



December 16, 2021

VIA ELECTRONIC DELIVERY

Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Mr. Daniel J. Barry
Acting General Counsel
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Re: Comment in Opposition to the Department of Health and Human Services' Proposal to Withdraw or Repeal the "Securing Updated and Necessary Statutory Evaluations Timely" Rule RIN 0991-AC24 [HHS-OS-2020-0012]

Dear Secretary Becerra and Mr. Barry:

Pacific Legal Foundation (PLF) submits this comment in opposition to the Department of Health and Human Services' (HHS) proposed repeal or withdrawal of the "Securing Updated and Necessary Statutory Evaluations Timely" Rule (Sunset Rule).¹ HHS published a Notice of Proposed Rulemaking (NPRM) in the Federal Register inviting comments to be filed on or before December 28, 2021.² HHS is proposing to repeal or withdraw the Sunset Rule.³ PLF submits this comment opposing the proposed repeal or withdrawal. HHS should retain in its entirety the Sunset Rule, which is currently codified at:

¹ 86 Fed. Reg. 5694 (Jan. 19, 2021).

² 86 Fed. Reg. 59,906-59,931 (Oct. 29, 2021).

³ 86 Fed. Reg. at 59,906.

- 21 C.F.R. § 6.1;
- 42 C.F.R. §§ 1.1, 404.1, 1000.1; and
- 45 C.F.R. §§ 8.1, 200.1, 300.1, 403.1, 1010.1, 1300.1.

Pacific Legal Foundation

Pacific Legal Foundation is the nation's leading public interest organization advocating in courts throughout the country to defend the principles of individual liberty and limited government. PLF is particularly concerned about the rights of individuals and small businesses affected by overreaching government regulation. As such, PLF attorneys have extensive experience defending limited government and the constitutional separation of powers against the growing administrative state. PLF's attorneys have represented clients in major administrative-law cases before the United States Supreme Court.⁴ They have also produced substantial scholarship on administrative law.⁵ PLF attorneys often provide their expertise on administrative law matters to policymakers through congressional testimony,⁶ rulemaking petitions,⁷ and

⁴ See, e.g., *U.S. Army Corps of Eng'rs v. Hawkes Co., Inc.*, 136 S. Ct. 1807 (2016); *Sackett v. U.S. Env'tl. Prot. Agency*, 566 U.S. 120 (2012); *Rapanos v. United States*, 547 U.S. 715 (2006).

⁵ See, e.g., John Yoo & Todd Gaziano, *Presidential Authority to Revoke or Reduce National Monument Designations*, 35 YALE J. ON REG. 617 (2018); Jonathan Wood, *Standing up to the Regulatory State: Is Standing's Redressability Requirement an Obstacle to Challenging Regulations in an Over-Regulated World?*, 86 UMKC L. REV. 147 (2017); Damien M. Schiff & Luke A. Wake, *Leveling the Playing Field in David v. Goliath: Remedies to Agency Overreach*, 17 TEX. REV. L. & POL. 97 (2013).

⁶ See, e.g., *Federally Incurred Cost of Regulatory Change and How Such Changes Are Made: Hearing Before the Subcomm. on Federal Spending Oversight and Emergency Management of the S. Comm. on Homeland Sec. and Government Affairs*, 116 Cong. 116–62 (2019) (Testimony of Mr. Thomas Berry, Attorney, Pacific Legal Foundation).

⁷ See, e.g., Damien M. Schiff & Anthony L. François, *Petition for Rulemaking to Establish Notice and Hearing Procedures for Compliance Orders Issued Under Section 309(a) of the Clean Water Act*, PacificLegal.org (Jan. 10, 2020), <https://bit.ly/3H5lhAR>.

policy papers.⁸ PLF submitted a comment letter supporting the adoption of the Sunset Rule.⁹

Summary of the Reasons Why PLF Opposes the Repeal or Withdrawal of the Sunset Rule

The Sunset Rule ensures that HHS and its component agencies comply with the Regulatory Flexibility Act (RFA).¹⁰ The RFA was enacted in 1980.¹¹ It stated that “each agency *shall* publish in the Federal Register a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities.”¹² That duty is nondiscretionary. As the Supreme Court has noted, Congress’s use of the word “shall” “imposes a mandatory duty.”¹³ Almost *forty years later*, HHS published that plan by issuing the Sunset Rule. HHS now wants to scrap it. It should not.

