.,* a plan that can be adjusted as circumstances arise to preserve and support underlying programs. The fact that Congress chose not to direct agencies to issue binding regulation to implement the RFA, and the fact that such binding regulations would by their nature place outsized importance on retrospective review, weigh heavily in favor of wholesale withdrawal (rather than modification) of the SUNSET final rule.

Second, the Department must keep in mind its statutory obligations to follow lawful regulatory processes and to fulfill substantive statutory objectives. As explained earlier in this section, many comments asserted that the expiration provision in the SUNSET rule violates the APA. In the SUNSET final rule, HHS previously asserted that the expiration provision is a cornerstone of the SUNSET rule. It described the rule as not just creating a framework for retrospective review but also ''impos[ing] a strong incentive on [the Department] to perform retrospective review.'' 86 FR 5697. It stated that ''absent such a forcing mechanism, the Department will not conduct as many retrospective reviews as desired'' and that ''it is nearly impossible to see how a satisfyingly comprehensive review could occur without a sunset mechanism.'' 86 FR 5723, 5702. HHS even considered whether the expiration provision should be severable from other portions of the rule, but expressed doubt ''that the proposed rule could properly function without the expiration dates.'' 86 FR 5734. Thus, the expiration provision is a key animating feature of the SUNSET final rule. However, as explained above, HHS now agrees with the many commenters who asserted that the expiration provision is not adequately justified and is unlawful under the APA. Moreover, in Section V.C.1, we expressed doubt that the expiration provision is consistent with the intent and purpose of the RFA. And, where Congress has empowered the Department to promulgate specific substantive regulations, automatic expiration of those regulations could conflict with Congressional purpose, as well as violate the APA. In light of our new conclusions about a fundamental premise of the SUNSET final rule, the best course is for the rule to be retracted and for the Department to then take a fresh look at next steps.

Third, even if the Department determined that a binding regulation for retrospective review were appropriate, and even if the legal issues with the automatic expiration provision did not fundamentally undermine the rule, HHS has considered alternatives within the ambit of the existing policy and has determined that they either are not viable or should not be adopted.[60] Most of the alternate proposals presented by commenters retain the key animating feature of the SUNSET final rule—automatic expiration. But as explained in the Withdrawal NPRM and in this preamble, the automatic expiration provision is in our view unlawful and could lead to significant harm, including a significant burden on stakeholders such as small entities. The uncertainty resulting from the sudden expiration and threat of sudden expiration of regulations could create numerous negative repercussions for stakeholders and for the public health, including undermining the effective

[60] As explained further in the regulatory impact analysis in Section VI, the Department conducted a quantitative analysis of four alternatives, including alternatives recommended by commenters.

implementation of Federal/State partnership programs such as Medicaid that rely on HHS rules establishing national standards for these programs, hindering the ability of programs that rely on Federal funding to apply for or receive that funding or engage in long-term planning, and impeding product development and innovation. Moreover, as explained in a prior comment response, regulatory uncertainty created by the SUNSET final rule, if effective, would disproportionately burden small entities who rely on regulations to level the playing field and lack resources to navigate the resulting confusing regulatory landscape. This result would be inconsistent with the RFA's purpose of alleviating disproportionate burdens on small entities. Furthermore, the expiration of any regulations under the SUNSET final rule—which the Department now predicts would be unavoidable—means the public would lose any protections, entitlements, and other public health benefits those regulations provide. Leaving the automatic expiration provision intact in any form would not address the Department's concerns that the provision is unlawful under the APA and inconsistent with the RFA and, in some cases, the Congressional purposes of the authorizing statutes for particular sets of regulations.

Other commenters proposed modifying the SUNSET final rule to eliminate the automatic expiration provision. HHS has considered this alternative as well, and we have determined that a regulation that retains any of the other key features of the SUNSET final rule—such as widespread assessments or provisions imposing accelerated timelines for assessments and reviews—is not viable or appropriate because those provisions impose significant and unnecessary burdens on the Department and stakeholders. As explained in a prior comment response, the requirement to conduct thousands of assessments on a continuing basis, including the requirement to comply with notice and comment procedures for each assessment, are both onerous and unnecessary methods of identifying the minority of rules which have or will have a SEISNOSE and is inconsistent with the intent of section 610 and the RFA's purpose. Even if the Department also limited the scope of rules subject to assessment, as some commenters suggested, those proposals raise the concerns that (1) the Department could miss rules that have or will have a SEISNOSE (because the scope would be limited based on criteria unrelated to SEISNOSE, such as imposing an unfunded mandate), and (2) the process for assessments under the SUNSET final rule, such as the inclusion of a comment period, is still unnecessarily burdensome. In addition, the five-year timeframe for assessing and reviewing existing regulations and the two-year timeframe for amending or rescinding regulations based on the results of a SUNSET final rule review impose additional unnecessary burdens on the Department. Proposals that do not eliminate these requirements are not viable or desirable because they fail to resolve the Department's concerns with the drain on resources resulting from these provisions and force the Department to elevate retrospective review above other public health initiatives that may be more important. The Department has the discretion to ''prioritize regulatory actions in a way that best achieves the objectives'' of the RFA, other applicable statutes, and its public health and welfare mission, *see WildEarth Guardians* v. *EPA,* 751 F.3d 649, 656 (D.C. Cir. 2014), and the Department has determined that these proposals would not best achieve its objectives.

