December 17, 2021

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

VIA ELECTRONIC SUBMISSION

Re: **"Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal" (RIN 0991-AC24)**

The Center for Reproductive Rights ("the Center") respectfully submits the following comment on the Notice of Proposed Rulemaking ("the proposed rule") on "Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal," published by the Department of Health and Human Services ("HHS" or "the Agency") on October 29, 2021.We commend HHS for its proposal to withdraw or repeal Securing Updated and Necessary Statutory Evaluations Timely ("the SUNSET final rule"), published by the Agency on January 19, 2021.

Since 1992, the Center for Reproductive Rights has used the power of law to advance reproductive rights as fundamental human rights worldwide. Our litigation and advocacy over the past 28 years have expanded access to reproductive health care around the nation and the world. We have played a key role in securing legal victories in the United States, Latin America, Sub-Saharan Africa, Asia, and Eastern Europe on issues including access to life-saving obstetrics care, contraception, safe abortion services, and comprehensive sexuality information. We envision a world where every person participates with dignity as an equal member of society, regardless of gender; where every woman is free to decide whether or when to have children and whether or when to get married; where access to quality reproductive health care is guaranteed; and where every woman can make these decisions free from coercion or discrimination.

On November 4, 2020, the Agency issued a Notice of Proposed Rulemaking on Securing Updated and Necessary Statutory Evaluations Timely ("the 2020 NPRM").[1] The 2020 NPRM required HHS to review every regulation within ten years of promulgation, or else the regulation would automatically expire. With respect to regulations that are already ten years old, the 2020 NPRM required HHS to review such regulations within two years to prevent the automatic expiration of the regulations. As the Agency notes in the proposed rule, the 2020 NPRM provided an unusually short comment period of just 30 days for comments on the NPRM's effects on most regulations, except for comments on Medicare program regulations, which were given a 60-day comment period. On December 4, 2020, the Center for Reproductive Rights timely filed a comment opposing the promulgation of the rule.

[1] "Securing Updated and Necessary Statutory Evaluations Timely," 85 Fed. Reg. 70,096 (proposed Nov. 4, 2020) (to be codified at 21 CFR, chapter I, 42 CFR chapters I and IV and 45 CFR subtitle A).

HHS issued the SUNSET final rule on January 19, 2021.[2] The SUNSET final rule retained the basic structure of the 2020 NPRM, but updated the time frame for the review of most existing regulations from two to five years, provided for a one-time, maximum one-year "continuation" of a regulation subject to expiration, and created exemptions for a small subset of Federal Drug Administration ("FDA"), Centers for Disease Control and Prevention ("CDC"), and Centers for Medicaid & Medicare Services ("CMS") regulations. The SUNSET final rule also added an additional publication requirement.

As articulated below, we support the Agency's proposal to withdraw or repeal the SUNSET final rule because (1) the SUNSET final rule would likely violate the Administrative Procedure Act ("APA") if allowed to go into effect, and (2) the SUNSET final rule is in direct conflict with executive orders and policy statements issued by the current administration.

I. The SUNSET Final Rule Likely Violates the APA

A. The Unusually Short Comment Period on the 2020 NPRM Did Not Provide a Meaningful Opportunity for Participation As Required by the APA

The Agency failed to provide any justification for the unusually short 30-day comment period[3] in both the 2020 NPRM and the SUNSET final rule. A large number of the comments on the 2020 NPRM strenuously objected to the compressed comment period on the grounds that it denied a meaningful opportunity for participation as required by the APA.

In the SUNSET final rule, HHS nominally acknowledged these comments, but argued that the requirements for notice and comment rulemaking are limited to the plain language of §553(c) of the APA and claimed that an "opportunity for interested parties to participate in the rule making process" had "occurred".[4] However, the Agency was required to engage in individualized analysis of the impact and scope of the 2020 NPRM to determine whether the length of a comment period met the APA's procedural requirements. [5]

The ability of the public to meaningfully and thoroughly comment on all aspects of the 2020 NPRM was compromised by the lack of prior notice and the shortened comment period.

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[2] "Securing Updated and Necessary Statutory Evaluations Timely", Final Rule, 86 Fed. Reg. 5694 (Jan. 19, 2021).
[3] The 2020 NPRM provided a 60-day time period on Medicare regulations, due to the 60-day comment period mandated by 42 U.S.C. 1395hh(b).
[4] 86 Fed. Reg. at 5706.
[5] *Centro Legal de la Raza v. Exec. Off. for Immigr. Review*, 524 F.Supp.3d 919, 955 (N.D. Cal., 2021) (absent "exigent circumstances requiring a compressed comment period," complex rules with sweeping effects require longer comment periods) (citing *Florida Power & Light Co. v. U.S.*, 846 F.2d 765, 772 (D.C. Cir. 1988)). *See also Omnipoint Corp. v. F.C.C.*, 78 F.3d 620, 629 (D.C. Cir. 1996) (14-day notice and comment period was justified by a congressional mandate to implement the enabling statute without administrative or judicial delays)(internal citation omitted); *North Carolina Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 770 (4th Circ. 2012) (situations where shortened notice and comment proceeding are appropriate "are generally characterized by the presence of exigent circumstances in which agency action was required in a mere matter of days"); *Prometheus Radio Project v. F.C.C.*, 652 F.3d 431, 453 (3d. Cir. 2011) (a 28-day comment period was inappropriately short for an "important and complex rule.")

