



The Leadership Conference
on Civil and Human Rights

December 4, 2020

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

Submitted via regulations.gov

**Re: RIN 0991–AC24 Securing Updated and Necessary Statutory Evaluations
Timely, Docket No. HHS-OS-2020-0012**

Dear Secretary Azar:

On behalf of The Leadership Conference on Civil and Human Rights (The Leadership Conference), we write in response to the U.S. Department of Health and Human Services' (HHS) proposed rule, "Securing Updated and Necessary Statutory Evaluations Timely" (proposed rule). This proposed rule is ill-conceived at best and is an illegitimate use of authority, creating tremendous administrative burdens for HHS and wreaking havoc across a broad swath of department programs and regulated entities — from Medicaid and Medicare, to the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) — all during a global pandemic and the worst public health crisis that our nation has experienced in generations — one that has disproportionately harmed the Black community and other communities of color, as well as people with disabilities. The Trump administration also introduced the proposed rule the day after the presidential election with only a 30-day comment period. The Leadership Conference strongly objects to the substance of the proposed rule, as well as the truncated 30-day comment period, which is insufficient for a rule of this broad scope. For these reasons, The Leadership Conference urges HHS to immediately withdraw this NPRM.

The Leadership Conference is a coalition charged by its diverse membership of more than 220 national organizations to promote and protect the rights of all persons in the United States. Central to our work is the understanding that economic justice and civil rights are inextricably linked, and that health care is a human right. The proposed rule would retroactively impose an expiration provision on most HHS regulations and establish "assessment" and "review" procedures to determine which, if any, regulations should be retained or revised. This blunt instrument would create tremendous administrative burdens for HHS and force a shift in resources to regulatory review and away from combatting the COVID-19 pandemic. Especially during crisis situations, it is of critical importance that HHS have the flexibility and bandwidth to shift focus and respond quickly to immediate needs.

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Vanita Gupta

In the proposed rule, HHS argues that it will promote “accountability, administrative simplification [and] transparency. . . .”¹ However, HHS itself modestly estimates that the proposed rule would cost nearly \$26 million dollars over 10 years, needing 90 full-time staff positions to undertake the required reviews.² Within the first two years, HHS estimates the need to assess at least 12,400 regulations that are over 10 years old.³ These estimates most likely underestimate the time and resources needed for the review process, and do not accurately account for any complications that could come up.

The proposed rule would necessarily have an adverse impact on the ability of HHS to focus on the administration of current programs, to issue new regulations, and appropriately review current regulations that need modification. Regulations play an important role in implementing HHS policies and programs. This includes programs like Medicaid and the Children’s Health Insurance Program (CHIP), which both provide health coverage for more than 75.5 million people — white, Black, and brown — including 36.6 million children. A strong regulatory framework provides states the clarity they need to run these programs on a day-to-day basis, gives providers and managed care plans guidance as to their obligations, and explains to recipients what the rules are. The proposed rule would create legal uncertainty regarding the validity and enforceability of regulations throughout the review process.

A significant and realistic danger posed by the proposed rule is that important regulations may be arbitrarily rescinded because there are simply not enough HHS staff or resources to undertake such a sweeping review process. Regulations that do not complete the complicated and time-consuming review process would expire, potentially leaving large, gaping holes in the regulatory framework implementing HHS programs and policies. For example, several regulations implementing critical parts of the Affordable Care Act are approaching their 10-year anniversary, including the Medicaid cost-sharing rule. Regulations like these that will soon hit the 10-year mark would need to be reviewed within the next two years, or they would expire. And if the regulations expire, the underlying law would still exist — creating confusion and lack of clear guidance for states, which would still be required to implement cost-sharing amounts.

Finally, The Leadership Conference believes that the proposed rule is both unnecessary and that HHS does not have the authority to propose automatic expiration dates on almost all regulations under its purview. In the proposed rule, HHS claims that automatic expiration dates give the department the incentive necessary to conduct regular assessments of existing regulations and comply with the 40-year-old Regulatory Flexibility Act (RFA). But agencies within HHS already commonly update regulations when needed. The argument that HHS needs to “incentivize” regulation review by imposing a mandatory rescission is not supported by the facts.⁴ Moreover, nothing in the RFA authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations. The RFA simply

¹ 85 Fed. Reg. 70104.

² 85 Fed. Reg. 70116.

³ 85 Fed. Reg. 70112. To be specific, HHS states that “because the Department estimates that roughly five regulations on average are part of the same rulemaking, the number of Assessments to perform in the first two years is estimated to be roughly 2,480.”
Id.

⁴ 85 Fed. Reg. 70099, 70106.

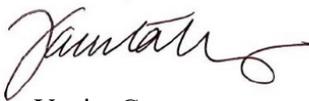
requires each agency to publish “a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities.”⁵

This proposal also goes against the Administrative Procedure Act’s (APA) requirements for rulemaking. In the APA, Congress established clear procedures and standards for agencies seeking to modify or rescind a rule. The APA requires agencies to go through the same rulemaking process to revise or rescind a rule as they would for a new rule, with public notice and the opportunity to comment.⁶ In the proposed rule, HHS states that it has authority under the APA to add end dates or conditions whereby a previously promulgated rule would expire.⁷ While we do not dispute that federal agencies can later amend existing regulations, the proposed rule would modify *thousands* of separate, distinct rules across HHS in a single act — in violation of the APA. The attempt by HHS to apply a blanket amendment to 18,000 regulations violates the APA’s requirements that review of an existing rule take place on an individual basis, requiring specific fact-finding relevant to the individual rule that the agency wants to amend.

Simply put, the proposed rule is an attempt to sabotage and destroy duly promulgated regulations by retroactively imposing an arbitrary end date to duly promulgated regulations. It would divert critical resources from combating the COVID-19 pandemic and ensuring access to health care. And it is unnecessary and would create havoc in current HHS programs.

We strongly oppose this rule and urge HHS to withdraw it immediately. Thank you for the opportunity to comment. If you have further questions, please contact Emily Chatterjee at chatterjee@civilrights.org.

Sincerely,



Vanita Gupta
President and CEO



LaShawn Warren
Executive Vice President for Government Affairs

⁵ 5 U.S.C. 610(a) (In the case of the RFA, periodically is defined as 10 years, unless such review is not feasible, in which case the review can be extended another 5 years).

⁶ 5 U.S.C. § 551(5); *see also* Maeve P. Carey, Specialist in Government Organization and Management, *Can a New Administration Undo a Previous Administration's Regulations?*, Congressional Research Service (Nov. 21, 2016), <https://fas.org/sgp/crs/misc/IN10611.pdf> (“In short, once a rule has been finalized, a new administration would be required to undergo the rulemaking process to change or repeal all or part of the rule.”); Office of Information and Regulatory Affairs, Office of Management and Budget, *The Reg Map 5 (2020)* (noting that “agencies seeking to modify or repeal a rule” must follow the same rulemaking process they would under the APA).

⁷ 85 Fed. Reg. 70104, fn 85 & 86, citing to separate, specific rulemakings changing interim final rules implementing mental health parity and foreign quarantine provisions, respectively.