



Institute for
Policy Integrity

NEW YORK UNIVERSITY SCHOOL OF LAW

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VIA ELECTRONIC SUBMISSION

Department of Health & Human Services

Re: Securing Updated and Necessary Statutory Evaluations Timely, 85 Fed. Reg. 70,096 (proposed November 4, 2020)

Docket ID: HHS-OS-2020-0012

The Institute for Policy Integrity (“Policy Integrity”) at New York University School of Law¹ respectfully submits the following comments to the Department of Health and Human Services (“HHS” or “the Department”) regarding its proposal to both retrospectively and prospectively establish an “expiration date” for each Department regulation—that is, a date on which the regulation will be automatically rescinded unless the Department first completes a retrospective review of the regulation’s effects on small entities pursuant to the Regulatory Flexibility Act (“Proposed Rule”).² Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

For the following reasons, the Proposed Rule is neither lawful nor rational:

- HHS offers neither a meaningful opportunity to comment on the Proposed Rule nor a reasoned explanation for promulgating it.
- HHS unreasonably disregards the Proposed Rule’s potential costs in the form of (1) the regulatory opportunity costs of allocating staff time to retrospective review rather than the promulgation of new rules, (2) the forgone net benefits of automatically rescinded rules, and (3) monitoring costs for members of the public who seek to prevent automatic rescissions by ensuring that HHS performs timely retrospective reviews.
- HHS provides insufficient evidence that the Proposed Rule will improve retrospective review or lead to welfare-enhancing regulatory changes.
- HHS fails to consider any reasonable alternative means of improving retrospective review.

I. HHS offers neither a meaningful opportunity to comment on the Proposed Rule nor a reasoned explanation for promulgating it

HHS erroneously reasons that, because the Department has authority to conditionally rescind an individual regulation through a notice-and-comment rulemaking, it also has authority to

¹ This document does not purport to present New York University School of Law’s views, if any.

² See Securing Updated and Necessary Statutory Evaluations Timely, 85 Fed. Reg. 70,096 (proposed Nov. 4, 2020).

conditionally rescind *almost all of its existing regulations at once* through a notice-and-comment rulemaking.³ But this blanket approach violates the Administrative Procedure Act (“APA”) for at least two reasons: it fails to afford the public with a meaningful opportunity to comment on the wisdom of the repeals, and it fails to provide a reasoned explanation for the repeals.

HHS does not provide a meaningful opportunity to comment on the Proposed Rule

Unlike the precedents HHS cites—individual rules that specified dates or events upon which they would cease to have effect⁴—the Proposed Rule does not provide “sufficient detail on its content and basis in law . . . to allow for meaningful and informed comment” on each regulation it slates for rescission.⁵ The Department estimates that “the vast majority” of its approximately 18,000 existing regulations will be scheduled for automatic repeal under the Proposed Rule.⁶ But HHS makes no effort to explain what any of these regulations require, what problems they were intended to solve, or what harms might result from their elimination. Instead, in the 30 days afforded for comment on the Proposed Rule, the public is left to review 18,000 HHS regulations independently, determine which might qualify for one of the Department’s vaguely articulated exemptions (such as the exception for “any Regulation whose expiration . . . would violate any other Federal law”⁷), and, for each seemingly non-exempt rule, “comment on the wisdom of repeal”⁸—or forever forgo that right. This is a patently absurd burden to place on commenters and a violation of HHS’s obligation under the APA to provide “concrete and focused” information on the Proposed Rule “so as to make criticism or formulation of alternatives possible.”⁹

The Department suggests that, even if the Proposed Rule is finalized, members of the public will have a later opportunity to prevent repeal of any individual regulation they “believe[] is important or beneficial.”¹⁰ Specifically, the Department plans to create a website through which members of the public can “remind the Department” to conduct retrospective review of any regulation for which the review “deadline is nearing,” thus ensuring that automatic repeal will not be triggered.¹¹ But this request system still places the burden on the public to determine which regulations are up for repeal and what the consequences of their rescission will be. Furthermore, the Department does not commit to acting on any request for review submitted by the public. Nor does it provide that a regulation’s automatic expiration will be delayed if a request is submitted but ignored.

In any event, even though they are conditioned on a future event (the non-performance of retrospective review), the repeals in question are being effected through *this* rulemaking. Thus, HHS is obligated to provide a “meaningful opportunity for comment” on the desirability of those

³ 85 Fed. Reg. at 70,104.

