



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 6

Public Health Service

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Centers for Medicare and Medicaid Services

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Office of the Inspector General

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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

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

ACTION: Final rule; delay of effective date.

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, and a final rule correction published in the Federal Register of March 23, 2021.

DATES: As of [INSERT DATE OF PUBLICATION OF IN THE FEDERAL REGISTER], the effective date of the SUNSET final rule published January 19, 2021 (86 FR 5694), which was delayed until March 22, 2022, by an order that took effect as of March 19, 2021 (86 FR 15404, March 23, 2021), is further delayed pursuant to 5 U.S.C. 705 for six months until September 22, 2022.

As of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], the effective date of the correction published March 23, 2021 (86 FR 15404), is delayed until September 22, 2022.

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

SUPPLEMENTARY INFORMATION:

I. Overview

The SUNSET final rule, if implemented, would establish a new process for regulatory review of HHS regulations, which includes the automatic expiration of regulations under certain circumstances. It was scheduled to take effect on March 22, 2021. After a lawsuit was filed on March 9, 2021, seeking to overturn the SUNSET final rule, HHS issued an Administrative Delay of Effective Date (First Administrative Delay), which took effect as of March 19, 2021, which postponed the effective date of the SUNSET final rule, pending judicial review, until March 22, 2022. 86 FR 15404 (Mar. 23, 2021).

After conducting a thorough review of the SUNSET final rule including the oral and written comments on its proposal and the allegations in the lawsuit, HHS published a notice of proposed rulemaking to withdraw or repeal the SUNSET final rule (Withdrawal NPRM). 86 FR 59906 (Oct. 29, 2021). The comment period on the Withdrawal NPRM closed on December 28, 2021. HHS received approximately 80 comments. Some comments were submitted by Plaintiffs

in the lawsuit seeking to overturn the SUNSET final rule, and their comments incorporated by reference the Complaint they had filed.

HHS is currently in the process of reviewing the comments and developing a final rule. For the reasons described below, HHS finds that the interests of justice require that the SUNSET final rule's effective date be postponed pending judicial review because: (1) a postponement will permit HHS to continue and complete its review of the SUNSET final rule in light of the claims raised in the litigation; (2) the resolution of the rulemaking will inform the government's position in this lawsuit; and (3) based on HHS's review of the Complaint, HHS believes that the Court may find that: (a) some of Plaintiffs' claims have merit; (b) Plaintiffs' allegations of harm are credible; and (c) 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.

II. Background

A. The SUNSET Proposed and Final Rules

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. The SUNSET 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. HHS received 532 comments total throughout the 60-day comment period, and the commenters "generally opposed the proposed rule, although some commenters supported it." 86 FR 5704.

HHS also held a public hearing on November 23, 2020, to receive information and views on the proposed rule (Public Hearing). Over twenty interested parties provided oral comments at the Public Hearing. See Transcript, Public Hearing on the Securing Updated and Necessary Statutory Evaluations Timely Notice of Proposed Rulemaking (Nov. 23, 2020) (available at <https://www.regulations.gov/document/HHSOS-2020-0012-0501>) (Public Hearing Transcript).

HHS issued the SUNSET final rule on January 19, 2021. 86 FR 5694. The substance of the SUNSET proposed and final rules are more fully described in the First Administrative Delay, and that description is adopted by reference into this preamble. See 86 FR 15405.

B. The *Santa Clara* Complaint

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.). The substance of the Complaint is more fully described in the First Administrative Delay, and that description is adopted by reference into this preamble. See 86 FR 15405.

