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United States Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20210

Re: Public Comments on Securing Updated and Necessary Statutory Evaluations Timely; Proposal To Withdraw or Repeal—RIN 0991-AC24

To whom it may concern:

Alliance Defending Freedom, on behalf of American College of Pediatricians, Catholic Medical Association, and Jeanie Dassow, submits this comment concerning "Securing Updated and Necessary Statutory Evaluations Timely; Proposal To Withdraw or Repeal," RIN 0991-AC24, 86 Fed. Reg. 59,906 (Oct. 29, 2021).

HHS improperly delayed the SUNSET Rule, and now improperly proposes its repeal. HHS purported to issue that delay earlier this year. 86 Fed. Reg. 15404 (Mar. 23, 2021) (hereinafter "Delay Rule"). HHS should acknowledge the impropriety of the Delay Rule and restore the implementation of the SUNSET Rule before it considers any repeal such as proposed in the present proposed rule. Likewise, HHS should not finalize the proposed rule because it fails to sufficiently consider a variety of central issues or provide the public with a fulsome description of HHS's views on those issues *before* seeking public comment, thus depriving the public of the ability to comment on those essential rationales behind the agency's proposal.

The Delay Rule Was Untimely

The delay of the SUNSET Rule violated the requirements that agency action not be finalized until published in the Federal Register, and that agency rules are not effective until thirty days after publication, absent an express finding of good cause. Under 5 U.S.C. § 706(2)(D), an agency "shall separately state and currently publish in the Federal Register" its rules; under 5 U.S.C. § 552(a)(1), all "substantive rules of general applicability adopted as authorized by law" must be published in the Federal Register; and under 5 U.S.C. § 553(d), unless there is a finding of good

cause to waive this specific requirement, the "required publication" of a rule may not be less than 30 days before a rule's effective date. But HHS purported not only to make the delay of the SUNSET Rule effective before its publication in the Federal Register, but to make it effective immediately, rather than 30 days after publication in the Federal Register, and HHS made no express finding of good cause to skip this 30-day notice requirement.

HHS claimed that deciding on the delay internally or posting the delay on its website made it final and effective. But under the APA, a substantive rule is final only on Federal Register publication, and this is true even if the effective date and compliance date is for some point after publication. *NRDC v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009) ("Agencies must publish substantive rules in the Federal Register to give them effect."). Indeed, it is a "basic tenet of administrative law, set out by the APA," that regulations do not take effect or have any legal effect until they are published in the Federal Register. *NRDC v. NHTSA*, 894 F.3d 95, 106 (2d Cir. 2018). When an agency purports to delay the effective dates of a prior final rule, "Congress intended for publication to be the operative event." *Id.* Before publication, an action is not final, and the agency may change it without new notice or comment; after that point, it is final, and an agency can only change it after new notice and comment. *Humane Soc'y of the United States v. United States Dep't of Agric.*, 474 F. Supp. 3d 320, 330 (D.D.C. 2020).

What is more, "publication" in the Federal Register requires more than mere "filing" the document for publication; it requires actual publication. *Rowell v. Andrus*, 631 F.2d 699, 704 (10th Cir. 1980). HHS was on notice of this requirement. Moreover, only last year its improvements to conscience protections were enjoined in part on just this ground. *Walker v. Azar*, 480 F. Supp. 3d 417, 424, 430 (E.D.N.Y. 2020) (enjoining an HHS rule protecting conscience rights because the rule could not be final or effective before publication in the Federal Register, even though the agency claimed to date and finalize the rules sooner).

