



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 6**

### **Public Health Service**

#### **42 CFR Part 1**

### **Centers for Medicare and Medicaid Services**

#### **42 CFR Part 404**

### **Office of the Inspector General**

#### **42 CFR Part 1000**

### **Office of the Secretary**

#### **45 CFR Part 8**

### **Administration for Children and Families**

#### **45 CFR Parts 200, 300, 403, 1010, and 1300**

**[Docket No. HHS–OS–2020–0012]**

**RIN 0991–AC24**

### **Securing Updated and Necessary Statutory Evaluations Timely; Administrative Delay of Effective Date; Correction**

**AGENCY:** Department of Health and Human Services (HHS).

**ACTION:** Final rule; delay of effective date and correction.

**SUMMARY:** The Department of Health and Human Services (HHS or Department) is postponing, pending judicial review, the effective date of a final rule entitled “Securing Updated and Necessary Statutory Evaluations Timely” (SUNSET final rule) and published in the Federal Register of January 19, 2021. This document also corrects certain errors in the SUNSET final rule.

**DATES:** As of March 19, 2021, the effective date of the final rule published January 19, 2021 (86 FR 5694), is delayed pursuant to 5 U.S.C. 705 for one year until March 22, 2022.

This correction is effective as of March 22, 2022, and amendatory instruction #10 in FR 2021-00597 (86 FR 5694), published on January 19, 2021, is corrected.

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

**SUPPLEMENTARY INFORMATION:** The SUNSET final rule was scheduled to take effect on March 22, 2021. On March 9, 2021, a lawsuit was filed seeking to overturn the SUNSET final rule. HHS finds that the interests of justice require that the SUNSET final rule's effective date be postponed pending judicial review because: based on HHS's initial review of the Complaint, HHS believes that the Court could find merit in some of Plaintiffs' claims; Plaintiffs' allegations of harm are credible; a postponement will permit HHS to review the SUNSET final rule in light of the claims raised in the litigation; and the balance of equities and the public interest warrant postponement of the effective date to preserve the status quo while the Court considers the challenge to the SUNSET final rule. This document also corrects certain errors in the SUNSET final rule.

In the *Federal Register* of November 4, 2020 (85 FR 70096), HHS published a notice of proposed rulemaking entitled "Securing Updated and Necessary Statutory Evaluations Timely" (SUNSET). Under the rule as proposed, 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 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 expire. The 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 proposed rule contained certain publication requirements, including that (1) the Department publish the results of all “assessments” and “reviews,” including the full underlying analyses and data used to support the results, in the Federal Register, and (2) the Department announce the commencement of an “assessment” or “review” of a particular regulation on the agency website, with an opportunity for public comment. The proposed rule provided that comments could be submitted until December 4, 2020, except for comments on the portion of the rule amending 42 CFR parts 400–429 and parts 475–499, which were due by January 4, 2021.

In the *Federal Register* of November 16, 2020 (85 FR 73007), HHS announced a public hearing, scheduled for November 23, 2020, to receive information and views on the proposed rule (Public Hearing).

In the *Federal Register* of January 19, 2021 (86 FR 5694), HHS issued the SUNSET final rule. The final rule provides that all regulations, subject to certain exceptions, issued by the Secretary of the Department of Health and Human Services (Secretary) or their delegates or sub-delegates in titles 21, 42, and 45 of the CFR shall expire at the end of (1) five calendar years after the year that the SUNSET final rule first becomes effective, (2) ten calendar years after the year of the regulation’s promulgation, or (3) ten calendar years after the last year in which the Department “assessed” and, if required, “reviewed” the regulation, whichever is latest. Thus, the final rule contains the same basic expiration framework as the proposed rule, but extends the timeframe for “assessment” and any applicable “review” of most existing regulations from two calendar years to five calendar years. The final rule also provides for “continuation” of a regulation that is subject to expiration if the Secretary makes a written determination that the public interest requires continuation. In addition, the final rule contains exemptions for a small

set of certain Food and Drug Administration (FDA) regulations. The final rule maintains the timeframe for amendment or rescission of regulations, as well as the publication requirements, and includes a new Federal Register publication requirement. The final rule also expands its reach to include additional provisions regarding parts of HHS not specifically included in the proposed rule. The final rule states that its effective date is March 22, 2021.