⁴ *See id.* at 70,104 nn. 85 & 86.

⁵ *Am. Med. Ass’n v. Reno*, 57 F.3d 1129, 1132 (D.C. Cir. 1995) (citation omitted).

⁶ 85 Fed. Reg. at 70,112.

⁷ *Id.* at 70,109.

⁸ *Consumer Energy Council of Am. v. Fed. Energy Regulatory Comm’n*, 673 F.2d 425, 446 (D.C. Cir. 1982) (“The value of notice and comment prior to repeal of a final rule is that it ensures that an agency will not undo all that it accomplished through its rulemaking without giving all parties an opportunity to comment on the wisdom of repeal.”).

⁹ *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 (D.C. Cir. 1977).

¹⁰ 85 Fed. Reg. at 70,117.

¹¹ *Id.* at 70,110.

repeals now, in this proceeding.¹² For the reasons discussed above, the Department has not done so.

HHS does not provide a reasoned explanation for the Proposed Rule

The Proposed Rule also violates the APA’s requirement that policy changes be accompanied by a “reasoned explanation” for “disregarding facts and circumstances that underlay or were engendered by the prior policy.”¹³ HHS makes no effort to acknowledge the facts and circumstances that motivated the initial promulgation of the thousands of regulations it now schedules for automatic repeal. Nor does it discuss the “serious reliance interests” that have no doubt been engendered by at least some of those regulations,¹⁴ given that more than 12,000 of them have been in effect for a decade or more.¹⁵ Instead, the Department claims that it “is considering the important factors”—without articulating what, exactly, those factors are—and asserts that it “believes the benefits of retrospective review, and the need to strongly incentivize it, are so great that the risk of a Regulation inadvertently expiring is outweighed by the benefit of institutionalizing retrospective review in this manner.”¹⁶ But HHS cannot reasonably reach such a conclusion without bothering to identify the regulations that are vulnerable to rescission under the Proposed Rule or to describe the nature and magnitude of the harm that might result from their expiration. As a result, the Department’s “unsupported and conclusory” assertions “add nothing to the agency’s defense of its thesis except perhaps the implication that it was committed to its position regardless of any facts to the contrary.”¹⁷

II. HHS does not adequately grapple with the Proposed Rule’s potential costs

In its Regulatory Impact Analysis for the Proposed Rule, HHS estimates that, in the first two years of implementation, completing reviews of the roughly 12,400 regulations that would otherwise expire will require the full-time efforts of between approximately 27 and 67 employees, at a wage-and-fringe-benefit cost of between approximately \$8 and \$19 million.¹⁸ But even assuming that these labor costs are not underestimated, the Department’s assessment is incomplete, because it fails to consider at least three additional categories of potential cost: the regulatory opportunity costs of allocating staff time to retrospective review, the forgone net benefits of rules that expire due to lack of review, and the costs to the public of monitoring

¹² *N. Carolina Growers’ Ass’n, Inc. v. United Farm Workers*, 702 F.3d 755, 770 (4th Cir. 2012) (finding that a comment opportunity for a regulatory suspension was not meaningful where the agency did not allow discussion of the “substance or merits” of the suspended policy).

¹³ *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

¹⁴ *Id.*

¹⁵ 85 Fed. Reg. at 70,112.

¹⁶ *Id.* at 70,106.

¹⁷ *Chem. Mfrs. Ass’n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994).

¹⁸ 85 Fed. Reg. at 70,112 (estimating number of regulations set to expire in first two years); *id.* at 70,116 (estimating cost of reviewing those regulations).

HHS’s review activities in hopes of preventing the expiration of regulations. Ignoring these “important aspect[s] of the problem” violates the APA.¹⁹

HHS fails to consider regulatory opportunity costs

Assuming a fixed workforce, HHS’s decision to task a large number of its career employees with retrospectively reviewing existing regulations—rather than preparing analyses in support of new regulations—could carry opportunity costs in the form of forgone net benefits from forgone or delayed new rules. Given HHS’s central role in facilitating the federal government’s response to the ongoing coronavirus pandemic, such opportunity costs could be severe and include, for example, forgone avoided mortalities.