The Delay Rule Unlawfully Skipped Notice and Comment

The delay of the SUNSET Rule was a legislative or substantive rule that unlawfully skipped notice and comment under the APA. Any agency action delaying the effective date or compliance dates of a prior rule is itself a new substantive rule, is subject to judicial review, and requires notice and comment. A delay of a rule's effective date is an act of substantive rulemaking subject to the notice-and-comment requirements and reasoned decision making requirements of the APA. *E.g., Pineros y Campesinos Unidos del Noroeste v. Pruitt*, 293 F. Supp. 3d 1062, 1066 (N.D. Cal. 2018); *Open Communities All. v. Carson*, 286 F. Supp. 3d 148, 163, 174 (D.D.C. 2017). The same is even more true for attempts to change compliance dates. *Becerra*

v. United States Dep't of Interior, 276 F. Supp. 3d 953, 964 (N.D. Cal. 2017). Removing the possibility of forced compliance with regulations, as well as leaving in place legal obligations, creates legal consequences. *Clean Air Council v. Pruitt*, 862 F.3d 1, 6–7 (D.C. Cir. 2017).

Stays issued under Section 705 are thus not "committed to agency discretion by law" and are therefore subject to judicial review for their procedural propriety, for their legal authority, and for arbitrariness and capriciousness. *Nat. Res. Def. Council v. U.S. Dep't of Energy*, 362 F. Supp. 3d 126, 144 (S.D.N.Y. 2019). An agency must take comments on the same questions on which it bases its delay. *State v. Bureau of Land Mgmt.*, 286 F. Supp. 3d 1054, 1072 (N.D. Cal. 2018). Were it otherwise, agencies could effectively repeal rules—without going through the process required for repeal—because they could delay rules indefinitely. That is essentially what HHS improperly did in this case.

To reconsider a regulation, agencies "must use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Perez v. Mortgage Bankers Association*, 135 S. Ct. 1199, 1206 (2015). But, if changes to effective dates were not final rules, "an agency could guide a future rule through the rulemaking process, promulgate a final rule, and then effectively repeal it, simply by indefinitely postponing its operative date," even though the "APA specifically provides that the repeal of a rule is rulemaking subject to rulemaking procedures." *Nat. Res. Def. Council, Inc. v. U.S. E.P.A.*, 683 F.2d 752, 762 (3d Cir. 1982). For this reason, "an order delaying the rule's effective date" is "tantamount to amending or revoking a rule." *Clean Air Council v. Pruitt*, 862 F.3d 1, 6–7 (D.C. Cir. 2017).

The Delay Rule was a substantive or legislative rule subject to notice and comment under the APA. It changed effective dates or compliance dates, and so it prescribed "law or policy," 5 U.S.C. § 551(4). This it amounted to the promulgation of a regulation. *Envtl. Def. Fund, Inc. v. Gorsuch*, 713 F.2d 802, 813 (D.C. Cir. 1983). It had substantive effects on regulated entities because it removes procedural opportunities for public participation on set deadlines. Indeed, issuing technical "corrections" to the SUNSET Rule and modifying its operative text only highlights that the Delay Rule was a substantive rulemaking.

The Delay Rule amounted to amending or revoking the SUNSET Rule because it was a modification of the standards for the time that the delay is imposed, HHS did not intend to reconsider this delay, and thus the Delay Rule "represents the final agency position on this issue, has the status of law, and has an immediate and direct effect on the parties," leaving "no difficulty concluding that the Secretary has issued a final decision" subject to APA review. *See Int'l Union, United Mine Workers of America v. Mine Safety & Health Admin.*, 823 F.2d 608, 614–15 & n.5 (D.C. Cir.

1987). The Delay Rule thus is exactly the kind of binding rule Congress insisted must be issued only after public notice and an opportunity to comment.
In addition, at a minimum, the Delay Rule was a significant guidance or policy document subject to independent notice-and-comment and publication requirements under 45 C.F.R. §§ 1.2, 1.3, 1.4. It is a "statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation." 45 C.F.R. § 1.2. And it is also reasonably be anticipated to "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities," materially alter "the rights or obligations of grant or entitlement recipients, and "raise novel legal or policy issues arising out of legal mandates" and "the President's priorities." 45 C.F.R. § 1.2. Agencies often adopt procedural rules not required by statute, and federal courts enforce those rules for the time that they remain in effect. *See, e.g., Morton v. Ruiz*, 415 U.S. 199, 235 (1974).