On March 9, 2021, the County of Santa Clara, California Tribal Families Coalition, National Association of Pediatric Nurse Practitioners, American Lung Association, Center for Science in the Public Interest, and Natural Resources Defense Council sued the Department seeking to overturn the SUNSET final rule under the Administrative Procedure Act (APA). Complaint, *County of Santa Clara v. HHS*, Case No. 5:21-cv-01655-BLF (N.D. Cal.). Plaintiffs allege that the SUNSET final rule is *ultra vires*, *see id.* ¶¶ 123-30; arbitrary and capricious, *see id.* ¶¶ 131-33; in violation of the APA’s notice-and-comment requirements, *see id.* ¶¶ 134-39; and in violation of HHS’s Tribal Consultation Policy, *see id.* ¶¶ 140-44. Plaintiffs further allege that the SUNSET final rule threatens imminent and irreparable harm to them and the general public, including by creating regulatory confusion and uncertainty that will impede their ongoing operations, budgeting, and planning activities. *See, e.g., id.* ¶¶ 100-02; *see generally id.* ¶¶ 95-122.

Under 5 U.S.C. 705 of the APA, an agency “may postpone the effective date of action taken by it, pending judicial review,” when the “agency finds that justice so requires.” HHS has concluded that the interests of justice require that the SUNSET final rule be stayed pending judicial review. As discussed in greater detail below, HHS believes that the Court may find merit in some of Plaintiffs’ claims, that Plaintiffs’ allegations of harm are credible, and that the balance of equities and the public interest warrant postponement of the effective date pending judicial review. Accordingly, the interests of justice require a postponement in order to preserve the status quo, because, if the rule took effect while HHS was evaluating the rule in light of the claims raised in litigation, it could create significant obligations for HHS, cause confusion for the

public, including Plaintiffs, and may lead to compliance costs as entities, including Plaintiffs, plan steps necessary to deal with the rule's implementation, as explained below. HHS is unaware of any benefits from the implementation of the SUNSET final rule that would be significantly curtailed from a stay of its effective date.

The Department is taking a fresh and critical look at the SUNSET final rule in light of the allegations in the Complaint (although many of these concerns were also raised during the comment period on the proposed rule). The Complaint alleges serious legal vulnerabilities of the rule, and, while HHS does not concede any of these claims at this time, HHS requires additional time to evaluate the SUNSET final rule given the pending litigation. In addition, the Complaint raises the question as to whether the SUNSET final rule, issued in the final days of the last administration, is consistent with the policies and goals of the current administration, both in terms of the appropriate role of regulatory oversight of the health care industry and necessary engagement with the public, including tribal organizations.

The Complaint makes numerous allegations that the substantive provisions of SUNSET final rule violate the law. The Complaint alleges that the SUNSET final rule is contrary to and exceeds the Department's authority under the APA, substantive organic statutes, and the Regulatory Flexibility Act (RFA) because it schedules the rescission of thousands of regulations that were required by statute, amends regulations without the same level of process and statutory considerations required for the original regulations, and provides for automatic elimination of regulations without considering the requirements of the RFA. The Complaint further alleges that the SUNSET final rule is arbitrary and capricious and lacks a rational basis because, among other reasons, it assumes that HHS will conduct RFA reviews at an implausible pace; does not adequately consider the extreme degree of regulatory uncertainty the SUNSET final rule creates; underestimates the burden imposed on Plaintiffs for monitoring HHS regulations to ensure they do not expire; and fails to consider the specific regulations being amended to automatically expire.

Given the volume of HHS agency regulations that the Department would need to assess and, as applicable, review in a short period of time, HHS now believes it is likely some regulations would expire without any additional administrative process (contrary to the conclusions reached in the SUNSET final rule). Under the SUNSET final rule, for each covered regulation, HHS agencies would need to: collect data to conduct the relevant evaluation, perform an assessment and possibly a review, consider any comments to the public docket related to the evaluation, publish the results of this process in the Federal Register (“including the full underlying analyses and data used to support the results,” 86 FR at 5712), and, if warranted, complete a rulemaking to amend or rescind the regulation, which would itself require an additional investment of agencies’ resources and public input. If the work is unable to be conducted within the final rule’s time frames, the regulations would expire.

That outcome could raise interrelated administrative law questions regarding: whether regulations promulgated through notice and comment rulemaking can be terminated through an umbrella rule without individualized consideration of the expiring regulations, including any reliance interests of parties affected by them; and, if so, whether the proposed/final rule provided an adequate justification for implementing a process of automatic expiration.