It is wrong for HHS to ignore or overrule Congress’s mandate. Neither the President nor HHS can render optional a statutory directive that HHS publish a plan to

⁸ See TODD GAZIANO, ET AL., THE REGULATORY STATE’S DUE PROCESS DEFICITS: NINE CASE STUDIES HIGHLIGHT THE MOST COMMON AGENCY FAILINGS, Pacific Legal Foundation (2020), <https://bit.ly/3qjqpg7>; ANGELA ERICKSON & THOMAS BERRY, BUT WHO RULES THE RULEMAKERS: A STUDY OF ILLEGALLY ISSUED REGULATIONS AT HHS, Pacific Legal Foundation (2019), <http://bit.ly/2GJJCA8>.

⁹ Pacific Legal Foundation, Comment in Support of HHS Proposed Rule “Securing Updated and Necessary Statutory Evaluations Timely” (Dec. 4, 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0167>.

¹⁰ 5 U.S.C. §§ 601–612.

¹¹ Pub. L. No. 96-354, 94 Stat. 1169 (Sept. 19, 1980).

¹² 5 U.S.C. § 610(a) (emphasis added). While Congress amended other sections of the RFA on three separate occasions, Congress has *not* amended 5 U.S.C. § 610 since enactment. See Pub. L. No. 104-121, 110 Stat. 864 (Mar. 29, 1996) (amending 5 U.S.C. §§ 601, 603, 604, 605, 609, 611, 612); Pub. L. No. 111-203, 124 Stat. 2112 (July 21, 2010) (amending 5 U.S.C. §§ 603, 604, 609); Pub. L. No. 111-240, 124 Stat. 2551 (Sept. 27, 2010) (amending 5 U.S.C. § 604). Put differently, Congress has *not* amended the following sections of the RFA since enactment: 5 U.S.C. §§ 602, 606, 607, 608, 610.

¹³ *Kingdomware Technologies, Inc. v. United States*, 579 U.S. 162, 172 (2016).

periodically review its code of regulations. That published plan—the Sunset Rule—is also entirely consistent with the Regulatory Flexibility Act and the Administrative Procedure Act (APA).

The RFA expressly contemplates rule rescission as one of the outcomes of the retrospective review.¹⁴ The Sunset Rule preserves rule rescission as one of the options available to HHS upon completion (or not) of the RFA’s required retrospective review. The Sunset Rule accomplishes nothing new, different from, or contrary to what the RFA itself states.

The Sunset Rule is also fully consistent with the APA. The Sunset Rule’s provision that a regulatory section is rescinded if HHS fails to conduct a retrospective review or fails to extend the deadline for such review is consistent with APA’s rulemaking procedures. HHS lacks any sound reason to withdraw or repeal the Sunset Rule.

Reasons HHS Should Retain the Sunset Rule in Its Entirety

I. The Sunset Rule Is Consistent with the Regulatory Flexibility Act

To prevent outdated regulations from imposing unnecessary and excessive burdens on small businesses, organizations, and government units, the RFA requires that each federal agency review existing regulations at least once every ten years to ensure that these rules are not imposing such burdens.¹⁵ Such retrospective review serves two functions. First, it requires agencies to analyze the real-world impacts of rules, rather than relying solely on sometimes unreliable predictions about costs and benefits at the proposed-rule stage. Second, it avoids ineffective or overly burdensome rules remaining in place indefinitely due to regulatory inertia. If, after conducting a retrospective review, the agency determines that the rule is not achieving its purpose or that its purpose could be better achieved by a less burdensome approach, the RFA requires the agency to amend or rescind the rule.¹⁶

¹⁴ 5 U.S.C. § 610(a) (second sentence).

¹⁵ 5 U.S.C. § 610(a).

¹⁶ *Id.*

The RFA uses “mandatory” language—“shall publish.”¹⁷ According to Congress’s directive, “each agency” (which includes HHS and its component agencies) must publish “a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities.”¹⁸ In issuing the Sunset Rule, HHS was correct in stating: “The retrospective review provided by 5 U.S.C. 610 is a congressional mandate. Under the plain terms of the Act, having a plan for such reviews is not optional.”¹⁹

HHS was already about *forty* years late in publishing such a plan. Congress had directed HHS to publish the periodic-review plan “[w]ithin one hundred and eighty days after the effective date of this chapter.”²⁰ The effective date of the chapter was January 1, 1981.²¹ The 180-day deadline ran in mid-1981. HHS issued the Sunset Rule in January 2021—close to forty years after the deadline.²² Late as it is, now HHS at least has a retrospective-review plan as required by the RFA. Withdrawing or repealing it will return HHS to its pre-2021 forty-year noncompliance with the RFA.²³

¹⁷ 5 U.S.C. § 610(a) (first sentence); *Kingdomware*, 579 U.S. at 172.

