State of California
Office of the Attorney General
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December 4, 2020

Via e-filing at www.regulations.gov

Secretary Alex M. Azar II
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: "Securing Updated and Necessary Statutory Evaluations Timely"
RIN 0091–AC24; Docket No. HHS-OS-2020-0012

Dear Secretary Azar:

The undersigned Attorneys General of the States of California, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, Wisconsin, and the District of Columbia (the States) submit these comments on "Securing Updated and Necessary Statutory Evaluations Timely" (Proposed Rule). The Proposed Rule is a misguided and dangerous attempt at deregulation by the U.S. Department of Health and Human Services (HHS) and would hamstring the incoming Biden Administration in the midst of a global pandemic. We urge you to withdraw it immediately.

Under the guise of implementing the Regulatory Flexibility Act (RFA), the Proposed Rule proposes to automatically "sunset" any HHS regulation that the agency does not review within a prescribed period. The Proposed Rule applies its dramatic remedy to all 18,000 of HHS's regulations, despite the fact that the majority of them do not actually fall within the scope of the RFA. It would empower HHS to revoke any of these regulations, not by the ordinary rulemaking process, but by mere inaction. In so doing, the Proposed Rule puts at risk trillions of dollars in federal funding on which the States rely, and threatens critical programs as wide-ranging as Medicaid, food safety, and medical and pharmaceutical research.

The Proposed Rule will make it difficult, if not impossible, for the incoming Administration to enact new regulations aimed at controlling the COVID-19 pandemic. In this crucial time, we Attorneys General seek to work together with the federal government to safeguard our residents' health and safety. This Proposed Rule threatens to make that task impossible and will hurt our residents nationwide.

I. The Proposed Rule is unprecedented and dramatic in scope.

The scope of the Proposed Rule is extraordinary. It takes an aggressive, unprecedented approach to the problem of "outdated" regulations. In order to "incentivize" retrospective review of its own regulations, HHS proposes to set an automatic expiration date for any regulation that the agency does not review through its "Assessment" and "Review" process. 85 Fed. Reg. at 70,106, 70,123 (to be codified at 45 C.F.R. § 6.1(c)). HHS has given itself (or, in reality, its successors) two years to review thousands of regulations, and imposed a severe, automatic penalty for any failure to do so. *Id.* at 70,123. Under the Proposed Rule, any regulation that HHS does not Assess and (where applicable) Review within its compressed timeframe—two years of the Proposed Rule's effective date, 10 years after the Proposed Rule's promulgation, or 10 years after the regulation's last Review or Assessment (whichever is later)—automatically expires, no matter the consequences. *Id.*

HHS has "regulatory responsibilities as wide-ranging as food safety, drug approval, adoption and childcare, and healthcare financing." In order to meet these responsibilities, HHS has promulgated some 18,000 regulations. 85 Fed. Reg. at 70,112. HHS estimates that only 11% of those regulations fall within the RFA's scope as having "a significant economic impact upon a substantial number of small entities." *Id.* Yet the Proposed Rule applies its threat of automatic expiration to every HHS regulation on the books—including the vast majority of regulations that have no impact on small entities at all—unless they meet certain limited exceptions. At the same time, the Proposed Rule gives the agency plenary control over which regulations to "Assess" or "Review," while insulating that decision from judicial review. *See* 85 Fed. Reg. at 70,124. This could have dire consequences for those who stand to lose health benefits or services, yet have no recourse to prevent that loss. The draconian reach of the Proposed Rule is unlike anything that has come before it.

The Proposed Rule poses a direct threat to the States' healthcare systems and the health and safety of our residents. The States depend on HHS to administer trillions of dollars in federal funding, which is governed by an intricate web of regulations and requirements. For instance, States accept funding from the federal government to administer their Medicaid programs under federal guidance. This dense patchwork of regulations covers everything from the State Children's Health Insurance Program (commonly known as CHIP) to the confidentiality of health information under the Health Insurance Portability and Accountability Act (HIPAA). In similarly critical areas such as food safety, medical and pharmaceutical research, and health insurance, the States work in partnership with HHS and its sub-agencies to manage public health and provide critical healthcare services to our residents. The States depend on HHS to set national standards and have built vast regulatory systems within that framework. The catastrophic consequences that might result from letting any of these regulatory regimes lapse due to inaction cannot be overstated.