The expiration component of the SUNSET final rule also raises significant policy and public health questions concerning the value of the assessment and review processes and whether those processes are so important that they outweigh the value of the regulations that would likely expire.

The potential automatic expiration of regulatory programs could create uncertainty and unpredictability regarding large swathes of the rules governing health care, which would upend the status quo and in turn could result in compliance costs to HHS grantees, contractors, and health care providers and suppliers, many of whom may have structured matters such as financial arrangements and business operations to satisfy the conditions set forth in the current regulations. The resulting disruption in the marketplace could impact stakeholders who rely on the regulatory

functions of each HHS agency. This uncertainty could have serious implications for insurance markets, hospitals, physicians, and patients, among other affected parties, which could lead physicians and other regulated entities to forgo future investments because of the lack of clarity. In addition, because States depend on HHS to set national standards and have built vast regulatory systems within that framework, the possibility that many regulations would lapse could pose a direct threat to the States' healthcare systems and the health and safety of individuals. The expiration of regulations could also muddle the clarity and predictability of existing regulations, which in turn would impede program implementation and reduce HHS's overall efficiency.

HHS is similarly concerned that the SUNSET final rule may have significantly underestimated the burden of the assessments and reviews for this magnitude of regulations and fails to account for the substantial resources that would be needed for the HHS agencies to simultaneously evaluate thousands of regulations in a short period of time. For example, the Regulatory Impact Analysis (RIA) included in the final rule appears to focus on the number of staff and staff hours required for "reviews," but provides an incomplete estimate for the cost of the initial "assessment" phase. That raises questions regarding whether the RIA significantly underestimated the costs that will be incurred by agencies and overestimates the purported cost savings. Currently, there is no accurate impact analysis of the substantial redirection of resources (both financial and employee) required to provide the necessary expertise and input from economists, epidemiologists, medical officers, legal and regulatory counsel, and other subject matter experts.

The Complaint also alleges that the promulgation of the SUNSET final rule suffered from procedural deficiencies. Plaintiffs allege that, despite widespread requests for more time, HHS issued the SUNSET final rule after providing 30 days to comment on the rule's effect on non-Medicare regulations and 60 days to comment on its effects on Medicare regulations, seriously interfering with meaningful public participation. The comments likewise raised concerns about

the adequacy of the comment period for a rule with this magnitude of impact and the timing of the proposal, particularly during the COVID-19 pandemic, both of which may have impeded the full and deliberate consideration of all of the potential issues related to the SUNSET rule. For example, at the Public Hearing, almost all commenters agreed that HHS should have lengthened the comment period, and offered several reasons in support of a longer comment period, all of which were expressed by multiple commenters: that a proposal with this breadth, scope, and potential harmful impact, including unintended detrimental consequences to regulated industries, merited more time for thoughtful public input; that impacted stakeholders included small businesses that would not be able to digest and comment on a rule of this breadth in such a short period of time; that it was irresponsible for HHS to engage in this rulemaking during the height of the pandemic when stakeholder resources were devoted to addressing the public health emergency; and that the already short comment period included Thanksgiving weekend, which exacerbated the time-crunch for commenters. *See* Transcript, Public Hearing on the Securing Updated and Necessary Statutory Evaluations Timely Notice of Proposed Rulemaking (Public Hearing Transcript) (Nov. 23, 2020) (available at <https://www.regulations.gov/document/HHS-OS-2020-0012-0501>). As with Plaintiffs' above substantive claims, HHS requires additional time to review the SUNSET final rule's compliance with these procedural obligations, in light of Plaintiffs' claims, before determining how to proceed in litigation and before creating uncertainty among the regulated community. The SUNSET final rule is uniquely situated in that it affects an extraordinarily large number of regulations, which lends support for Plaintiffs' procedural claims.