The Department also considered alternatives that combine proposals from various commenters (even though these combinations were not specifically proposed), and we reject those alternatives for various reasons. As discussed, retaining any portion of the SUNSET final rule would run counter to HHS's view that its section 610 ''plan'' should not be codified in regulations, and it would not address the concern that elimination of the expiration provision fundamentally changes the nature and purpose of the SUNSET final rule such that wholesale reevaluation of the effort is required. We have also determined that lengthening the various timelines in the rule would not adequately address our concerns. The Regulatory Impact Analysis for this withdrawal rule considers the policy alternative of an initial ten-year period following the effective date to assess and review all regulations, for example, and while that policy alternative temporally shifts some of the burden on HHS, it does not meaningfully reduce the burdens. Indeed, even if HHS eliminated all of the most concerning provisions of the SUNSET final rule—such as the expiration provision, the assessment process, and the narrow timeframes—the remaining portions of the SUNSET final rule are still fundamentally flawed because they do not provide for a logical or reasonable approach to retrospective review under the RFA. For example, these provisions require recurring review of ''Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter).'' *See, e.g.,* 86 FR 5751. But such Sections are often themselves ''amendments or additions'' to existing rulemakings, so this language suggests that these Sections would need to be reviewed multiple times in connection with each of those existing rulemakings and any future rulemakings amending such Sections. This methodology for implementing the RFA is unreasonable and should not be retained. As another example, the SUNSET final rule contains exceptions from the review processes, but upon review, these exceptions are not only ambiguous and difficult to implement, but also apparently inconsistent with the language in section 610 of the RFA that contemplates review of all regulations based on whether they have or will have a SEISNOSE. In sum, HHS has not identified any substantive portion of the SUNSET final rule that is worth retaining.[61]

As evidenced by the discussion in this preamble, the Department has considered numerous alternatives to withdrawal of the SUNSET final rule, including commenters' proposed alternatives, and has explained its reasons for rejecting those alternatives. Contrary to one commenter's suggestion, the alternatives considered by HHS were not limited to the alternatives identified in the Withdrawal NPRM's economic analysis. Therefore, the Department has satisfied its obligation to ''consider the 'alternative[s]' that are 'within the ambit of the existing [policy],' '' *Regents,* 140 S. Ct. at 913 (2020) (quoting *State Farm,* 463 U.S. at 51), and give ''adequate reasons for its abandonment'' of any such alternatives, *State Farm,* 463 U.S. at 51. Moreover, the Department notes that those precedents make clear that an agency is ''not required to . . . 'consider all policy alternatives in reaching [its] decision' '' and is ''not compelled to explore 'every alternative device and thought conceivable by the mind of man.' '' *Regents,* 140 S. Ct. at 1914 (first quoting *State Farm,* 463 U.S. at 51; then quoting *Vt. Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council, Inc.,* 425 U.S. 519, 551 (1978)); *see State Farm,* 463 U.S. at 51 (''Nor do we broadly require an agency to consider all policy alternatives in reaching

[61] The Department notes that several comments suggest that extensively revising the rule would require a new rulemaking under the APA or at least an additional notice and comment period.

decision. It is true that a rulemaking 'cannot be found wanting simply because the agency failed to include every alternative device and thought conceivable by the mind of man . . . regardless of how uncommon or unknown that alternative may have been . . . .''). Therefore, HHS has satisfied any obligation to consider alternatives to withdrawal of the SUNSET final rule under *State Farm* and *Regents.*

4. Other Legal Issues

*Comment:* One comment alleged various legal defects associated with the Administrative Delay, which delayed the effective date of the SUNSET final rule under 5 U.S.C. 705. 86 FR 15404. The comment stated, for example, that the Administrative Delay was untimely, that HHS unlawfully skipped notice-and-comment processes under 5 U.S.C. 553, and that the Administrative Delay was not lawfully issued under section 705. The comment stated that because the Withdrawal NPRM ''relies essentially on the purported legitimacy of the [Administrative Delay],'' it ''is part and parcel of an unlawful delay, and therefore is fruit of a poisonous tree that is arbitrary and capricious and abuse of discretion under the APA.''

*Response:* HHS disagrees with the suggestion that the Administrative Delay suffers from any legal defect, and we are not aware of any legal basis for the commenter's assertion regarding the applicability of a fruit-of-the-poisonous-tree doctrine.

In any event, criticisms of the Administrative Delay are outside the scope of this rulemaking proceeding. In this proceeding, HHS has proposed and has sought comment on withdrawal of the SUNSET final rule. That proposal is separate from the Administrative Delay. While the Department continues to believe that the Administrative Delay was lawful, we disagree with the commenter that the Administrative Delay—whether lawful or unlawful—affects or is otherwise relevant to this withdrawal action.

Moreover, the Department is withdrawing the SUNSET final rule well before the first deadline for completing assessments and reviews of Department regulations would have occurred if the rule had taken effect absent the Administrative Delay. Accordingly, any question of the validity of the Administrative Delay is now moot.

*Comment:* One comment noted that the Withdrawal NPRM proposed to ''withdraw or repeal'' the rule and requested that the Department clarify whether it intends to withdraw vs. repeal the SUNSET final rule and identify any advantages and disadvantages associated with each action. Although the comment acknowledged that both withdrawal and repeal are methods to revoke a rule, it asserted that withdrawal of a rule from the Office of the Federal Register ordinarily takes place prior to a rule's publication whereas a notice-and-comment rule that has become effective generally needs to be repealed through notice-and-comment rulemaking.