It also appears that HHS finalized the SUNSET final rule prior to the end of the 60-day comment period on Medicare regulations. On December 18, 2020, the Office of Information and Regulatory Affairs (OIRA) received the SUNSET final rule for review and clearance and posted it on the OIRA dashboard for E.O. 12866 Regulatory review. However, the conclusion of the statutorily mandated 60-day comment period was on January 4, 2021.[6] That the SUNSET final rule was then published just 15 days later in the Federal Register on January 19, 2021, suggests the notice-and-comment process may have been shortened to finalize the rule in the last moments before the inauguration of a new administration.

B. The Agency Failed to Take into Account the Harmful Impacts of the SUNSET Final Rule, As Required by the APA

The SUNSET final rule likely violated the APA because the HHS failed to meaningfully consider the potential serious and harmful impacts of an automatic expiration rule.

As HHS notes in the proposed rule, "One of the basic procedural requirements of administrative rulemaking is that an agency must give adequate reasons for its decisions."[7] Under the APA, "agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" shall be set aside.[8] An agency must provide "adequate reasons" for its rulemaking, in part by "examin[ing] the relevant data and articulat[ing] a satisfactory explanation for its action including a rational connection between the fact found and the choice made."[9] The agency must provide a more detailed justification when "its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account."[10] Ultimately, "a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy."[11] Moreover, an agency

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[6] Office of Info. and Regul. Affairs, Office of Mgmt. and Budget, Securing Updated and Necessary Statutory Evaluations Timely, RIN 0991-AC24, https:/www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104-&RIN=0991AC24%20 (last visited December 16, 2021.)

[7] *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016).

[8] 5 U.S.C. § 706(2)(A).

[9] *See Encino Motorcars*,579 U.S. at 221 (2016) (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 103 (1983)). Typically, a court will find an agency action to be arbitrary and capricious if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43; *Envtl. Def. Fund, Inc. v. Costle*, 657 F.2d 275, 283 (D.C. Cir. 1981) ("While we are admonished from rubber stamping agency decisions as correct, our task is complete when we find that the agency has engaged in reasoned decision-making within the scope of its Congressional mandate[.]") (internal citations and quotations omitted).

[10] *Encino Motorcars,* 579 U.S. at 221.; *see also Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 106 (2015) (reaffirming that an agency must provide "more substantial justification when 'its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account'" (quoting *F.C.C. v. Fox Television Stations, Inc*, 556 U.S. 502, 515 (2009)).

[11] *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009).

may not simply "[n]o[d] to concerns raised by commenters only to dismiss them in a conclusory manner".[12]

With the SUNSET final rule, the Agency made no attempt to meaningfully consider the possible harms—potentially severe—to patients and health care consumers caused by the automatic expiration of rules. The SUNSET final rule includes a list of rules which commenters had identified as likely to cause harm if allowed to expire, among them rules governing eligibility for Medicaid and the Children's Health Insurance Program ("CHIP"),[13] implementing the Title X Family Planning Program,[14] and regulations concerning Section 1557 of the Affordable Care Act.[15] But rather than address the seriousness of the potential harms that would result from the expiration of each of these rules, the Agency simply stated that it did not intend to allow regulations to expire[16] and that it would prioritize the retrospective review of the identified rules.[17] That attempted justification does not measure the impact if specific rules are sunsetted, fails to meaningfully consider alternatives, and does not explain why the benefits of retrospective review are so great that they outweigh the damage that would be caused by the inadvertent expiration of a rule.

Most concerning of all, the SUNSET final rule's cursory justification relied on flawed estimates of the burden the final rule would impose. In its comment on the 2020 NPRM, the Center expressed concern about the Agency's estimates of the significant amount of labor required to implement the rule.[18] In the proposed rule, HHS states that it now believes that the 2020 NPRM underestimated "the costs of complying with the rule at least by a factor of four."[19] The fact that

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[12] *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020).

[13] Medicaid and the Children's Health Insurance Program ("CHIP") rely on regulations at 42 C.F.R. § 435.603 to determine financial eligibility, and without these regulations, programs would be free to redefine eligibility rules with no standards, consistency, or accountability. Automatic expiration of these regulations would wreak havoc on the programs and their beneficiaries.