The Complaint also alleges that, despite the SUNSET final rule's sweeping scope and tribal implications, the Department neglected to consult with tribal governments. Again, these same concerns were raised in the written comments on the SUNSET proposed rule. Under Executive Order 13175, entitled "Consultation and Coordination With Indian Tribal Governments," HHS is required, before any action is taken that will significantly affect Indian

Tribes, to consult with Indian Tribes in the development of the proposed rule to the extent practicable and permitted by law. 65 FR 67249 (Nov. 6, 2000). This required consultation is in recognition that Tribes should be afforded an opportunity to comment meaningfully on the rule's impact. However, multiple comments from representatives of several Tribes and related groups explained that, despite the enormous impact that this rule, if implemented, would have on Tribes, HHS failed to consult with Tribal governments (or even notify them regarding the proposal), contrary to procedures required under Executive Order 13175. *See, e.g.*, Comments from the: Saint Regis Mohawk Tribe; Chickahominy Indian Tribe; Jena Band of Choctaw Indians; Nez Perce Tribe; Affiliated Tribes of Northwest Indians; Mohegan Tribe of Connecticut; Tanana Chiefs Conference; Chippewa Cree Tribe of the Rocky Boy's Reservation; Alaska Native Tribal Health Consortium; United South and Eastern Tribes Sovereignty Protection Fund; Northwest Portland Area Indian Health Board; Quinault Indian Nation; California Tribal Families Coalition; National Indian Child Welfare Association; Tribal Law and Policy Institute; Tribal Technical Advisory Group; Native American Rights Fund, and the National Congress of American Indians, *available at* <https://www.regulations.gov/document/HHS-OS-2020-0012-0001/comment>. In light of the allegations in the Complaint, we need to reconsider the conclusion in the SUNSET final rule that the rule does not significantly affect Indian Tribes or have Tribal implications. Accordingly, HHS requires additional time to review the SUNSET final rule in light of the pending litigation.

In publishing the SUNSET final rule, the Department previously took the position that the rule complies with the APA and that the comment period was adequate, among other things. The Department's conclusions rested on certain assumptions that the Complaint challenges. For example, the Department expressed a view that it has the resources to complete assessments and reviews and avoid expiration, thus avoiding many of the legal concerns related to automatic repeal of regulations. *See, e.g.*, 86 FR 5694, 5705 ("The regulatory impact analysis in this final rule explains how HHS has the resources and personnel to perform the Assessments and Reviews

called for by this final rule.”); *id.* at 5710 (“HHS does not intend to allow a regulation to simply expire.”); *id.* at 5711 (“HHS believes that this final rule does not significantly affect Indian Tribes or have Tribal implications . . . HHS intends that all rules will be Assessed and (if necessary) Reviewed timely. Therefore, this final rule would have no direct impact on Indian Tribes”); *id.* at 5714 (“The Department does not intend for any regulations to inadvertently sunset, and it is unlikely that any regulations with significant benefits would slip through the cracks.”). However, the Complaint alleges that “there is no realistic probability that the Department will be able to conduct the number of reviews required to prevent automatic rescission,” based in part on the quantity of analyses that would be required in the first five years and the agency’s past practices. Complaint, ¶¶ 84-85. As noted above, the Department now believes that the RIA developed for the SUNSET final rule may not have fully taken into account all of the resource implications of this rule and therefore misjudged the likely expiration of existing regulations, elevating the administrative law concerns and concerns about the adequacy of the RIA.

In addition, the Department previously took the view that a 30-day comment period was adequate. However, the Complaint challenges the sufficiency of a 30-day comment period for complex rules, Complaint, ¶ 54, and the SUNSET rule’s unique breadth, affecting an extraordinarily large number of regulations, could add force to such claims. The Department also took the view that the lack of tribal consultation was mitigated by the fact that Tribes will be able to comment on regulations during the Assessment and Review processes, 86 Fed. Reg. at 5711, but, as noted above, HHS is reconsidering that conclusion in light of the claims raised in the Complaint.

The Complaint also alleges that Plaintiffs and others are immediately harmed by the SUNSET final rule. The Complaint alleges that the uncertainty resulting from its implementation impacts the entire healthcare sector, which accounts for nearly one-fifth of the U.S. economy and secures individual and community health for hundreds of millions of

Americans, and that participants in every single industry the Department regulates, including Plaintiffs, must plan their futures and operations without knowing what regulations will govern their businesses in these notoriously complex regulatory arenas. *See* Complaint, ¶¶ 2, 95-122. While HHS does not concede that Plaintiffs would establish irreparable harm in litigation, HHS agrees that it is appropriate to postpone the effective date of the SUNSET final rule to preserve the status quo and to ensure that HHS has time to evaluate the rule before it takes effect to avoid the possibility of confusion among the regulated community.

