

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
24-Mar-22 .....	PA	Wilkes-Barre .....	Wilkes-Barre Wyoming Valley.	2/6226	2/7/22	RNAV (GPS) RWY 7, Orig-B.
24-Mar-22 .....	WI	Green Bay .....	Green Bay-Austin Straubel Intl.	2/7089	2/7/22	RADAR 1, Amdt 9E.
24-Mar-22 .....	ND	Mohall .....	Mohall Muni .....	2/7090	2/7/22	RNAV (GPS) RWY 31, Orig-A.
24-Mar-22 .....	WA	Toledo .....	Ed Carlson Meml Fld—South Lewis County.	2/7092	2/7/22	RNAV (GPS) RWY 6, Orig.
24-Mar-22 .....	MN	Granite Falls .....	Granite Falls Muni/Lenzen-Roe-Fagen Meml Fld.	2/8599	2/8/22	RNAV (GPS) RWY 33, Orig-A.
24-Mar-22 .....	MN	Granite Falls .....	Granite Falls Muni/Lenzen-Roe-Fagen Meml Fld.	2/8604	2/8/22	VOR/DME RWY 33, Orig-C.

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**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****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 March 4, 2022, 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 March 4, 2022, 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](mailto: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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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 7**

**[Docket No. FDA-2018-D-2074]**

**Initiation of Voluntary Recalls; Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry and FDA staff entitled "Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C." The guidance for industry and FDA staff provides guidance on timely initiation of voluntary recalls of FDA-regulated products. It also discusses preparations that firms in a distribution chain should consider making to ensure timely responses to a recall communication. In addition, the guidance discusses how FDA assists firms with carrying out their recall responsibilities to protect the public health from distributed products in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other laws administered by FDA. This guidance finalizes the draft guidance of the same title issued on April 24, 2019.

**DATES:** The announcement of the guidance is published in the **Federal Register** on March 4, 2022.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any

confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2018-D-2074 for "Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this