*Response:* As used in this rulemaking, the terms ''withdraw'' and ''repeal'' refer to the timing of the issuance of this final rule relative to the effective date of the SUNSET final rule. When HHS issued the Withdrawal NPRM, it was not certain about future timing and therefore referred to both withdrawal and repeal in the alternative. Because the effective date of this final rule will occur before the effective date of the SUNSET final rule,[62] HHS is withdrawing the SUNSET final rule before it ever becomes effective.

Because the Department has engaged in notice and comment rulemaking, it need not address the question of whether it could have withdrawn the rule *without* notice and comment procedures. Whether this final rule is characterized as a ''withdrawal,'' ''repeal,'' or ''rescission'' is ultimately of no consequence to the validity of this rulemaking,[63] because HHS has engaged in notice and comment under the APA, and the revocation (under any label) of the SUNSET final rule is fully justified for all of the reasons we have set forth in this preamble. In addition, even if ''withdrawal'' of the SUNSET final rule were not appropriate due to some alleged defect in the Administrative Delay (which HHS does not believe exists), the Department would have repealed the rule, through a process identical to this process, for the reasons explained throughout this preamble.

*Comment:* One comment urged HHS to fully incorporate all public comments to the SUNSET proposed rule into the administrative record for its withdrawal of the SUNSET final rule. The commenter noted with approval that the Withdrawal NPRM discusses concerns raised in the comments to the SUNSET proposed rule.

*Response:* The Department agrees with the comment that all public comments to the SUNSET proposed rule are properly part of the administrative record for this rulemaking proceeding. As the comment acknowledged, the Department considered the public comments to the SUNSET proposed rule before it issued the Withdrawal NPRM. *See, e.g.,* 86 FR 59906 (''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.''). Therefore, those comments are properly part of the administrative record for this final rule. *See, e.g.,* 21 CFR 10.3 (FDA regulation defining ''Administrative record'' as ''documents . . . on which the Commissioner relies to support the action''); 42 CFR 405.1042 (Office of Medicare Hearings and Appeals regulation defining administrative record as ''complete record of the evidence and administrative proceedings on the appealed matter''). The Department notes that many of the comments to the Withdrawal NPRM discussed or attached copies of public comments to the SUNSET proposed rule and are therefore part of the administrative record for this rulemaking for that reason, as well. *See, e.g.,* 21 CFR 10.40(g) (FDA regulation instructing that the record of the administrative proceeding for the promulgation of rules consists of ''[a]ll comments received on the proposal, including all information submitted as part of the comments''); 42 CFR 431.416 (CMS regulation defining administrative record for State Medicaid and CHIP demonstration projects to include ''[w]ritten public comments sent to the CMS and any CMS responses'' and ''all documentation related'' to a project application).

*E. Vague and Confusing Provisions*

In the Withdrawal NPRM, we explained that, upon reconsideration, the Department found many ambiguities in the SUNSET final rule that could impede the ability of the Department and the public to determine the scope and timing of the assessment and review process. 87 FR 59922. This confusion would have increased the burden on stakeholders trying to navigate the assessment and review process. Process

[62] *See* 86 FR 15404 (extending SUNSET final rule effective date of until March 22, 2022); 87 FR 12399 (further extending SUNSET final rule effective date until September 22, 2022).

[63] However, we note that, upon judicial review, a decision to withdraw a rule that is not yet effective may be accorded even more deference than a decision to repeal a rule in effect. *Cf. Int'l Union, United Mine Workers of Am.* v. *U.S. Dep't of Lab.,* 358 F.3d 40, 43 (D.C. Cir. 2004) (courts ''give more deference to an agency's decision to withdraw a proposed rule than . . . to its decision to promulgate a new rule or to rescind an existing one''); *Williams Nat. Gas Co.* v. *F.E.R.C.,* 872 F.2d 438, 444 (D.C. Cir. 1989) (noting that the ''application of the 'arbitrary and capricious' standard must be informed by [the court's] recognition that an agency's decision to retain the status quo may be more easily defensible than a shift in policy would be'').

ambiguities would also increase the risk of the automatic expiration of HHS regulations due to inadvertent noncompliance or misapplication of the requirements. We received the following additional comments on this topic.

*Comment:* Many commenters agreed that the SUNSET final rule would create burdens, confusion, and uncertainty over which regulations are likely to remain in effect, and overall decrease predictability, transparency, and public engagement critical to the regulatory process. Ambiguities in the regulatory text would contribute to those problems. One comment, for example, stated that the SUNSET final rule contained many ambiguities that could impede the ability of HHS and the public to determine the scope and timing of the assessment and review process. Another comment criticized the SUNSET final rule for confusing definitions. Another comment opined that the rush to issue the SUNSET final rule, with the extremely short time for stakeholder comment and unprecedented acceleration of the timeline for completion of the rulemaking, resulted in an inadequately considered and drafted final rule, with provisions that are overly vague, lack needed details, and are impractical to implement.

*Response:* We agree with these concerns. For example, as explained in Section V.D of this preamble, the SUNSET final rule requires recurring review of ''Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter).'' But such Sections are often themselves ''amendments or additions'' to existing rulemakings, so this language suggests that these Sections would need to be reviewed multiple times in connection with each of those existing rulemakings and any future rulemakings amending such Sections. This methodology for implementing the RFA is unreasonable and confusing.