In addition, given the scope of work and timeframes set forth in the SUNSET final rule, the review required under the rule would divert the Department's resources from mission-critical endeavors for HHS agencies. For example, based on a count cited in the SUNSET final rule, under the timeline and definitions provided in the final rule, over 7,000 sections of the Code of Federal Regulations promulgated by the Food and Drug Administration (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 its current regulations. Unless one of the exemptions applied, these regulations would need to be assessed within five years and, if applicable, reviewed, or be subject to expiration. If the SUNSET final rule were to become effective as scheduled on March 22, 2021, then, in order to meet these new obligations within the specified timeframe to avoid automatic expiration of its regulations, FDA and the Department would need to immediately divert resources toward assessment and review during the ongoing COVID-19 public health emergency. In that event, FDA's reviews of medical product applications, fulfillment of user fee commitments, and actions to address urgent public health matters such as ongoing COVID-19 pandemic relief efforts, outbreaks of foodborne illness, inspections, recalls, and other public health priorities would be significantly impacted. This concentration of resources in conducting regulatory review pursuant to the SUNSET rule could prevent FDA from modernizing its regulatory oversight more efficiently and addressing new regulatory needs.

These considerations further support HHS's determination that justice requires a postponement of the SUNSET final rule's effective date. *See* 5 U.S.C. 705.

The SUNSET final rule presents similar burdens for HHS's seven other Public Health Service agencies and three human services agencies, such as the Centers for Medicare & Medicaid Services (CMS), with implications for many initiatives. For example, comments at the Public Hearing from the American College of Obstetricians and Gynecologists, Center on Budget and Policy Priorities, National Immigration Law Center, and Service Employees International Union raised concerns that the SUNSET rule would undermine the regulations underpinning the Affordable Care Act, potentially with catastrophic consequences for the health care of millions of individuals and families. *See* Public Hearing Transcript. As another example, Medicare regulations are numerous and have an expansive reach, affecting many health care providers and suppliers in this country. Permitting the rule to go into effect would require CMS to assess thousands of regulations within a relatively short timeframe, and would likely entail a massive expenditure of resources and significantly increase the Department's workload. The rule would also likely result in significant uncertainty and compliance costs to Medicare providers and suppliers, many of which are small businesses. In addition, this rule could cause the loss of program protections to the beneficiaries of HHS programs and create uncertainty for individuals and entities subject to administrative sanctions, or those who seek reinstatement after exclusion from participation in Federal health care programs. The National Health Law Program also commented at the Public Hearing that the rule would create havoc in the Medicaid industry. *See* Public Hearing Transcript. All of these potential consequences would be detrimental to the public health, underscoring that justice requires a postponement of the SUNSET final rule's effective date pursuant to 5 U.S.C. 705.

Because of these public health concerns, and the harms alleged by the Plaintiffs and echoed in the comments, the balance of equities and the public interest favor the issuance of a

stay of the effective date of the SUNSET final rule to preserve the status quo and allow for judicial review of its legality before any implementation.

Accordingly, HHS is issuing this stay of the effective date of this final rule pending judicial review. This postponement applies to all of the regulations established under the SUNSET final rule. As noted above, the Complaint alleges that the SUNSET final rule suffers from a variety of defects, including procedural defects related to its promulgation. The Department believes it is appropriate to review the entire rule in light of the claims raised in the litigation. Thus, this postponement reaches the full rule, consistent with the Complaint's prayer for relief.

Separately, this document addresses and corrects several technical errors identified by the Office of the Federal Register in the SUNSET final rule.

### **Corrections**

In FR 2021–00597 (86 FR 5694), published on January 19, 2021, the following corrections are made:

1. On page 5694, first column, the list of CFR citations in the heading under “Administration for Children and Families” that reads “45 CFR Parts 200, 300, 403, 1010, and 1390” is corrected to read “45 CFR Parts 200, 300, 403, 1010, and 1300.”

2. On page 5751, first column, the reference to “45 CFR Part 1390” in the List of Subjects is corrected to read “45 CFR Part 1300.”

### **SUBCHAPTER A [Corrected]**

3. On page 5763, first column, in instruction 10, the heading for subchapter A and the table of contents for part 1300 are corrected to read as follows:

SUBCHAPTER A—Administrative Matters

PART 1300—REVIEW OF REGULATIONS

Sec.

1300.1 Retrospective Review of Existing Regulations.

1300.2 through 1300.5 [Reserved]

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Norris Cochran,

Acting Secretary.

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