[14] Inadvertent expiration of the regulations implementing the Title X Family Planning Program, which distributes $286.5 million to grantee organizations that provide family planning services to predominantly low-income women under age 30, would likely result in confusion and delays in the provision of these critical services. *Title X Program Funding History*, OFFICE OF POPULATION AFFAIRS, U.S. DEPT OF HEALTH AND HUMAN SERVS., (December 16, 2021), https://opa.hhs.gov/grant-programs/archive/title-x-program-archive/title-x-program-funding-history.

[15] The Agency is currently engaged in rulemaking regarding Section 1557 of the Affordable Care Act, which prevents discrimination on the basis of race, color, national origin, age, disability, or sex (including pregnancy, sexual orientation, and gender identity) in healthcare settings. If the SUNSET final rule were not withdrawn or repealed, a future administration could simply allow whatever rules the Agency puts into place to expire without conducting notice and comment procedures, permitting plans to immediately change their rules to unlawfully discriminate against beneficiaries.

[16] *See* 86 Fed. Reg. at 5710. However, the Agency then contradicted this statement while attempting to perfunctorily weigh the benefits and risks of the SUNSET rule, stating that it "believe[d] 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 Fed. Reg. at 5723.

[17] 86 Fed. Reg. at 5735.

[18] In the 2020 NPRM, HHS estimated a total cost of "between roughly $10,066,719 to $25,781,696, or approximately 35.4 to 90.7 FTE." 85 Fed. Reg. at 70,116. Bizarrely, in the SUNSET final rule, the HHS estimate of total cost skyrocketed while the estimate of required FTEs dropped slightly; the Agency estimated a total cost of between $60.2 to $199.3 million and estimated the total number of employees needed to implement the rule "to be 34.5 to 88.5 FTEs over ten years." 86 Fed. Reg. at 5745.

[19] 86 Fed. Reg. 59,906, 59,909 (Oct. 29, 2021).

the regulatory burden imposed by the SUNSET final rule is significantly larger than initially estimated weighs heavily in support of HHS withdrawing or repealing the law.

As the Agency now recognizes, the scope of the review required by the SUNSET final rule would result in the diversion of critical HHS resources, and would "likely impede efforts to adopt new rules to address national priorities and advance equity for all, including historically underserved and marginalized communities."[20] In light of this updated assessment, there is no doubt that the rule would have an even greater impact on the Agency's ability to fulfill its mission to "enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services."[21] Critically, given the SUNSET final rule's lack of a good cause exception to avert the expiration of a regulation in the event of a pandemic or other declared national or public health emergency, the SUNSET final rule would be particularly damaging to the Agency's ability to respond to public health emergencies such as the ongoing COVID-19 pandemic and the opioid crisis.[22]

C. The SUNSET Final Rule's Automatic Expiration Scheme Would Likely Violate the APA If Allowed to Take Effect

The Center also supports the Agency's proposal to withdraw or repeal the SUNSET final rule because the automatic expiration provisions would violate the APA if allowed to take effect. HHS concedes that the repeal of a regulation is a final agency action. Final agency actions are reviewable, and a court must set aside final agency actions that are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[23] Given that an "agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act," it is difficult to imagine a more arbitrary final action than the automatic repeal of a regulation due to HHS's failure to review a regulation in a timely manner.

The SUNSET final rule failed to grapple with this basic legal problem. It notes only that an agency may, "through notice-and-comment rulemaking, amend its regulations to provide that they expire at a future date."[24] But that is precisely the problem: under well-established Supreme Court precedent, the rescission of rules requires the same administrative protections and procedures as the promulgation of rules.[25] It should be clear, then, that an agency may not

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[20] 86 Fed. Reg. at 59,909.

[21] *About HHS*, U.S. DEP'T OF HEALTH AND HUMAN SERVS., (Nov. 22, 2021), https://www.hhs.gov/about/index.html.

[22] *See* 86 Fed. Reg. at 59,912.

[23] 5 U.S.C. § 706.

[24] 86 Fed. Reg. at 5703 (Jan. 19, 2021).