HHS never undertook notice and comment for its delay of the SUNSET Rule, nor did HHS make any express finding of good cause to skip any of these procedures under the APA or its own regulations. Given the "salutory purposes" of notice and comment, courts recognize exceptions "'only reluctantly.'" *Nat'l Ass'n of Home Health Agencies v. Schweiker*, 690 F.2d 932, 949 (D.C. Cir. 1982). To establish good cause to skip notice and comment for a delay rule postponing the effective date of another rule, an "agency faces an uphill battle." *Nat'l Venture Cap. Ass'n v. Duke*, 291 F. Supp. 3d 5, 16 (D.D.C. 2017). It must show a new emergency or other serious harm. Id. It is not enough to say that a delay "provides clarification or guidance." *Id.* at 19. And a "new administration's simple desire to have time to review, and possibly revise or repeal, its predecessor's regulations falls short of this exacting standard." *Pineros y Campesinos Unidos del Noroeste v. Pruitt*, 293 F. Supp. 3d 1062, 1067 (N.D. Cal. 2018). HHS did not even attempt to explain under these stringent authorities why the APA's good cause exception for notice and comment were met. Instead, the Delay Rule shows no awareness that HHS was skipping these requirements.

The public deserved a chance to raise important concerns that the agency ignored about its massive effect on small entities who Congress intended to protect from outdated regulatory burdens. But HHS disregarded their interest in public participation or in the benefits of regulatory review. Now, because this proposed repeal rule relies essentially on the purported legitimacy of the Delay Rule, HHS has not properly notified the public concerning the essential factors needed for commenting on a proposed repeal. Therefore the proposed repeal cannot be finalized. HHS must correct its unlawful failure to implement the SUNSET Rule

and further consider issues described below before proceeding with a proposed repeal. This proposed repeal is part and parcel of an unlawful delay, and therefore is fruit of a poisonous tree that is arbitrary and capricious and abuse of discretion under the APA.

APA 705 Did Not Support the Delay Rule

The Delay Rule also violated the APA's procedural requirements to stay previously published final agency action—procedural requirements that apply on top of the APA's usual three requirements of Federal Register publication, 30-day notice, and notice-and-comment procedures for all new rules. HHS invoked 5 U.S.C. § 705 as its authority to stay the final, previously published SUNSET Rule, but HHS did not meet the requirements to issue a stay under Section 705.

First, HHS could not issue a delay of the SUNSET Rule under 5 U.S.C. § 705 because Section 705 does not allow an agency to delay the compliance dates of a prior, already-effective, already-published rule. Instead, Section 705 only allows an agency to delay the effective date of a published rule. "The plain language of the statute authorizes postponement of the 'effective date,' not 'compliance dates.'" *State v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1118—20 (N.D. Cal. 2017).

The SUNSET Rule had already taken effect before HHS purported to issue a stay under Section 705. When agency action like the delay has to be published in the Federal Register, such as rules, the agency action is only final upon publication. *NRDC v. NHTSA*, 894 F.3d 95, 106 (2d Cir. 2018). The SUNSET Rule's effective date was March 22, 2021, one day before HHS published its delay in the Federal Register on March 23, 2021, and HHS's delay could not be final agency action, with any effect, before its publication. (And, under Section 553(d), the Delay Rule could not go into effect until another 30 days from March 23, 2021, which would be April 22, 2021.)

HHS thus sought not to change the effective date of the SUNSET Rule, but its compliance dates, which Section 705 does not permit. Section 705 does not allow an agency to delay the compliance dates of the already effective, published final SUNSET rule. Instead, the agency had to go through the normal process of rulemaking to delay compliance dates.

Even if HHS had managed to issue its delay before the SUNSET Rule took effect, HHS still could not use Section 705 to delay the SUNSET Rule's effective date because HHS did not satisfy the standard under 5 U.S.C. § 705 that "justice so

requires" the agency to "postpone the effective date of action taken by it, pending judicial review."