II. The Proposed Rule is unlawful.

The Proposed Rule also rests on doubtful legal authority. It purports to implement the RFA, which Congress enacted to minimize the impact of regulations on "small entities" such as small businesses, small organizations, and small governmental jurisdictions with limited resources. *See* Pub. L. 96-354, 94 Stat. 1164, 1165 (Sept. 19, 1980); 5 U.S.C. § 601 (defining "small entity"). By its plain terms, the RFA only reaches those regulations that "have a significant economic impact upon a substantial number of small entities." 5 U.S.C. §§ 602, 604, 605. Yet the Proposed Rule does not limit its reach to those regulations covered by the RFA. It proposes to add expiration dates to *all* HHS regulations, not just those that "have a significant economic impact upon a substantial number of small entities." *See* 85 Fed. Reg. at 70,123; *id.* at 70,104-05 (defining "Regulations" broadly as "a section of the Code of Federal Regulations").

HHS lacks authority for such an expansive interpretation of the RFA. Courts have uniformly recognized the limited scope of the RFA, emphasizing that it is a procedural rule, which "only requires an agency to consider the economic impact of a proposed regulation on 'regulated small entities.'" *Permapost Prod., Inc. v. McHugh*, 55 F. Supp. 3d 14, 30 (D.D.C. 2014); *see also, e.g.*, *Cement Kiln Recycling Coal. v. E.P.A.*, 255 F.3d 855, 869 (D.C. Cir. 2001); *Mid-Tex Elec. Co-op., Inc. v. F.E.R.C.*, 773 F.2d 327, 342 (D.C. Cir. 1985); Connor Raso, Agency Avoidance of Rulemaking Procedures, 67 Admin. L. Rev. 65, 81 (2015). Indeed, as one scholar has observed, "[t]he only notable interpretative work the courts have done with the RFA has restricted its reach." Raso at 97. This Proposed Rule does just the opposite. Its expansive scope finds no support in the text or purpose of the RFA.

The Proposed Rule's attempt at amending all of the agency's regulations through a single rulemaking is also dubious under the Administrative Procedure Act (APA). The Proposed Rule claims that it complies with the APA because "[a]n agency can, through notice-and-comment rulemaking, amend its regulations to provide that they expire at a future date." 85 Fed. Reg. at 70,104. Yet the only authority cited for that proposition refers to the individual amendment of a single rule. *Id*. at 70,104 n.85 (citing Amendment to the Interim Final Regulation for Mental Health Parity, 70 Fed. Reg. 42,276, 42,277 (July 22, 2005)).[1] And that amendment *extended* a regulation's existing sunset date to conform to legislation extending the sunset date for the statute that the regulation implemented. The Proposed Rule does not explain how case law allowing it to amend any single regulation authorizes it to amend all of them in one fell swoop to cause their automatic expiration. We are unaware of any instance in which a federal agency has sought to amend all of its regulations in a single rulemaking, nor of any legal authority that would permit it to do so, let alone to amend them so that they expire automatically without substantive consideration in a subsequent rulemaking. HHS's proposal seems to be an end-run around the APA's requirements for notice-and-comment rulemaking. But even if the APA's

[1] The Proposed Rule also cites to *Clean Air Council v. Pruitt,* 862 F.3d 1, 9 (D.C. Cir. 2017) for the general proposition that "an agency can amend or revoke a legislative rule through notice-and-comment rulemaking." 85 Fed. Reg. at 70,104 n.85. The agency action at issue in *Pruitt* did not concern the expiration of regulations.

procedural requirements permitted such a tactic, HHS's blunderbuss approach could not satisfy its basic requirement of reasoned decision making.

III. The Proposed Rule will drain agency resources and create significant uncertainty for regulated entities.

The Proposed Rule promises to drown HHS in thousands of hours of retrospective review, which will hamstring its ability to respond to the global COVID-19 pandemic. The Proposed Rule estimates that over the coming two years, HHS will be required to conduct approximately 2,480 Assessments and almost 300 Reviews in order to save longstanding regulations from expiration. 85 Fed. Reg. at 70,112, 70,115. This significant drain on agency resources would be crippling to any incoming Administration, let alone during a global pandemic during which HHS resources will be critical. Each of HHS's sub-agencies will be essential to confronting the pandemic—from collecting data from hospitals, developing guidance for schools and businesses, approving test kits for expanded testing, and overseeing the approval and distribution of a vaccine.[2] Requiring regulators to conduct thousands of hours of retrospective review would significantly interfere with the rollout of these critical initiatives.