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). 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. The SUNSET final rule suggests that, because these revised sections were issued as part of the 2015 rulemaking, the Department would need to review these revised sections multiple times—first, as part of a review of the 2015 rulemaking, and then again as part of the Department's reviews of the rulemakings in which those sections were first promulgated or previously revised. Moreover, the complexity of this process would be compounded by the fact that each of these sections of the CFR, because they were promulgated at different times, would have different expiration dates under the SUNSET final rule.

*Comment:* The Withdrawal NPRM also expressed concern about ambiguity in the categories of exceptions described in the proposed rule and included in the final rule.[64] Numerous commenters on the SUNSET proposed rule noted the lack of examples provided, and stated the lack of clarity for the categorical exceptions would leave the public unable to know which regulations would be eligible for the exceptions. Accordingly, some commenters stated that stakeholders would face a burden to conduct their own legal analysis.

*Response:* In the Withdrawal NPRM, we agreed with these comments, and we continue to agree with them now. We explained that the SUNSET final rule failed to provide meaningful examples of these exceptions and recognized 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. Commenters on the Withdrawal NPRM confirmed this view. For example, one commenter explained that, rather than vaguely indicate that certain types of regulations may be subject to exceptions, the SUNSET final rule should have identified the regulations more specifically, so that commenters could engage in the comment process, and stakeholders could better understand the rule if implemented. Another commenter criticized the scope of the exceptions in the SUNSET final rule for their failure to ensure that these exceptions would avert the expiration of a regulation in the event of a pandemic or other declared national or public health emergency.

In addition, many commenters on the original SUNSET proposed rule stated that it was improper for the final rule to exclude the SUNSET final rule itself from the requirements of Section (c) of each of the codified provisions, meaning that under the rule, the rule itself is not subject to assessment, review, or expiration. The SUNSET final rule based this exemption on an assumption that the SUNSET final 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 concludes that this assumption was incorrect and therefore does not justify the double-standard inherent in this aspect of the SUNSET final rule.

## VI. Final Regulatory Impact Analysis

### *A. Introduction, Summary, and Background*

#### 1. Introduction

We have examined the impacts of the final withdrawal 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). E.O.s 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 final withdrawal 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 final withdrawal rule would result in cost savings to regulated entities, this analysis concludes, and the Secretary certifies, that the final withdrawal 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 $165 million,

[64] The regulatory text of the SUNSET final rule consisted of one regulation, with multiple subsections, substantially replicated 10 times. Subsection (g) in the replicated regulatory text excluded (1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section; (2) Sections whose expiration pursuant to this section would violate any other Federal law; (3) The SUNSET final rule; (4) Sections that involve a military or foreign affairs function of the United States; (5) Sections addressed solely to internal agency management or personnel matters; (6) Sections related solely to Federal Government procurement; and (7) Sections 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. Subsection (g) also excludes individual regulations specific to each HHS agency. 86 FR 5729.

using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final withdrawal rule will result in an expenditure in at least one year that meets or exceeds this amount.

2. Summary of Costs and Benefits

The final withdrawal rule will withdraw the SUNSET final rule. This regulatory action will 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 anticipated under the SUNSET final rule. We monetize the likely reductions in time spent by the Department and the general public and report these impacts 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 final withdrawal rule will also reduce regulatory uncertainty and regulatory confusion anticipated under the SUNSET final rule. Given the scope of the SUNSET final rule, these impacts would have been experienced by 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 final withdrawal rule will also reduce the time spent by the Department on other activities that we have not monetized or quantified, such as the time developing Small Entity Compliance Guides (SECGs), and it will reduce the time spent by the public monitoring regulations undergoing assessment or review and set to expire. The final withdrawal rule will also result in a disbenefit with respect to forgone information as a result of not performing the assessments and reviews.

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

| Category | Primary estimate | Low estimate | High estimate | Units | | | Notes |
|---|---|---|---|---|---|---|---|
| | | | | Year dollars | Discount rate (%) | Period covered | |
| Benefits: | | | | | | | |
| 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. | | | | | | |
| Costs: | | | | | | | |
| Annualized Monetized $millions/year | −$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. |
| | −69.9 | −37.2 | −102.7 | 2020 | 3 | 2022–2031 | |
| Annualized Quantified ..... | ..... | ..... | ..... | ..... | 7 | ..... | |
| | ..... | ..... | ..... | ..... | 3 | ..... | |
| Qualitative. | | | | | | | |
| Transfers: | | | | | | | |
| Federal Annualized Monetized $millions/year. | ..... | ..... | ..... | ..... | 7 | ..... | |
| | ..... | ..... | ..... | ..... | 3 | ..... | |
| From/To ..... | From: | | | To: | | | |
| Other Annualized Monetized $millions/year. | ..... | ..... | ..... | ..... | 7 | ..... | |
| | ..... | ..... | ..... | ..... | 3 | ..... | |
| From/To ..... | From: | | | To: | | | |
| Effects: | | | | | | | |
| State, Local or Tribal Government: | | | | | | | |
| Small Business: | | | | | | | |
| Wages: | | | | | | | |
| Growth: | | | | | | | |

3. Summary of Changes

Compared to the preliminary regulatory impact analysis, this final regulatory impact analysis expands the discussion of regulatory alternatives, including a quantitative analysis of two additional alternatives recommended in public comments. Specifically, we analyze a policy option that would maintain the general framework of the SUNSET final rule but limit its scope to regulations that the Department previously identified as having a significant economic impact on a substantial number of small entities. We also analyze a policy option that would maintain the SUNSET final rule's requirements related to the timeline for assessing and reviewing all of the Department's existing regulations, but without the automatic expiration provision contained in the SUNSET final rule.