The standard that "justice so requires" a delay is not a blank check for agencies to unilaterally delay a rule anytime a lawsuit is filed against it. To "justify a stay under § 705, an agency must do more than pay lip service to the pending litigation, or merely assert, without any specificity that the litigation raises serious questions concerning the validity of certain provisions of the rule." *Bauer v. DeVos*, 325 F. Supp. 3d 74, 107 (D.D.C. 2018) (internal quotation marks and citations omitted). "Most significantly, the relevant equitable considerations are not free-floating but, rather, must be tied to the underlying litigation." *Bauer*, 325 F. Supp. 3d at 106. A stay is supposed to be grounded on "the existence or consequences of the pending litigation" and Section 705 cannot be used "simply because litigation in the court of appeals happens to be pending." *Nat. Res. Def. Council v. U.S. Dep't of Energy*, 362 F. Supp. 3d 126, 150 (S.D.N.Y. 2019) (citations omitted).

It is thus not enough for an agency to claim that litigation "raised serious questions" about the challenged rule, or to recite that "the delay would not cause the government any significant harm; and the Department was, in any event, reconsidering the regulations." *Bauer*, 325 F. Supp. 3d at 107. The desire to reconsider a rule is also not an appropriate factor because it is "unrelated to the pending [court] case and are thus beyond the scope of the relevant § 705 considerations." *Id.* So, too, the "mere fact that parties would avoid the costs of complying with the existing regulations, however, is plainly insufficient to support a § 705 stay." *Id.* at 107–08. But that is all that HHS said here.

The Delay Rule typifies a delay that, under precedent, is not grounded on or tailored to the litigation. HHS stated that (1) "the Court may find merit in some of Plaintiffs' claims" even if "HHS does not concede any of these claims at this time"; (2) "that Plaintiffs' allegations of harm are credible,"(3) "that the balance of equities and the public interest warrant postponement"; (4) and that the SUNSET Rule "could create significant obligations for HHS, cause confusion for the public, including Plaintiffs, and may lead to compliance costs." 86 Fed. Reg. at 15,405. HHS also said that "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." *Id.* HHS also questioned whether the SUNSET Rule "is consistent with the policies and goals of the current administration." 86 Fed. Reg. at 15,405. And HHS admitted that it now wishes to take a "fresh and critical look at the SUNSET final rule" now "although many of these concerns were also raised during the comment period on the proposed rule." 86 Fed. Reg. at 15,405. HHS's rationale for the Delay Rule thus amounts to mere disagreement with the rule and the raising of serious questions about its issuance, which is an insufficient reason for a Section 705 stay.

All policy issues raised by HHS in the Delay Rule, such as uncertainty or disruption for the public, or burdens on the agency, or the length of the SUNSET Rule's comment window, or the need for tribal consultation, or the ongoing pandemic, or the deregulatory effect of the SUNSET Rule, were already raised in comments on the SUNSET Rule itself and addressed in its response to comments, 86 Fed. Reg. at 5,704–5,750. HHS's lack of sufficient reason to change course means there was an insufficient basis to issue the Delay Rule under 5 U.S.C. § 705. Because all issues in the suit or mentioned in the Delay Rule were apparent from the earlier notice and comment process, the only changed circumstances were the arrival of a new Administration and the foreseen urgency of the costs of the next compliance deadline, as well as the agency's new "position with respect to whether those costs are justified." *State v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017). And that does not justify a Section 705 stay.

Furthermore, claiming that a delay was required for judicial review of the SUNSET Rule was a pretext not tailored to any actual delays needed for litigation deadlines, as shown by the government's desire for extensions in the litigation so that it could just buy time to repeal the SUNSET Rule. *State v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1122 (N.D. Cal. 2017).