Somewhat comically, HHS observes that the Proposed Rule’s review requirements “do not impose new burdens . . . if incomplete compliance [with the Regulatory Flexibility Act] is not accounted for in the regulatory baseline.”²⁰ But HHS’s entire rationale for the Proposed Rule is that incomplete compliance with existing review requirements *is and will continue to be* a problem under the regulatory baseline (i.e., absent the Proposed Rule).²¹ That HHS, as a normative matter, thinks this *shouldn’t* be the case is irrelevant. To assess the Proposed Rule’s costs, HHS must examine the policy’s effects on the world as it is and is likely to be, not the world as HHS wishes it to be.²² And in the real world, the Proposed Rule will result in a greater allocation of HHS employee time to retrospective review, which could, in turn, carry opportunity costs that the Department must consider.

HHS fails to consider the forgone benefits of expired rules

In the event that HHS fails to review an existing, net-beneficial rule by its expiration date, that failure will carry a cost in the form of the expired rule’s forgone net benefits. HHS dismisses the potential for such expirations, but its reasoning is unpersuasive. First, the Department says it “believes it can complete Review for all regulations that are more than ten years old in the proposed two-year time frame.”²³ But asserting that the Department *can* complete all of the required reviews is not equivalent to asserting that it *will* complete all of the reviews, much less to supporting the latter assertion with an analysis of the number of HHS employees who have the skills to complete such reviews and of the likely competing demands on those employees’ time over the next two years.

Second, the Department claims that the risk of expirations “may be lowered by members of the public reminding the Department” of an approaching deadline.”²⁴ But as discussed above, the

¹⁹ *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted).

²⁰ 85 Fed. Reg. at 70,112.

²¹ *See, e.g., id.* at 70,116 (“The Department’s experience over the last forty years suggests that, absent a strong incentive such as the potential expiration of a regulation, the Department will not review an adequate number of its regulations.”).

²² Office of Mgmt. & Budget, Circular A-4, at 15 (2003), <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf> (noting that the baseline for a regulatory cost-benefit analysis “should be the best assessment of the way the world would look absent the proposed action” and may reflect, among other factors, “the degree of compliance by regulated entities with other regulations”).

²³ 85 Fed. Reg. at 70,111.

²⁴ *Id.*

filing of such a reminder by a member of the public will not result in an extension of the subject regulation's expiration date. Thus, if HHS's failure to review the regulation prior to receiving the reminder is due to any factor other than a mere lack of awareness of the approaching deadline, a reminder from the public seems unlikely to avert expiration.

HHS fails to consider review-monitoring costs for the public

Whether or not public efforts to prompt review of soon-to-expire rules are successful, the hours spent on such efforts will themselves be costs of the Proposed Rule. Indeed, given the huge number of regulations that are potentially subject to expiration, as well as the Department's failure to clearly identify these vulnerable regulations in the Proposed Rule, such monitoring costs are likely to be substantial.

Each of these categories of potential cost is a "relevant factor" in this rulemaking, and HHS's failure to consider the costs and justify their imposition is arbitrary and capricious.²⁵

III. HHS provides insufficient evidence that the Proposed Rule will improve retrospective review or lead to welfare-enhancing regulatory changes

The Proposed Rule cites scant evidence for its extreme claim that applying automatic expiration dates to HHS's existing and future rules will lead to more meaningful retrospective reviews. The evidence that HHS does cite is often inapposite or misinterpreted. Indeed, one report that the Proposed Rule misleadingly cites as "noting the benefits of sunset provisions"²⁶ was written by one of the authors of this letter (Schwartz), and the report in fact concluded that sunset provisions overall were costly and wasteful.²⁷ Tying the threat of an automatic repeal to the retrospective review process has often in the past led to merely perfunctory reviews and renewals, rather than meaningful examinations of how best to enhance net social welfare by amending or eliminating existing rules.

The Proposed Rule relies heavily on a single academic article by Yoon-Ho Alex Lee to conclude that the lack of a sufficiently "strong incentive" prevents meaningful retrospective reviews.²⁸ Notably, the article explicitly did not consider any evidence of agencies' retrospective reviews following Executive Order 13,563.²⁹ Moreover, the article does not propose retroactively forcing existing rules to expire after a set period, but instead merely suggests that agencies consider, when issuing a new rule, whether to incorporate a conditional sunset, recommending that

²⁵ *Michigan v. EPA*, 135 S. Ct. 2699, 2707–08 (2015) ("Agencies have long treated cost as centrally relevant factor when deciding whether to regulate," and costs "include[] more than the expense of complying with regulations"; instead, "any disadvantage could be termed a cost."); see also *Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin.*, 956 F.2d 321, 326-27 (D.C. Cir. 1992) (remanding fuel-efficiency rule due to agency's failure to consider indirect safety costs); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (striking down rule for failure to consider indirect safety effects of substituting asbestos-free car brakes); *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012) (when agency relies on a cost-benefit analysis to support its rulemaking, "a serious flaw undermining that analysis can render the rule unreasonable").