¹⁸ 5 U.S.C. § 610(a) (first sentence).

¹⁹ 86 Fed. Reg. at 5695.

²⁰ 5 U.S.C. § 610(a) (first sentence).

²¹ Pub. L. No. 96-354, § 4, 94 Stat. 1170 (Sept. 19, 1980) (“The provisions of this Act shall take effect January 1, 1981[.]”).

²² Notice of Final Rulemaking, 86 Fed. Reg. 5694 (Jan. 19, 2021).

²³ HHS published guidance for retrospective review of agency rulemaking in 2011, which it followed until 2016. 86 Fed. Reg. at 59,920. That plan was not an adequate response to 5 U.S.C. § 610. The 2011 plan was not even published in the Federal Register. *See id.* Moreover, as HHS concedes, absent the Sunset Rule, HHS’s compliance with the RFA was “sporadic” at best. 86 Fed. Reg. at 5708. Indeed, in the years following the 2011 plan, HHS remained in widespread noncompliance with the requirements of the RFA. 85 Fed. Reg. at 70,099. HHS would remain in noncompliance with the RFA if its substitute is to publish the retrospective-review plan in HHS’s semi-annual unified agenda. *See* Office of Information and Regulatory Affairs, OMB, *Agency Rule List – Fall 2021*, https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPub=true&agencyCode=&showStage=active&agencyCd=090

The RFA plainly spells out the purpose and the relevant deadlines for conducting retrospective review. The “purpose” of retrospective review “shall be to determine whether such rules should be ... rescinded ... to minimize any significant economic impact of the rules upon a substantial number of such small entities.”²⁴ For rules that existed before RFA’s enactment, the RFA requires (“shall provide for”) that HHS conduct the retrospective review within ten years of RFA’s effective date.²⁵ For rules enacted after RFA’s enactment, it requires (“shall provide for”) that HHS conduct the retrospective review within ten years after the rule was published as final.²⁶ Congress was aware that some agencies might need to extend these ten-year deadlines. So, it expressly stated that if the agency head—the HHS Secretary, as relevant here—“determines that completion of the review of existing rules is not feasible by the established date,” the agency head “shall so certify in a statement published in the Federal Register and may extend the completion date by one year at a time for a total of not more than five years.”²⁷ All of these RFA provisions are “shall” provisions. Congress deliberately used “mandatory” language in establishing a series of nondiscretionary duties.²⁸ HHS has no option now to render such mandatory language optional by repealing the Sunset Rule. RFA allows HHS only to “amen[d]” the Sunset Rule.²⁹

[O&csrf_token=5B8E0754896D00EB6E21BF6607F983D031D99D6D81B639B9CB1F2E6A834D13291F1833D7D73854F2E7A292652B78BB5F4118](https://www.federalregister.gov/?token=5B8E0754896D00EB6E21BF6607F983D031D99D6D81B639B9CB1F2E6A834D13291F1833D7D73854F2E7A292652B78BB5F4118). Sneaking in retrospective review into the unified agenda fails to meet the “shall publish in the Federal Register” and the “a plan” requirement of the Act. 5 U.S.C. § 610(a) (first sentence). The retrospective-review plan must be published in the Federal Register, not elsewhere. Also, the retrospective-review plan under the RFA must be *one* plan that encodes the procedure for reviewing all HHS regulations. *Niz-Chavez v. Garland*, 141 S. Ct. 1474, 1480 (2021) (concluding that “a notice” means “a single document” not multiple documents). Publishing separate plans whenever HHS feels the need to publish them in the semi-annual unified agenda for specific regulatory sections satisfies neither the “a plan” nor the “shall publish in the Federal Register” requirements of Section 610(a).

²⁴ 5 U.S.C. § 610(a) (third sentence).

²⁵ 5 U.S.C. § 610(a) (fourth sentence).

²⁶ *Id.*

²⁷ 5 U.S.C. § 610(a) (last sentence).

²⁸ *Kingdomware*, 579 U.S. at 172.

²⁹ 5 U.S.C. § 610(a) (second sentence).

By implementing the RFA's requirement, the Sunset Rule ensures that HHS and its component agencies remain accountable to real-world impacts of its regulations. The Sunset Rule also makes sure that outdated HHS regulations do not unnecessarily burden the American public through sheer inertia. Nothing in the Sunset Rule prevents HHS from prioritizing the review of some rules over others. And nothing in the Sunset Rule prevents HHS from starting the retrospective-review process earlier if HHS thinks a particular rule section might generate some controversy or a lot of public input.