We have revised the discussion and estimates contained in this regulatory impact analysis to reflect regulatory action that administratively postponed the effective date of the SUNSET final rule. This analysis now states that the regulatory action will withdraw the SUNSET final rule, whereas the preliminary regulatory impact analysis

covered regulatory actions to withdraw or repeal the SUNSET final rule. We have made minor edits for clarity throughout the document. Finally, we have read and considered public comments addressing the regulatory impact analysis and respond to these comments in Sections V.A.3, C.3, and D.3 of this preamble.

4. 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 expire ten years after issuance, unless HHS performs an assessment of the regulations and a more detailed review of those regulations that have a significant economic impact upon a substantial number of small entities. The SUNSET final rule also provides for regulations older than ten years to expire unless assessed and, if applicable, reviewed within an initial five-year period. After this initial assessment and review process, the SUNSET final rule requires continuing assessments and reviews every ten years under threat of expiration. 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 SUNSET final rule by one year to March 22, 2022. HHS issued a second administrative delay of effective date, effective as of March 4, 2022, which further extended the effective date of the final rule by six months to September 22, 2022. For the purposes of this analysis, we refer to the January 19, 2021, final rule and the two administrative delays collectively as the SUNSET final rule. On October 19, 2021, HHS published a proposed rule to withdraw or repeal the SUNSET final rule.

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

The SUNSET final rule established automatic expiration dates for most of the Department's regulations, and a recurring assessment and review process that it must follow to avoid such expirations. The SUNSET final rule's RIA likely underestimated 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 and heterogeneity of regulations affected, our current evaluation 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. 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 and this analysis. This final withdrawal 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 Final Withdrawal Rule*

The purpose of the final withdrawal rule is to revoke the SUNSET final rule. This regulatory action will directly address the potential harm from the automatic expiration of the Department's regulations. The final withdrawal rule will generate cost savings to the Department from reductions in staff time spent on assessments and reviews, and on related activities. It will 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 final withdrawal rule will 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 [65] remain in place over the period of our analysis, accounting for the administrative delays of the effective date.[66] The SUNSET final rule 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 final rule RIA that the Department will satisfy the requirements of the SUNSET final rule and no regulations will automatically expire.[67] We also maintain various assumptions in the SUNSET final rule 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 final rule 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 final rule 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. This analysis of the baseline scenario concludes that the SUNSET final rule likely underestimated to a significant degree the resources needed for the required undertaking.

Regulations Subject to the SUNSET Final Rule

We adopt the SUNSET final rule RIA's estimate of 18,000 regulations potentially subject to the SUNSET final rule that will 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 final rule 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. Although we adopt the SUNSET final rule RIA's estimate that the Department would perform 3,600 assessments, this estimate may understate the number of assessments performed under the SUNSET final rule, since certain regulations would need to be assessed multiple times as part of separate

[65] 86 FR 5694.

[66] 86 FR 15404; 87 FR 12399.

[67] This approach allows for a more direct comparison with the estimates contained in the SUNSET final rule 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.*), Chapter 4 ''Assess Costs,'' contains a more complete discussion of this approach.

assessments. The SUNSET final rule RIA assumes that 11% of these assessments, or 396, are for regulations previously determined to have 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 [=3600 − (396–370)].

For each of these 370 rulemakings, the Department will need to perform a review, which includes a retrospective regulatory flexibility analysis. The SUNSET final rule RIA distinguishes between the 44 rulemakings that predate the RFA 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 final rule RIA also estimates there will be an additional 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. The Department 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 final rule 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. Of the 3,574 total assessments anticipated under the SUNSET final rule, 3,415 would occur during the first five-year period, an average of 683.0 assessments per year; while 159 assessments would occur during the second five-year period, an average of 31.8 assessments per year. Of the total reviews anticipated under the SUNSET final rule, 506 would occur during the first five-year period, an average of 101.2 reviews per year; while 24 assessments would occur during the second five-year period, an average of 4.8 reviews per year. Table D1 presents yearly counts of assessments and reviews anticipated under the baseline scenario. These figures are broadly consistent with the figures contained in the SUNSET final rule RIA; however, unlike that analysis, we do not reduce the number of assessments under the SUNSET final rule by the number of reviews performed, since these assessments occur first and serve to identify those regulations requiring review.

TABLE D1—BASELINE ASSESSMENTS AND REVIEWS UNDER THE SUNSET FINAL RULE

| Year | Total assessments | Reviews | | | |
|---|---|---|---|---|---|
| | | Pre-RFA | Post-RFA | Not specified | Total |
| 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 | 3574.0 | 44.0 | 326.0 | 160.0 | 530.0 |

Time per Assessment and per Review

The SUNSET final rule RIA contains estimates of the time per assessment and time per review performed under the SUNSET final rule. For each assessment, the SUNSET final rule 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. 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 Department now concludes 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 by a significant degree. The Small Business Administration (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.[68] For each of the 3,574 rulemakings requiring an assessment under the SUNSET final rule, the Department 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. The SUNSET final rule also requires HHS to open a docket and review public comments on each rulemaking being assessed. 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

[68] Available at *https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf.*

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 final rule 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 final rule RIA contains two estimates for the time necessary to perform a retrospective analysis as part of a review. For rulemakings published before the RFA was enacted, the SUNSET final rule RIA assumes between 250 and 500 hours per review. For rulemakings published after the RFA was enacted, the SUNSET final rule 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 final rule 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 agrees that the commenter is likely correct.