A Section 705 stay is pretextual and unconnected to judicial proceedings "where the parties are content to keep the case indefinitely on hold." *Nat. Res. Def. Council v. U.S. Dep't of Energy*, 362 F. Supp. 3d 126, 150–51 (S.D.N.Y. 2019). In that event, "[t]he purpose of such a stay is not to preserve the status quo during litigation, but to permit" noncompliance with the rule. *Id.*

Rather than answer the complaint or take any action in the case, HHS stipulated that a complete stay of the case is appropriate because "HHS is currently reviewing the Rule in light of Plaintiffs' claims raised in this litigation, and needs additional time to evaluate the claims and its position before taking further steps in this litigation." Stipulated Request For Order Staying Case, *County of Santa Clara*, No. 5:21-cv-01655-BLF (ECF 32) (N.D. Cal. April 21, 2021). HHS then asked for and obtained the same day another stay, on the same ground, and added that "HHS is preparing to issue a notice of proposed rulemaking repealing the SUNSET Rule." Stipulated Request For Order Staying Case, *County of Santa Clara*, No. 5:21-cv-01655-BLF (ECF 32) (N.D. Cal. July 30, 2021). After HHS proposed withdrawing the SUNSET Rule, the case was stayed again by stipulation. Order, id. (ECF 39) (Nov. 1, 2021) (extending stay to February 1, 2022). The case has thus had no action since its filing and presumably will be stayed further upon the same stipulations. The Delay Rule purported to remove the need for any compliance of the SUNSET Rule regardless of the outcome of judicial review.

HHS's illegal failure to comply with the SUNSET Rule from the time of that delay until today means HHS does not have the data or experience to show there is a sufficient basis to justify repeal of the SUNSET Rule.

This Proposed Repeal Would Violate the Regulatory Flexibility Act

Because the SUNSET Rule put HHS into compliance with the Regulatory Flexibility Act (RFA), and this proposed repeal offers no alternative of compliance, this proposed repeal (along with HHS's Delay Rule) violate section 3(a) of the RFA, 5 U.S.C. § 610. HHS purports to repeal or delay the SUNSET Rule without otherwise providing for HHS compliance with the RFA. HHS admitted that it did not otherwise comply with the RFA in the SUNSET Rule. Section 3(a) of the RFA, requires each agency to "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." 5 U.S.C. § 610(a). It must "provide for the review of all such agency rules existing on the effective date of this chapter within ten years of that date and for the review of such rules adopted after the effective date of this chapter within ten years of the publication of such rules as the final rule." *Id.*

HHS admitted that all prior plans did not meet this requirement, because each prior plan hopelessly failed to provide for any review of each regulation within ten years, if ever. "The Department's experience over the last forty years is that, absent a strong incentive such as the potential expiration of a regulation, the Department will not review an adequate number of its regulations." 86 Fed. Reg. at 5,739. Under all prior plans, despite sporadic reviews, "the Department's efforts to comply with 5 U.S.C. 610 have at times been lacking" and overall HHS has had "limited success in performing retrospective regulatory review." 86 Fed. Reg. at 5,696, 5,738 (collecting examples of HHS's failure to review regulations despite statutory mandates and reporting the results of an AI-driven data analysis of past efforts).

Yet this proposed rule would leave HHS in that situation of noncompliance, and thus the proposed repeal, like the purported delay, violates the RFA. HHS has identified no other "plan" for periodic review which meets the requirements of 5 U.S.C. 610(a). The failure to identify such a plan in the proposed rule also would render its finalization unlawful, because the public deserves notice and an opportunity to comment on HHS's alternative to compliance with the RFA in the wake of the repeal, and the public has been deprived of that opportunity.

This Repeal Would Be, and the Delay Rule Was, Arbitrary and Capricious

In addition, this repeal would be, and the Delay Rule was, "arbitrary, capricious, [or] an abuse of discretion" under 5 U.S.C. § 706. HHS has ignored important factors, and the reasons offered by HHS in the proposed repeal or the Delay Rule cannot satisfy the requirement of reasoned decision making. "Agency action is lawful only if it rests on a consideration of the relevant factors." *Michigan*, 576 U.S. at 750 (internal quotation marks omitted). This is why "the reviewing court should not attempt itself to make up for such deficiencies: [it] may not supply a reasoned basis for the agency's action that the agency itself has not given." *State Farm*, 463 U.S. at 43 (quotation marks omitted).