"Each year," the RFA already requires ("shall publish") HHS to "publish in the Federal Register a list of the rules ... which are to be reviewed pursuant to this section during the succeeding twelve months."³⁰ HHS has not complied with this "mandatory" language so far.³¹ The Sunset Rule only incentivizes HHS to faithfully comply with the RFA going forward. The Sunset Rule furthers the nondiscretionary provisions of Section 610. Complying with mandatory duties that Congress has imposed on HHS is the opposite of *ultra vires* agency action. Indeed, HHS's forty-year history of extensive noncompliance with the RFA necessitates the system of incentives and disincentives instituted and formalized by the Sunset Rule, including default repeal deadlines if retrospective review does not occur.

II. The Sunset Rule Is Consistent with the Administrative Procedure Act

In proposing to repeal the Sunset Rule, HHS argues that repeal is necessary because the Sunset Rule's provision repealing specific regulatory sections if not timely reviewed violates the APA.³² HHS posits that it is required to follow "the same process for amending or rescinding" regulations as the one it followed in adopting them.³³

³⁰ 5 U.S.C. § 610(c) (first sentence).

³¹ *Kingdomware*, 579 U.S. at 172.

³² 86 Fed. Reg. at 59,921.

³³ 86 Fed. Reg. at 59,921 (citing *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 101 (2015)).

But HHS has already followed the APA's rulemaking procedure in adopting the Sunset Rule, which inserted default expiration dates in regulatory sections.³⁴ Those expiration dates can be amended or rendered ineffectual by following the procedures laid down by the Sunset Rule, the RFA, and the APA. The Sunset Rule's review-delay process adequately protects against inadvertent expiration. If a section were to expire under the Sunset Rule for want of retrospective review, HHS can follow the APA's flexible rulemaking procedure to readopt it. Recission, expiration, repeal, or however one chooses to characterize it, the Sunset Rule merely encoded what the RFA already contemplates,³⁵ by using the APA's rulemaking procedure.³⁶ The default expiration dates that the Sunset Rule inserted in HHS regulations meet *State Farm's* "satisfactory explanation" requirement and *Perez's* "same procedures" requirement.³⁷

The concern that the Sunset Rule will lead to widespread expiration of regulations is overstated.³⁸ The Sunset Rule's purpose is not to repeal any regulation, but rather to set forth a plan for periodic retrospective review, as required by the RFA.³⁹ The default repeal deadlines if review does not occur are an incentive that ensures the retrospective review mandated by the RFA actually occurs and that HHS and its component agencies faithfully discharge their statutory duties.⁴⁰ The Sunset Rule correctly assumes that HHS will comply with the RFA and, therefore, that automatic expiration of regulations will be a very rare event. The concerns about widespread expiration appear predicated on the flawed assumption that HHS will continue to fail

³⁴ 86 Fed. Reg. at 5703 & nn.104, 105 (explaining the legal basis for amending regulations to insert a conditional sunset date).

³⁵ 5 U.S.C. § 610(a) (third sentence).

³⁶ 5 U.S.C. § 553.

³⁷ *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *Perez*, 575 U.S. at 101. See also James Broughel, Mercatus Center, George Mason University, *Evidence Free Policymaking at the Department of Health and Human Services*, <https://www.mercatus.org/publications/regulation/evidence-free-policymaking-department-health-and-human-services> (Dec. 15, 2021) (Comment submitted at regulations.gov in opposition to HHS's proposed repeal of the Sunset Rule; providing a comprehensive "satisfactory explanation" for the Sunset Rule).

³⁸ 86 Fed. Reg. at 59,921.

³⁹ 86 Fed. Reg. at 5694, 5713.

⁴⁰ *Id.*

in its statutory duties, resulting in the expiration of unreviewed rules.⁴¹ Assuming that federal agencies will break the law is not a sound basis for repealing the Sunset Rule.⁴²

III. Neither the President Nor HHS Can Ignore or Overrule Congress's Mandate

HHS's proposed repeal of the Sunset Rule is unconstitutional. HHS cannot ignore or overrule Congress's mandate. Neither the President nor HHS can render optional a statutory directive that HHS publish a plan to periodically review its code of regulations. That published plan—the Sunset Rule—is also entirely consistent with the Regulatory Flexibility Act and the Administrative Procedure Act.

In proposing to repeal the Sunset Rule, HHS states that the basis for the repeal is President Biden's Executive Order 13992⁴³ issued on January 20, 2021.⁴⁴ But as explained in Parts I and II above, the Sunset Rule is based on and consistent with the RFA, the APA, and binding court precedent. And neither the President nor HHS can ignore or overrule acts of Congress or court precedent because the Take Care Clause, the Supremacy Clause, and the separation-of-powers doctrine forbid such executive actions.