For the analysis of this final withdrawal rule, we adopt the SUNSET final rule RIA estimate of 250 to 500 hours for all retrospective analyses performed as part of a review, regardless of when the underlying rulemaking was published, and regardless of whether the rulemaking was previously found to have a significant impact on a substantial number of small entities. 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 final rule. All else equal, this would suggest the average time per retrospective analysis 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 analysis closer to the upper-bound estimate of 500 hours. We do not address the assumption in the SUNSET final rule 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 final rule RIA underlying the time per review of the 160 rulemakings that are newly assessed to have a significant impact.

The SUNSET final rule 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 consideration of time spent on activities other than drafting the retrospective analysis. For example, the Department 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 Department 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 final rule RIA and our revised assumptions for the final 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 final rule RIA | | Final 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 final rule RIA includes a discussion of the costs to the stakeholders to monitor and comment on regulations as these 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 on the commencement of assessments and reviews, publishing the results of assessments and review (''including the full underlying analyses and data used to support the results'') once a year, and establishing a website dashboard to help the public monitor the Department's progress.

When estimating the impact on the public, the SUNSET final rule RIA assumes the public will wait until the assessments and reviews are complete and the Department has announced it intends to rescind or amend a rulemaking before commenting. Thus,

for example, the SUNSET final rule 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 final rule 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 final rule RIA assumes will take between 5 and 15 hours to prepare. 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.

We have reconsidered the SUNSET final rule RIA's assumption that the public will wait until the Department has announced it intends to rescind or amend a rulemaking before commenting. 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 assessments and reviews. The Department's prior assumptions appear at odds with the decision to invite public comment during both the assessment and review processes. Furthermore, as discussed by the SBA, ''insights 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.'' [69]

This means that we assume that the public will comment on all 3,600 rulemakings subject to the SUNSET final rule that will be available for public comment in connection with a Department assessment or review, in contrast with the SUNSET final rule RIA, which assumes the public will offer no comments. We adopt the SUNSET final rule RIA's estimate of 486 comments per rulemaking, but instead apply this to the 530 rulemakings that, following a threshold analysis in an assessment, the Department will begin to review. We believe that the public will submit fewer comments for rulemakings undergoing an assessment (rather than a review), and adopt an assumption of 25 comments per assessment. We also adopt the SUNSET final rule RIA's assumption about the time spent per comment (between 5 and 15 hours) and apply it in the context of assessments and reviews. Table D3 summarizes a comparison of the assumptions in the SUNSET final rule RIA and in the baseline analysis of this final withdrawal rule of the comments per assessment and review, and for the subsequent regulatory actions to rescind or amend rulemakings.

TABLE D3—BASELINE COMMENTS PER ACTION

| Baseline requirement | SUNSET final rule RIA | Final 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 final rule RIA envisions the Department identifying and rescinding 53 rulemakings and amending 159 rulemakings following completed reviews under the SUNSET final rule. Upon further reflection and analysis, the Department no longer believes it was appropriate to unambiguously attribute subsequent regulatory actions of this nature to the SUNSET final rulemaking in the context of a regulatory impact analysis. Even if the challenging attribution questions could be resolved, we maintain that the SUNSET final rule RIA understates the impact of the SUNSET final 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 given the resources required to undertake a full notice-and-comment rulemaking proceeding. 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 review by the Office of Management and Budget. We have not attempted to estimate the time and resources associated with developing these regulatory actions or unambiguously attributed the costs of those actions to the SUNSET final rule.

Baseline Effect of the SUNSET Final 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 (between 5 and 15 hours) to estimate the total time spent by the public. Table D4 presents yearly estimates of hours spent related to assessments performed under the

[69] Available at *https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf* pg. 83.

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 final rule related to assessments and reviews.

TABLE D4—HOURS RELATED TO ASSESSMENTS UNDER THE SUNSET FINAL RULE

| Year | Assessments | Department | | Public | |
|---|---|---|---|---|---|
| | | Low | High | Low | High |
| 2022 | 683.0 | 27,320 | 68,300 | 85,375 | 256,125 |
| 2023 | 683.0 | 27,320 | 68,300 | 85,375 | 256,125 |
| 2024 | 683.0 | 27,320 | 68,300 | 85,375 | 256,125 |
| 2025 | 683.0 | 27,320 | 68,300 | 85,375 | 256,125 |
| 2026 | 683.0 | 27,320 | 68,300 | 85,375 | 256,125 |
| 2027 | 31.8 | 1,272 | 3,180 | 3,975 | 11,925 |
| 2028 | 31.8 | 1,272 | 3,180 | 3,975 | 11,925 |
| 2029 | 31.8 | 1,272 | 3,180 | 3,975 | 11,925 |
| 2030 | 31.8 | 1,272 | 3,180 | 3,975 | 11,925 |
| 2031 | 31.8 | 1,272 | 3,180 | 3,975 | 11,925 |