The Proposed Rule also creates uncertainty for the very regulated entitles the RFA is meant to protect. Regulated parties cannot know if (or when) the agency will get around to Assessing or Reviewing rules that impact them. For the States, that uncertainty could be crippling. Innumerable state programs would be thrown into utter disarray if the federal regulations on which they rely were to suddenly expire. The Medicaid program, for instance, provides health coverage to millions of families across the nation and depends on thousands of federal regulations and guidance documents that "explain how laws will be implemented and what states and others need to do to comply."[3] The Proposed Rule casts uncertainty over those thousands of parameters. And although the Proposed Rule recognizes this serious problem, it

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[2] *See, e.g.*, Allison Aubrey, *President-Elect Biden Has a Plan to Combat COVID-19*, NPR (Nov. 8, 2020), https://www.npr.org/sections/health-shots/2020/11/08/930887069/hold-president-elect-biden-has-a-plan-to-combat-covid-19-heres-what-s-in-it; U.S. Dept. of Health and Human Services, *From the Factory to the Frontlines*, https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf.

[3] *See* Centers for Medicare & Medicaid Services, *Federal Policy Guidance*, https://www.medicaid.gov/federal-policy-guidance/index.html; *see also* Centers for Medicare & Medicaid Services, *Medicaid Program History*, https://www.medicaid.gov/about-us/program-history/index.html ("Although the Federal government establishes certain parameters for all states to follow, each state administers their Medicaid program differently, resulting in variations in Medicaid coverage across the country."); Georgetown Univ. Health Policy Inst., *What the Proposed "SUNSET" Regulation Means for Medicaid and CHIP* (Nov. 11, 2020), https://ccf.georgetown.edu/2020/11/11/what-the-proposed-sunset-regulation-means-for-medicaid-and-chip (explaining that the proposed rule "would require that, over the next two years, the Department reconsider literally thousands of Medicaid 'regulations'").

casts it aside. The agency simply warns that "if it has not announced that it is Assessing or Reviewing a Regulation, and the deadline is nearing, those who rely on the Regulation are on notice that it might expire, just as the public is on notice that a regulation might be rescinded when an agency issues a notice of proposed rulemaking to rescind the regulation." 85 Fed. Reg. at 70,110. That warning offers little comfort to the millions of people, States, and industries this regulation could affect.

Finally, the timing of this Proposed Rule is deeply problematic. Months before a presidential transition, in the midst of a global pandemic, HHS has proposed an unprecedented, expansive new rule and offered the public only 30 days to comment. While the Administrative Procedure Act requires a minimum of 30 days for public comment during rulemaking (5 U.S.C. § 553(d)), when a rule is economically significant (as this one surely is), the formal recommendation of the U.S. Administrative Conference is a 60-day comment period.[4] HHS has eschewed that standard practice here, rushing to enact this regulation in the waning days of the presidential administration. This truncated process cannot possibly be sufficient to provide the agency with the information it needs to promulgate such a far-reaching new rule, or to fulfill the purposes of the Administrative Procedure Act.

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HHS has stepped far beyond its authority in proposing this dramatic new rule. The Proposed Rule is unprecedented in scope and contrary to the purpose and the text of the statute that it purports to implement. The Proposed Rule promises to sow confusion and uncertainty in the midst of a presidential transition and global pandemic. It will mire the agency in red tape at a time when its resources are most needed to respond to our current national health crisis. And it deprives the States, along with all regulated entities, any meaningful opportunity to participate in its process of retrospective review. On behalf of the States, we respectfully request you withdraw the Proposed Rule.

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[4] *See* Administrative Conference of the United States, Administrative Conference Recommendation 2011-2 (June 16, 2011), *available at* https://www.acus.gov/sites/default/files/documents/Recommendation%202011-2%20%28Rulemaking%20Comments%29.pdf; 85 Fed. Reg. at 70,115 (recognizing the Proposed Rule will cost the agency $4,938,797 to $10,999,602 in the first two years of implementation alone); *see also* Martin Hahn et al., *HHS Proposes to sunset regulations Issued by FDA, CMS, and other regulatory agencies*, JD Supra (Nov. 19, 2020), https://www.jdsupra.com/legalnews/hhs-proposes-to-sunset-regulations-37748/ ("It is unprecedented for a government proposal of this magnitude to be published with only 30 days for public comment[.] … The short time frame calls into question the fundamental fairness principles underlying the Administrative Procedure Act, assuring a reasonable opportunity to review and comment on new government actions.").

Sincerely,

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