HHS has failed to consider its compliance with statutory duties to review regulations under the Regulatory Flexibility Act, and HHS has failed to explain why its actions during the delay complied with its RFA obligations. HHS did not argue, let alone even consider, how the necessary regulatory reviews would occur with no plans, deadlines, or sunset mechanisms. But, as the SUNSET Rule said, "[w]ithout a consistent process for periodically reviewing regulations, there is no guarantee that regulations will be reviewed and revised to align with technological, economic, and other developments." 86 Fed. Reg at 5,738-39. The Delay Rule showed HHS is resting on an incorrect position about Section 705. But, in addition to Section 705's requirements for a stay to be tailored to actual litigation needs, under arbitrary and capricious review, an agency likewise cannot simply issue a new action by noting the existence of "serious questions" about a past decision. Instead, an agency reviewing a past decision is supposed to answer such questions, not simply note them and move on. *See Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 44 (D.D.C. 2020) (finding agency action arbitrary when the agency "took no position whatsoever on the actual effects that a [policy change] would have"). This proposed repeal rule is based on a similar failure to explain how HHS will, in the alternative to the SUNSET Rule, comply with the RFA.

HHS has also failed to specifically address the inconsistency between its current view that the SUNSET Rule stands on a legally questionable footing, and its prior conclusion that it was legally sound under the RFA. To change policy, an agency must "display awareness that it is changing position." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). It "must show that there are good reasons for the new policy," id., and must "supply a reasoned analysis for the change," *Ark Initiative v. Tidwell*, 816 F.3d 119, 127 (D.C. Cir. 2016) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Based on the fact that, as shown above, each reason for the delay (and for this proposed rule) had been considered and rejected in the SUNSET Rule, HHS has not offered sufficient new reasons to change course and therefore lack a sufficient basis either for the

Delay Rule or for this proposed rule. *See Bauer*, 325 F. Supp. 3d at 106, 109–10; *Nat'l Women's L. Ctr. v. Off. of Mgmt. & Budget*, 358 F. Supp. 3d 66, 85, 89 (D.D.C. 2019). And, without disclosing to the public HHS's reasons for changing its views between the SUNSET Rule and this proposed repeal, HHS has inadequately informed the public so as to give the public an opportunity to comment on those reasons. Enunciating those reasons in the final rule or its preamble is an insufficient approach—any planned repeal needs to begin with a full accounting of HHS's reasons for changing its position.

A repeal or extended delay also "requires an impartial look at the balance struck between the two sides of the scale." *State v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1122 (N.D. Cal. 2017). But HHS's examination of the benefits of the SUNSET Rule and the harms of a delay lack any meaningful analysis or balance of the two sides of the issues, making the delay unlawful and this proposed rule inadequately supported. *Bauer*, 325 F. Supp. 3d at 110.

The SUNSET Rule's holistic retrospective review allows agencies to consider new developments in science and medicine, better respect legal rights of conscience and religion, and perform more accurate cost-benefit analyses, which would yield significant economic benefits and save lives. HHS has failed to consider the diminution of the benefits that the SUNSET Rule brings, or of the need for the immediate implementation of the SUNSET Rule. HHS has not substantively addressed the positive policies HHS itself adopted a few months ago in favor of the SUNSET Rule, as outlined in the SUNSET Rule itself, such as ensuring good governance, up-to-date regulations, revised cost-benefit analyses, correction of failures in past rulemakings, agency incentives for review, compliance with bipartisan executive orders, statutory compliance, regulatory successes in other jurisdictions from sunset provisions, and HHS's own particular need for a widespread retrospective review, highlighted by the pandemic, beginning immediately. 86 Fed. Reg. 5,695-703 (summarizing many policy reasons for the SUNSET Rule). The Delay Rule itself recognizes in many places that these concerns had been raised in the past and rejected. 86 Fed. Reg. at 15,404-08. Here or in the delay rule, HHS offers no "justification for rescinding the regulation before engaging in a search for further evidence" to change its resolution of this cost-benefit analysis. *State Farm*, 463 U.S. at 52.