TABLE D5—HOURS RELATED TO REVIEWS UNDER THE SUNSET FINAL RULE

| Year | Reviews | Department | | Public | |
|---|---|---|---|---|---|
| | | Low | High | Low | High |
| 2022 | 101.2 | 50,600 | 101,200 | 245,916 | 737,748 |
| 2023 | 101.2 | 50,600 | 101,200 | 245,916 | 737,748 |
| 2024 | 101.2 | 50,600 | 101,200 | 245,916 | 737,748 |
| 2025 | 101.2 | 50,600 | 101,200 | 245,916 | 737,748 |
| 2026 | 101.2 | 50,600 | 101,200 | 245,916 | 737,748 |
| 2027 | 4.8 | 2,400 | 4,800 | 11,664 | 34,992 |
| 2028 | 4.8 | 2,400 | 4,800 | 11,664 | 34,992 |
| 2029 | 4.8 | 2,400 | 4,800 | 11,664 | 34,992 |
| 2030 | 4.8 | 2,400 | 4,800 | 11,664 | 34,992 |
| 2031 | 4.8 | 2,400 | 4,800 | 11,664 | 34,992 |

TABLE D6—TOTAL HOURS RELATED TO THE SUNSET FINAL 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 final 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 guidances for the same or related 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. In addition, the estimates do not include the costs of resolving and communicating the meaning of ambiguous provisions in the SUNSET final rule. For example, HHS anticipates that it will take considerable work to determine when regulations must be assessed and reviewed as part of a particular rulemaking and when regulations fall within an exception. Even after that work is complete, additional resources are required to share those interpretations with the public. Furthermore, the figures do not account for the time and costs associated with HHS's efforts to reevaluate and redirect resources to support assessments and reviews and thereby preserve regulations.

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 final

rule RIA's estimate of 1,160 hours of work per year per employee.[70] 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, the costs of which have not been quantified in this analysis.

*E. Benefits of the Final Withdrawal Rule*

The monetized benefits of this regulatory action to withdraw 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 final rule RIA's ''estimates that the fully-loaded cost per hour to the Department to employ a person to conduct a Review or Assessment is $244.98 per hour'' [71] and ''fully loaded cost per hour of writing comments is $143.20.'' [72] Table E1 presents the yearly cost savings to the Department and the public expected under the final withdrawal 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 final withdrawal rule for both a 3% and 7% discount rate. All figures are reported in 2020 dollars, in millions.

TABLE E1—COST SAVINGS UNDER THE FINAL 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 final rule 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 will generate net cost savings. These cost savings estimates attributed to the final withdrawal rule 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 will be attributable to the final withdrawal rule. Other considerations relating to the appropriate frequency or nature of retrospective economic analyses of existing Departmental regulations are beyond the scope of this final rule RIA.

In the previous section, we discussed concerns about potential costs of the SUNSET final rule that were overlooked in the SUNSET final rule 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 final withdrawal rule are equally underestimated.

In addition to cost savings, the final withdrawal rule will 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. Withdrawing the SUNSET final rule will remove the expiration provisions, which will also remove the likelihood of any automatic expiration of regulatory requirements. The final withdrawal rule will 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 Final Withdrawal Rule*

The costs of the final withdrawal rule will 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 final

[70] This 1,160-hour estimate corresponds to a measure of the ''Net Supported Direct FDA Work Hours Available for Assignments'' (86 FR 5743).

[71] 86 FR 5743.

[72] 86 FR 5745.

rule RIA and make no attempt to quantify or monetize the value of this information. The SUNSET final rule 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 final withdrawal rule.

*G. Analysis of Regulatory Alternatives to the Final Withdrawal Rule*

We quantitatively analyze four alternative options to the final 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 SUNSET rule.[73] Second, we consider an option to maintain the general approach of the SUNSET final rule, but adopt an initial ten-year period following the effective date to assess and review all regulations, regardless of when these were first published. This option, Alternative 2, evenly distributes the time spent by the Department assessing and reviewing existing regulations. Third, we consider an option to maintain the general framework of the SUNSET final rule but limit its scope to regulations that the Department previously identified as having a significant economic impact on a substantial number of small entities. This option, Alternative 3, would include the 326 Reviews of Post-RFA rulemakings identified in Table D1. Fourth, we consider an option, Alternative 4, that would maintain the SUNSET final rule's requirements related to the timeline for assessing and reviewing all of the Department's existing regulations, but without the automatic expiration provision contained in the SUNSET final rule.

Table G1 presents the primary estimates of yearly cost savings under the final withdrawal rule and under the four policy alternatives described above. Each of these policy options are compared to the common baseline scenario described in section D. We report the PDV and annualized cost savings under the final withdrawal rule and two policy alternatives for both a 3% and 7% discount rate. All figures are reported in 2020 dollars, in millions. Negative cost-savings estimates indicate that a policy alternative would likely result in net cost increases compared to the baseline scenario.