[25] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 42 (1983) ("an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.") Notably, the SUNSET Final Rule also misstates the holding of *Clean Air Council v. Pruitt*, 862 F.3d 1 (D.C. Circ. 2017) in an attempt to justify its automatic expiration scheme. The *Pruitt* Court held that the EPA could not stay a rule pending reconsideration unless it engaged in notice and comment rulemaking, on the grounds that the APA "'mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance.'" 862 F.3d 1, 9 (D.C. Cir. 2017) (quoting *Perez v. Mortgage Bankers Association*, 572 U.S. 92, 100 (2015)).

rescind a rule through automatic expiration simply because it failed to review it within the specified timeframe. A single rule such as the SUNSET final rule cannot serve as a substitute for the individualized consideration, through notice-and-comment, of specific rules to be rescinded (or automatically expired). As HHS aptly notes in the proposed rule, the lawfulness of rules which provide for their own automatic expiration do not support the lawfulness of a broad automatic expiration scheme, because such rules have only been promulgated after engaging in individualized consideration.[26] Here, the SUNSET "final rule did not contain particularized consideration of the rules that were amended."[27]

II. The SUNSET Final Rule Conflicts with Policy of the Current Administration

Finally, the SUNSET final rule is at direct odds with the policy goals of the current administration. The SUNSET final rule relied on now-rescinded Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs," which limited agencies' ability to issue new regulations.[28] The SUNSET final rule would frustrate the objectives of the policies articulated by Executive Order 13985, entitled "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government"[29] by burdening the programs that serve rural communities, LGBTQ+ and HIV positive Americans, Black and Indigenous communities, and other medically underserved communities of color.[30] For instance, LGBTQ people, especially transgender people, face significant health disparities which have been worsened by the prior administration's rollback of many key protections and programs. HHS will need to dedicate significant resources in order to restore existing programs and take additional steps to improve health outcomes for this community.[31]

Similarly, the SUNSET final rule's automatic expiration provisions would directly undermine the policy goals of Executive Order 14009, Strengthening Medicaid and the Affordable Care Act,"[32] by weakening the strong regulatory framework necessary for states to implement these critical and complex programs that provide health care access to millions of otherwise uninsured Americans.[33] For example, 42 C.F.R. § 435.603 sets forth the modified adjusted gross income standard, which is used to determine financial eligibility for all Medicaid programs. If this rule

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[26] 86 Fed. Reg. at 59,921 (Oct. 29, 2021).
[27] *Id.*
[28] 86 Fed. Reg. at 5696 (Jan. 30, 2017), citing 82 Fed. Reg 9339 (Feb. 3, 2017).
[29] 86 Fed. Reg 7009 (Jan. 25, 2021).
[30] *See, e.g.*, American Ass'n of Family Physicians, Comment Letter on Securing Updated and Necessary Statutory Evaluations Timely (Dec. 8, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0494 (noting the automatic expiration provisions of the SUNSET rule would put critical programs serving Indigenous, rural, and other medically underserved communities at risk); Lambda Legal, Comment Letter on Securing Updated and Necessary Statutory Evaluations Timely (Dec. 4, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0111 (noting that HHS will need to dedicate significant resources to combatting the rollback of key healthcare programs serving HIV positive and LGBTQ+ Americans).
[31] Lambda Legal, Comment Letter on Securing Updated and Necessary Statutory Evaluations Timely (Dec. 4, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0111.
[32] 86 Fed. Reg 7793 (Feb. 2, 2021).
[33] *See, e.g.*, Jane's Due Process, Comment Letter on Securing Updated and Necessary Statutory Evaluations Timely (Dec. 8, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0258.

were to expire, states would be free to redefine the financial eligibility standard with no restrictions and eliminate health care access for millions of Americans.[34]

The Center also notes that the Agency's proposal to withdraw or repeal the SUNSET final rule is consistent with the Administration's recently-released National Strategy on Gender Equity and Equality ("the Gender Strategy Report").[35] Of particular note is the third priority in the Gender Strategy Report, "Protect and Expand Access to Health Care, including Sexual and Reproductive Health Care," which includes commitments to ensuring access to high-quality, affordable health care and providing comprehensive health services; promoting and expanding access to sexual and reproductive health care; and closing disparities in maternal health care.[36] Many of the specific goals outlined in the Report, such as strengthening the nondiscrimination provisions of the ACA, will require resource-intensive rulemaking. Similarly, expanding access to sexual and reproductive health care will require additional personnel to make and administer new grants under existing programs and implement new programs created by statute. Given that the SUNSET final rule would hinder the implementation of these priorities by presumably diverting resources towards reviewing regulations in order to prevent their expiration, the Center wholeheartedly supports the proposed rule in its entirety.

III. Conclusion

We appreciate the opportunity to comment on this proposed rule and support the Agency's decision to withdraw or repeal the SUNSET final rule in its entirety. If you require any additional information about the issues raised in this letter, please contact Katherine Gillespie, Acting Director, Federal Policy and Advocacy, at kgillespie@reprorights.org.

Signed,

The Center for Reproductive Rights

[34] *Id.* at 3.
[35] WHITE HOUSE GENDER POLICY COUNCIL, NATIONAL STRATEGY ON GENDER EQUITY AND EQUALITY (Oct. 22, 2021), https://www.whitehouse.gov/wp-content/uploads/2021/10/National-Strategy-on-Gender-Equity-and-Equality.pdf.
[36] *Id.* at 18.