²⁶ 85 Fed. Reg. at 70,102 (citing a report by Jason A. Schwartz).

²⁷ Jason A. Schwartz, *52 Experiments in Regulatory Review* 23-24 (Policy Integrity Report, 2010).

²⁸ 85 Fed. Reg. at 70,099 (citing Yoon-Ho Alex Lee).

²⁹ Lee, *An Options Approach to Agency Rulemaking*, 65 ADMIN. L. REV. 881, 897 (2013).

conditional sunsets may be appropriate if a traditional regulatory cost-benefit analysis provides “a close but not compelling case for the [new] rule.”³⁰

The Proposed Rule makes a sweeping claim, without adequate evidence, that an automatic expiration is “one of the most important factors for ensuring agencies conduct retrospective review.”³¹ In fact, much of the literature calls for ensuring that agencies have the resources they need to conduct retrospective reviews, both in terms of adequate staff time and also in terms of the necessary data.³² HHS fails to explain why it feels the threat of automatic repeals would lead to better retrospective review, rather than focusing on proactively collecting data on real-world regulatory outcomes.

The literature on the best practices for retrospective review was carefully studied in 2014 by the Administrative Conference of the United States (ACUS).³³ The Proposed Rule cites to ACUS’s recommendations on retrospective review,³⁴ but in fact those recommendations counsel strongly against the approach HHS has proposed. The consultant report prepared in connection with the recommendations references the idea of a sunset period only in passing,³⁵ and recommendations themselves do not endorse sunset periods. Instead, the recommendations specify that “[t]he rigor of analysis should be tailored to the rule being reviewed.”³⁶ HHS’s proposed automatic expiration period is an extreme one-size-fits-all approach to rulemaking that is decidedly *not* tailored, in violation of ACUS’s recommendations on best practices.³⁷ Moreover, ACUS’s recommendations included a list of factors for prioritizing retrospective reviews, and the age of the rulemaking is not listed as an appropriate factor for prioritizing retrospective reviews.³⁸

The Proposed Rule also miscites the aforementioned Schwartz report. For example, HHS quotes Schwartz’s report as saying that “sunset ‘provisions have been responsible for the analysis of thousands of state regulations and, on average, the repeal of twenty to thirty percent of existing

³⁰ *Id.* at 940 (“Overall, this Essay has argued that this approach provides a promising avenue for agencies to promulgate rules going forward.”) (emphasis added).

³¹ 85 Fed. Reg. at 70,097.

³² See Administrative Conference of the United States, Recommendation 2014-5, Retrospective Review of Agency Rules 5 (2014), https://www.acus.gov/sites/default/files/documents/Recommendation%25202014-5%2520%2528Retrospective%2520Review%2529_1.pdf [hereinafter “ACUS Recommendations”] (highlighting adequate agency resources and data collection as key factors for the success of retrospective review). See also U.S. Gov’t Accountability Office, *Reexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews* (2007) (identifying time, resources, data limitations, and lack of public participation as key barriers, and recommending pre-identifying data needs, prioritization strategies, and high-level management support as key solutions).

³³ ACUS Recommendations, *supra* note 32.

³⁴ 85 Fed. Reg. at 70,102 (misleadingly suggesting the proposed rule and the “stronger incentive” it seeks to create are consistent with ACUS’s recommendations); see *id.* at n.108 (admitting that the proposed rule fails to incorporate many of ACUS’s recommendations).

³⁵ Joseph E. Aldy, *Learning from Experience: An Assessment of the Retrospective Reviews of Agency Rules and the Evidence for Improving the Design and Implementation of Regulatory Policy* 65 (2014), <https://www.acus.gov/sites/default/files/documents/Aldy%2520Retro%2520Review%2520Draft%252011-17-2014.pdf>; see also *id.* at 62 (discussing how the National Marine Fisheries Service removed an isolated sunset provision as unnecessary).

³⁶ ACUS Recommendations, *supra* note 32, at 7.

³⁷ *Id.* at 6 (“In short, retrospective review is not a ‘one-size-fits-all’ enterprise.”).