TABLE G1—PRIMARY ESTIMATE OF COST SAVINGS UNDER THE FINAL WITHDRAWAL RULE AND ALTERNATIVES

[$M]

| Year | Final rule | Alternative 1 | Alternative 2 | Alternative 3 | Alternative 4 |
|---|---|---|---|---|---|
| 2022 | $125.2 | −$187.8 | $59.6 | $70.8 | $0.0 |
| 2023 | 125.2 | −187.8 | 59.6 | 70.8 | 0.0 |
| 2024 | 125.2 | 121.5 | 59.6 | 70.8 | 0.0 |
| 2025 | 125.2 | 121.5 | 59.6 | 70.8 | 0.0 |
| 2026 | 125.2 | 121.5 | 59.6 | 70.8 | 0.0 |
| 2027 | 5.9 | 2.2 | −59.6 | 2.9 | 0.0 |
| 2028 | 5.9 | 2.2 | −59.6 | 2.9 | 0.0 |
| 2029 | 5.9 | 2.2 | −59.6 | 2.9 | 0.0 |
| 2030 | 5.9 | 2.2 | −59.6 | 2.9 | 0.0 |
| 2031 | 5.9 | 2.2 | −59.6 | 2.9 | 0.0 |
| PDV, 3% | 596.7 | −26.6 | 37.5 | 335.9 | 0.0 |
| PDV, 7% | 530.6 | −54.5 | 70.2 | 298.9 | 0.0 |
| Annualized, 3% | 69.9 | −3.1 | 4.4 | 39.4 | 0.0 |
| Annualized, 7% | 75.5 | −7.8 | 10.0 | 42.6 | 0.0 |

The cost savings reported for the Sunset final rule match the estimates contained in Table E1 of this analysis. For Alternative 1, we estimate annualized cost savings of −$3.1 million using a 3% discount rate. This indicates that Alternative 1 would result in incremental annualized costs of $3.1 million above the baseline scenario of the SUNSET final rule. In addition to this quantified impact on cost savings, 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. Alternative 1 would also result in additional unquantified benefits associated with earlier completion of some of the retrospectives, and therefore earlier access to information from these assessments and reviews.

For Alternatives 2 and 3, we estimate annualized cost savings of $4.4 million and $335.9 million, respectively. Compared to the SUNSET final rule, Alternatives 2 and 3 would reduce the likelihood that the Department would need to hire non-government experts to perform a share of the retrospective work, and thus reduce the potential for additional overhead costs. Compared to the SUNSET final rule, Alternative 2 would result in non-quantified forgone benefits associated with later completion of some of the retrospective analyses, and therefore later access to information from these assessments and reviews. Alternative 3 would reduce the number of retrospective analyses and result in more foregone information.

For Alternative 4, we do not identify any incremental costs or cost savings compared to the baseline scenario of the SUNSET final rule, maintaining the assumption in the main analysis that the Department will fulfill the analytic requirements of the SUNSET final rule. However, compared to SUNSET final rule, Alternative 4 would generate non-quantified benefits from reduced regulatory uncertainty associated with the automatic expiration provision of the SUNSET final rule. Alternative 4 would, therefore, result in non-quantified benefits from reduced regulatory confusion among stakeholders, and non-quantified benefits from reduced harm to the public health related to the actuality of having regulations expire automatically.

[73] 85 FR 70096.

*H. Final Small Entity Analysis*

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

1. Description and Number of Affected Small Entities

The SBA maintains a Table of Small Business Size Standards Matched to North American Industry Classification System Codes (NAICS).[74] 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 final 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 will potentially be impacted under the baseline scenario of the SUNSET final rule. Similarly, it is impractical to identify the small entities that will be impacted by the final withdrawal rule. 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.'' [75] For practicality, we assume that the bulk of the potential impacts of the final withdrawal 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 final rule 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 final rule. Since the particular regulations impacted are unknowable prior to conducting the retrospective analyses, this results in uncertainty over the types of small entities that will be affected under the baseline scenario of the SUNSET final 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 retrospective analyses.

As described earlier, the Department no longer believes it was appropriate to unambiguously attribute to the SUNSET final 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 final withdrawal 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 final withdrawal rule, we note that, while the Department would seek to 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. This potential impact under the SUNSET final 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 final rule will remove the expiration provisions, which will also remove the likelihood of any automatic expiration of regulatory requirements. The final withdrawal rule will also eliminate the potential for regulatory confusion among stakeholders, including small entities. We anticipate that a large share of these non-quantified benefits will accrue to small entities.

Impacts to Small Entities Related to Commenting on Assessments and Reviews

When identifying the potential benefits of the final withdrawal rule, we estimate the cost savings to the public from not commenting on these assessments and reviews that will be performed under the baseline scenario of the SUNSET final 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. The final withdrawal rule will 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 will need to submit in one year such that the time spent on comments will 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 would share more than 6 comments per year on regulations undergoing a retrospective analysis under the SUNSET final rule. This indicates that the potential cost savings to small entities under the final withdrawal rule are unlikely to be significant for a substantial number of small entities. The Department

[74] U.S. Small Business Administration (2019). ''Table of Size Standards.'' August 19, 2019. *https://www.sba.gov/document/support--table-size-standards.*

[75] 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.*

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.

## XII. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 13132, ''Federalism.'' The Department has determined that this final rule 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.

## VIII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this final rule in accordance with the principles set forth in E.O. 13175, ''Consultation and Coordination With Indian Tribal Governments.'' As we acknowledged and agreed in the Withdrawal NPRM, 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. *See* 86 FR 59931. However, the Department further explained that tribal consultation on the Withdrawal NPRM was unnecessary because the withdrawal of the SUNSET final rule would continue the status quo, and because of the numerous comments already received from Tribal governments and representatives asking for the SUNSET final rule to be withdrawn. The Department nevertheless provided notice of the Withdrawal NPRM to Tribes, 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 the proposed withdrawal. The Department continues to conclude that the final withdrawal rule 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.

## IX. Analysis of Environmental Impacts

HHS had determined that the final 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 final rule and has 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).

Dated: May 24, 2022.

**Xavier Becerra,**

*Secretary.*

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