The President has the unique constitutional duty to take care that the laws are faithfully executed.⁴⁵ Via EO 13992, however, President Biden ordered HHS to ignore the Regulatory Flexibility Act, the Administrative Procedure Act, and binding court precedent. By so engaging in executive lawmaking, the chief executive cannot be expected to also comply with the Take Care Clause. The "policy goals of the current" President to derogate portions of the nation's laws is forbidden by the Take Care

⁴¹ 86 Fed. Reg. at 59,921.

⁴² *State Farm*, 463 U.S. at 43 (noting that agency decisionmaking is arbitrary and unreasoned where an agency has "relied on factors which Congress has not intended it to consider").

⁴³ Revocation of Certain Executive Orders Concerning Federal Regulation, 86 Fed. Reg. 7049 (Jan. 25, 2021) (EO 13992).

⁴⁴ 86 Fed. Reg. at 59,910.

⁴⁵ U.S. Const. art. II, § 3, cl. 4 (Take Care Clause).

Clause.⁴⁶ As is the President's decision to demote the nation's laws by elevating over them his policy preferences.⁴⁷

Nor can HHS on its own ignore or overrule court precedent interpreting and applying the Constitution and acts of Congress. The Constitution's separation of powers doctrine forbids such agency action. This principle is at least as old as the *Hayburn's Case*, decided in 1792.⁴⁸ Congress had enacted the Pensions Act of 1792, creating a scheme for the disabled veterans of the American Revolution to apply for pensions to federal courts. The federal-court decisions were appealable and subject to stay by the Secretary of War. Five of the then-six justices of the Supreme Court declared the Pensions Act unconstitutional.⁴⁹ The Court concluded that an agency head—such as the HHS Secretary—is rendered incompetent by the Constitution to revise, ignore, overrule, or stay decisions rendered by federal courts. And an Article III judge is forbidden by the Constitution to decide cases that will be subject to revision and review by an executive-branch officer of the United States.⁵⁰ HHS would be acting unconstitutionally, therefore, were it to repeal rules codifying binding statutes and court cases interpreting them because the act of repealing the Sunset Rule is an act of actively ignoring or overruling such binding, superior authority.

Conclusion

Should HHS proceed with its proposed rulemaking and rescind the Sunset Rule, it will find itself in immediate noncompliance with the mandatory duties set forth in the RFA. The Sunset Rule effectuates HHS's nondiscretionary duty to publish in the Federal Register a plan for the periodic review of its rules, and to conduct periodic review in accordance with that plan. HHS should retain in its entirety the Sunset

⁴⁶ 86 Fed. Reg. at 59,910.

⁴⁷ See also U.S. Const. art. VI, § 2 (Supremacy Clause) (stating that only “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the land”).

⁴⁸ *Hayburn's Case*, 2 U.S. 408 (1792).

⁴⁹ *Id.*

⁵⁰ *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 218 (1995) (“Congress cannot vest review of the decisions of Article III courts in officials of the Executive Branch.”).

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Rule, which is currently codified at: 21 C.F.R. § 6.1; 42 C.F.R. §§ 1.1, 404.1, 1000.1; and 45 C.F.R. §§ 8.1, 200.1, 300.1, 403.1, 1010.1, 1300.1.

If you have further questions, or require further information, please do not hesitate to contact Adi Dynar via email at ADynar@PacificLegal.org or by phone at (202) 888-6881.

Respectfully submitted,



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Kiren Mathews

From: Aditya Dynar
Sent: Thursday, December 16, 2021 5:54 AM
To: reviewnprm@hhs.gov
Cc: Charles T. Yates; Incoming Lit
Subject: Comment Opposing HHS's Proposed Repeal of the Sunset Rule, RIN 0991-AC24, HHS-OS-2020-0012
Attachments: HHS SUNSET Comment Final.pdf

Dear Mr. Barry,

The attached comment was submitted electronically using regulations.gov. I appreciate your attention to the matter.

Respectfully,

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From: Aditya Dynar
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Subject: FW: Your Comment Submitted on Regulations.gov (ID: HHS_FRDOC_0001-0839)

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Agency: DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Document Type: Proposed Rule
Title: Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal
Document ID: HHS_FRDOC_0001-0839

Comment:
Please see the attached pdf for Pacific Legal Foundation's comment opposing HHS's proposed repeal of the Sunset Rule.

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