C. The Administrative Delay of Effective Date and Stay of Litigation.

On March 9, 2021, HHS issued the First Administrative Delay, which took effect as of March 19, 2021, which postponed the effective date of the SUNSET final rule, pending judicial review, until March 22, 2022. HHS explained that it believed that the Court may find: (a) that some of Plaintiffs' claims have merit; (b) that Plaintiffs' allegations of harm are credible; and (c) that the balance of equities and the public interest warrant postponement of the effective date pending judicial review. Accordingly, the Department found that the interests of justice required 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. HHS also observed that it was unaware of any benefits from the implementation of the SUNSET final rule that would be significantly curtailed from a stay of its effective date. See 86 FR 15404-08.

With respect to the *Santa Clara* litigation, the parties requested that the court stay the case on the ground that HHS was reviewing the SUNSET final rule in light of Plaintiffs' claims raised in this litigation and needed additional time to evaluate the claims and its position before taking further steps in the litigation. The court granted the stay. Order, *County of Santa Clara v. HHS*, Case No. 5:21-cv-01655-BLF (N.D. Cal.) (Apr. 22, 2021). Since that time, the parties have periodically submitted joint status reports to the court and requested that the litigation stay be extended, and those requests have thus far, as of February 1, 2022, been granted.

D. 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 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 comments submitted to the SUNSET proposed rule docket and raised at the Public Hearing, and the current Administration's policies. 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 all 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. HHS is actively engaged in considering the comments and developing a final rule.

III. Discussion

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." On March

9, 2021, HHS issued the First Administrative Delay after concluding that the interests of justice required that the SUNSET final rule be stayed pending judicial review. For the reasons described in the First Administrative Delay and as further discussed in this document, the Department has concluded that the considerations supporting the First Administrative Delay remain true today, and the interests of justice require that the effective date of the SUNSET final rule should be further stayed until September 22, 2022.

In the First Administrative Delay, the Department explained that it was taking a fresh and critical look at the SUNSET final rule in light of the allegations in the Complaint. The Complaint alleged serious legal vulnerabilities of the rule, and, while HHS did not concede any of these claims at that time, HHS required additional time to complete its evaluation of the SUNSET final rule given the pending litigation. In addition, the Complaint raised 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.

After further review of the SUNSET final rule, the allegations in the Complaint, and the comments on the SUNSET proposed rule, we issued the Withdrawal NPRM in October 2021, in which we discussed our tentative conclusions for further public comment. Our discussion included concerns regarding the procedural shortcomings of the SUNSET rulemaking process, the fundamental errors in its Regulatory Impact Analysis, and the attendant legal vulnerabilities of the SUNSET final rule. Our reanalysis of the regulatory impact of this rule, as set forth in the Withdrawal NPRM, has underscored our belief that the *Santa Clara* court could find merit in at least some of Plaintiffs' claims.

Our review of the approximately 80 comments submitted on the Withdrawal NPRM is ongoing. A few substantive comments support the SUNSET final rule while many other substantive comments favor withdrawal or repeal. As noted, Plaintiffs in the *Santa Clara*

litigation submitted comments on the Withdrawal NPRM that attached copies of the Complaint. Accordingly, HHS's consideration of the Complaint's critique of the SUNSET final rule are part of its ongoing review.

The Complaint also alleges that Plaintiffs and others would be immediately harmed by the SUNSET final rule, if implemented. 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. 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.

We further conclude that extending the effective date of the SUNSET final rule will create no countervailing harms because this delay merely continues the status quo. And because implementation of the regulatory review framework provided under the SUNSET final rule would be a complex and lengthy process, any purported benefits from the retirement of regulations under the new process would not accrue for several years. Accordingly, given the public health concerns and the harms from the implementation of the SUNSET final rule alleged by the Plaintiffs and echoed in the comments to the SUNSET proposed rule and the Withdrawal NPRM, and the dearth of countervailing harms from extending the effective date, the balance of equities and the public interest favor the extension of the 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 further 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, which it continues to actively evaluate in conjunction with its consideration of the comments to the Withdrawal NPRM and its efforts to develop a final rule. Thus, this postponement reaches the full rule, consistent with the Complaint's prayer for relief.

Xavier Becerra,

Secretary.

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