³⁸ *Id.* at 9-10.

regulations and the modification of another forty percent.”³⁹ To begin, that sentence describes *legislative* sunset reviews, in which a state legislature or legislative committee reviews an existing regulation; the quoted sentence did not describe an automatic expiration period imposed by an agency on itself (as HHS proposes here).⁴⁰ Additionally, the report did not describe these regulatory repeals and modifications as a “benefit[] of sunset provisions” as the Proposed Rule suggests.⁴¹ To the contrary, the report concluded that, for both legislative sunset reviews and executive branch sunset reviews, the benefits are typically “insignificant compared to the costs,” and that the “burdens of such mandatory reviews can draw staff away from performing other vital oversight duties.”⁴²

The Proposed Rule notes the use of automatic regulatory expirations in New Jersey, Indiana, and Florida, but cites no evidence that that these policies have resulted in better retrospective reviews.⁴³ The lack of data from Florida is particularly unsurprising, given that the state’s sunset provision was adopted less than a year before HHS proposed its rule.⁴⁴ Nevertheless, the Proposed Rule leaps to the sweeping conclusion that “experience in the States suggests that sunset provisions can be an important tool to ensure reviews take place,” citing a single source: a 2012 working paper published by the Mercatus Center.⁴⁵ That working paper relied directly on data from Schwartz’s report for its count of states with sunset provisions,⁴⁶ and Schwartz’s report found only 5 states that had some type of sunset provision as of 2010.⁴⁷ From an empirical perspective, this is a very small dataset from which to draw sweeping conclusions. And again, Schwartz concluded that sunset provisions were on the whole costly and wasteful, based on a thorough review of historical and contemporary practices across all 50 states.

After offering no concrete evidence of success from any of the states, the Proposed Rule next looks to foreign legal systems for examples. To begin, the Proposed Rule fails to consider any relevant differences between those foreign legal systems and U.S. administrative law. Additionally, by the Proposed Rule’s own description, the Korean law offered as an example does not create the kind of automatic expiration period HHS seeks to adopt. Instead, the Proposed Rule describes the Korean approach as a process through which “existing regulations are to be reviewed on a regular basis (about every 3 to 5 years) and *become invalid if they are found to lack feasibility*.”⁴⁸ In other words, according to the Proposed Rule’s own example, a Korean regulation would not become invalid merely because retrospective review was not

³⁹ 85 Fed. Reg. at 70,102.

⁴⁰ See Schwartz, *supra* note 27, at 23-24 (citing Teske); see also Paul Teske, *The New Role and Politics of State Regulation*, REGULATION, Fall 2004 at 20-21 (discussing “sunset legislation” from multiple states, as well as a single executive-ordered retrospective review in California).

⁴¹ 85 Fed. Reg. at 70,102.

⁴² Schwartz, *supra* note 27. By calling such reviews “productive,” the report was merely referencing the thousands of pages that such legislative sunset periods reviewed. *Id.* at 23-24. The report’s overarching conclusion is that sunsets—far from being productive—“produce perfunctory reviews and waste resources.” This conclusion is not based entirely on a single academic article, as the proposed rule misleadingly suggests, 85 Fed. Reg. at 70,102 n.69, but also was informed by the thorough review of actual practices in all 50 states.

⁴³ 85 Fed. Reg. at 70,102.

⁴⁴ *Id.* at 70,102 n.65.

⁴⁵ *Id.* at 70,102 n.66.

⁴⁶ Russell S. Sobel & John A. Dove, *State Regulatory Review: A 50 State Analysis of Effectiveness* 16, 47 (Mercatus Ctr. Working Paper, 2012) (citing Schwartz).

⁴⁷ Schwartz, *supra* note 27, at 87; see also *id.* at Chart 5: Periodic Review.

⁴⁸ 85 Fed. Reg. at 70,103 (emphasis added).

completed by a set deadline. Moreover, the Proposed Rule’s underlying source for this example further explains that the Korean provision was enacted by legislation, not by individual regulatory entities.⁴⁹ The Proposed Rule’s other examples also seemingly fall apart upon closer scrutiny. For instance, the Proposed Rule relies on a publication by the OECD for evidence regarding the United Kingdom’s sunset provision.⁵⁰ That OECD publication references the U.K.’s *Small Business, Enterprise and Employment Act* of 2015.⁵¹ Once again, this is a legislatively enacted process for retrospective review, and not an automatic expiration date invented by an agency itself. Moreover, the plain text of that 2015 U.K. act both includes significant exceptions⁵² and explains that the ultimate “validity of any secondary legislation is not to be affected by any question as to whether a Minister of the Crown complied with” the retrospective review requirement.⁵³ HHS fails to explain how this U.K. example is at all comparable to what the Department proposes here.