By failing to discuss critical factors supporting the RFA's purpose for requiring an effective plan for regulatory review, HHS has again showed that the agency changed course without giving any reasoned explanations to change positions on these points. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Even if HHS could decide that other policy considerations outweighed the benefits of complying with the SUNSET Rule and

providing small entities meaningful regulatory review, *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1914 (2020), HHS did not in fact support such a decision in the delay rule or here. Considering these policy concerns "was the agency's job, but the agency failed to do it." *Regents of the Univ. of Cal.*, 140 S. Ct. at 1914.

Nor has HHS considered the disruption that the Delay Rule had or this repeal rule would have on the agency and on public participation in the review process, or the degree of regulatory uncertainty that they create. HHS ignored the burden imposed on private citizens for monitoring HHS regulations to see if the SUNSET Rule is perpetually delayed, and it also failed to consider the specific regulations being delayed that would otherwise automatically expire or be reviewed, without considering the effect of that delay on doctors.

Here, the administrative record contained numerous arguments against any delay, but "[n]either the record nor the text of the Delay Rule reveals any effort to engage with these arguments by [HHS], or to conclude that they need not be analyzed." *Nat. Res. Def. Council v. U.S. Dep't of Energy*, 362 F. Supp. 3d 126, 148 (S.D.N.Y. 2019). Instead, HHS just impermissibly sought in the Delay Rule to "bridge the gap to rescission." *Nat'l Venture Cap. Ass'n v. Duke*, 291 F. Supp. 3d 5, 14 (D.D.C. 2017). Only if that gap is refilled can HHS consider recission on a clean slate.

HHS has further failed to consider other important aspects implicated by the Delay Rule and by this proposed repeal, such as interests of First Amendment, liberty, and privacy rights. These include the interests of doctors who would benefit from the on-time implementation of the SUNSET Rule to rules like the gender identity mandate in HHS's Section 1557 rule under the ACA, HHS's gender identity mandate in its grants rule 45 CFR 75.300(c) and (d), and HHS's conscience rule at 45 CFR Part 88. They and the public also have interests in participating in notice and comment procedures to lift regulatory burdens on small entities. It is HHS's job to consider these liberty and reliance interests. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct.1891, 1910–15 (2020). HHS's failure to "overtly consider" these privacy and religious freedom reliance interests, and this proposed rule's similar failure, thus renders the delay and this proposed repeal fatally flawed. *Little Sisters of the Poor v. Pennsylvania*, 140 S. Ct. 2367, 2383 (2020).

Finally, HHS has improperly considered no alternative to delaying or repealing this rule, in a way that would respect the interests of doctors who have religious or moral objections to engaging in gender transition procedures and speech, or other practices that violate their religious liberty or federal conscience rights. "[W]hen an agency rescinds a prior policy its reasoned analysis must consider the alternatives that are within the ambit of the existing policy." *Regents*, 140 S. Ct. at 1912

(internal quotation marks and alterations omitted). With respect to the Delay Rule, HHS could have considered (1) allowing and expediting the pending litigation, (2) allowing a court to consider a stay of the SUNSET Rule after adversarial presentation, (3) allowing notice and comment on the Delay Rule before it was issued, (4) having an alternate but equally effective plan in place for compliance with the Regulatory Flexibility Act while the SUNSET Rule was delayed, (5) modifying the expiration dates set forth in the SUNSET Rule, rather than delaying and seeking to repeal it in its entirety, or (6) only applying the Delay Rule to some but not all HHS regulations to which the SUNSET Rule applied. HHS could also consider many such alternatives to this proposed repeal. But HHS has failed to do so. Instead HHS unilaterally purported to delay the SUNSET Rule and deprive members of the public of the procedural protections in the SUNSET Rule. This delay, and the proposed repeal, unlawfully remove an important procedural avenue for the repeal or modification of HHS rules that violate protected constitutional and statutory interests, including the right not to be subject to gender transition procedure and speech mandates.

Respectfully submitted,

Matthew S. Bowman