In short, the Proposed Rule offers only scant and misleading evidence of the need for or value of an automatic expiration period for existing and future regulations.

IV. HHS fails to consider any reasonable alternative means of improving retrospective review

Conducting more meaningful retrospective reviews is an admirable goal, but for the reasons explored above, the Proposed Rule is decidedly not a legally, economically, or practically sound approach to achieving it. There are many alternative approaches to retrospective review—all of which HHS has failed to consider. HHS should withdraw the Proposed Rule and instead issue a public request for information on designing a new approach to retrospective review.

Whereas the Proposed Rule in fact fails to comport with the ACUS recommendations on retrospective review, HHS would do well to follow those recommendations in designing a more appropriate alternative approach to retrospective review. A new approach to retrospective review should, as ACUS recommends, first prioritize the ongoing and proactive collection of data on real regulatory outcomes.⁵⁴ HHS should also ensure that it has sufficient resources to conduct retrospective reviews without “detract[ing] from other aspects of [HHS’s] regulatory missions.”⁵⁵ Then, given the available resources, HHS should identify how many and which rules to review, carefully tailoring the rigor of analysis to the particulars of the specific rules undergoing review.⁵⁶ Some of the most useful criteria for prioritizing retrospective reviews include the “likelihood of improving attainment of statutory objective,” the “likelihood of increasing net benefits and magnitude of those potential benefits,” the “uncertainty about the accuracy of initial estimates of regulatory costs and benefits,” and various changed circumstances, including “changes in the statutory framework” or “changes in underlying market

⁴⁹ OECD, *Latest Developments on Korea’s Regulatory Policy*, <https://www.oecd.org/gov/regulatory-policy/45347364.pdf>.

⁵⁰ 85 Fed. Reg. at 70,103 n.74.

⁵¹ OECD, *Better Regulation Practices Across the European Union*, table 4.1 (2019).

⁵² See *Small Business, Enterprise and Employment Act* 2015 § 31, https://www.legislation.gov.uk/ukpga/2015/26/pdfs/ukpga_20150026_en.pdf.

⁵³ *Id.* § 32(7).

⁵⁴ ACUS Recommendations, *supra* note 32, at 5.

⁵⁵ *Id.*

⁵⁶ *Id.* at 7.

or economic conditions, technological advances, evolving social norms, public risk tolerance, and/or standards that have been incorporated by reference.”⁵⁷

As the ACUS recommendations further advise, agencies “should also take advantage of simple opportunities to improve regulations when the changes are relatively minor (e.g., allowing electronic filing of forms in lieu of traditional paper filing).”⁵⁸ In the Proposed Rule, HHS laments the hundreds of broken cross-references it has uncovered in the Code of Federal Regulations and the dozens of rules that still call for forms to be submitted in triplicate, saying that HHS “unfortunately . . . has for years not gotten around to addressing these issues.”⁵⁹ Rather than proposing a complex, burdensome, and legally questionable automatic expiration period for all rules, HHS should start by addressing these simple problems that it has already identified and that can be easily remedied.

Finally, HHS should follow ACUS’s recommendations by “periodically evaluat[ing] the results of [the Department’s] retrospective reviews.”⁶⁰ In other words, the plan for retrospective review itself should be periodically reevaluated. The Proposed Rule very conspicuously violates this principle by seeking to exempt *itself* from any future review or automatic expiration period.⁶¹

For all of the foregoing reasons, the Proposed Rule is neither legal nor rational and should be withdrawn.

Respectfully,

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⁵⁷ *Id.* at 9; *see also* Policy Integrity’s Comments to HHS on Reducing Regulatory Burden (June 30, 2011), https://policyintegrity.org/documents/Policy_Integrity_Final_Comments_on_HHS_Retro_Plan.pdf.

⁵⁸ ACUS Recommendations, *supra* note 32, at 10.

⁵⁹ 85 Fed. Reg. at 70,101-12.

⁶⁰ ACUS Recommendations, *supra* note 32, at 11.

⁶¹ 85 Fed. Reg. at 70,109; *see* proposed 21 C.F.R. § 6.1(g)(3).