



December 4, 2020

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

Re: RIN 0991–AC24 Securing Updated and Necessary Statutory Evaluations Timely

Dear Secretary Azar:

The Children's Defense Fund (CDF) appreciates the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) proposed rule, "Securing Updated and Necessary Statutory Evaluations Timely" (hereinafter referred to as the "proposed rule"). For 47 years, CDF has been advocating for children and seeking strong support for families through passage of laws and implementation of rules, programs, and services in their best interest. CDF's Leave No Child Behind® mission is to ensure every child a Healthy Start, a Head Start, a Fair Start, a Safe Start, and a Moral Start in life and successful passage to adulthood with the help of caring families and communities.

Regulations play an important role in implementing a wide range of HHS policies and programs serving children and families, including child care, substance use treatment, child welfare, food safety, and health care. **CDF is very concerned that the proposed rule will disrupt the ability of the Department of Health and Human Services to efficiently administer critical programs and services for children and families and should be withdrawn immediately.**

The proposed rule would create tremendous administrative burden for HHS, severely impacting its ability to effectively implement critical programs and services for children and families.

While CDF supports measures to review and improve regulations in order to make them more effective and less burdensome, we believe the proposed rule's approach would be ineffective and overly burdensome. According to the Department, the rule would give HHS only two years to assess more than 12,400 regulations, most of which would require review.¹ Estimates also released by the Department suggest this would require 90 full time staff over the next ten years, at a cost of nearly \$26 million.² These estimates represent a best case scenario, however, not accounting for complications that will inevitably arise over the course of such a monumental review process or for the costs that will be passed along to state and local governments, providers of HHS-administered programs, and the programs' beneficiaries who will be forced to quickly adapt to an arbitrarily shifting regulatory environment.

Unnecessarily diverting such significant resources from HHS is potentially dangerous for the millions of children and families that rely on programs and services managed or regulated by the Department, including,

¹ 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.*

² 85 Fed. Reg. 70116.

for example, Medicaid and the Children’s Health Insurance Program (CHIP) which together make up the bedrock of the health insurance system for children in this country, ensuring comprehensive, affordable health coverage for more than 36 million children, as well as tens of millions of parents and other caregivers. HHS already has extremely limited capacity to administer the wide array of necessary services under its purview and this will be especially true over the course of the next two years, as HHS will need to marshal its resources in response to the COVID-19 pandemic and the attendant economic impact the pandemic will have on families. This crucial responsibility will require the Department to be agile in its response to the immediate needs of children and families, which will be impossible if it is constrained by the need to conduct unnecessary reviews under and an arbitrarily condensed timeline.

In addition, the proposed rule would undermine the clarity of the regulatory environment. Several regulations implementing important parts of the Affordable Care Act, for example, are approaching their ten-year anniversary, including the Medicaid cost-sharing rule. Regulations like these would need to be reviewed within two years, or they would expire. However, the underlying law would still exist, even if the regulations expired. Without the cost-sharing rule, states would not have clear guidance on how to implement cost-sharing amounts. The resulting regulatory uncertainty would make it impossible for health care businesses and organizations to conduct their work, introducing dangerous inefficiency into the sector. Injecting regulatory uncertainty across the full portfolio of HHS-administered programs would have disastrous impacts on the economy and the well-being of children and families.

Furthermore, requiring such a broad and arbitrary review of regulations that are currently effective—including regulations that have been subsequently amended within the last ten years—would undermine the purported goal of this proposed rule. By diverting staff time and knowledge to review thousands of policies in such a short time frame, the proposed rule would limit the time that could be devoted to reviewing regulations that truly need to be updated in order to most effectively operate current programs, thus hindering efforts to meaningfully address outdated regulation. HHS sub-agencies, overwhelmed by the requirement that they complete thousands of unnecessary reviews, would be unable to devote resources to thorough reviews or updates of regulations that need amending, and would be forced to either continue the regulations without change or rush through the amendment process to fit within the time frame. Our children deserve a regulatory environment that has been carefully considered to protect their safety and well-being, not one that has been hastily constructed under arbitrary rules.

CDF is also concerned about the precedent that this rule would create. Automatic sunset provisions could permit future administrations to sidestep the regulatory process. By simply ignoring the requirement to review regulations, future administrations could do away with valuable regulations that protect the health and safety of children and families simply by letting them lapse. This repeal-by-attrition would deny the public the important opportunity to comment on proposed changes and would erode stability in the regulatory environment by introducing unnecessary uncertainty. It would allow a future administration to undermine the safety of children without public scrutiny, in direct contravention of the stated desire that this proposed rule would promote “accountability, administrative simplification and transparency.”³

HHS has existing authority and mechanism to conduct a periodic review of regulations and does not have authority to propose automatic expiration dates on almost all regulations.

The proposed rule claims that automatic expiration dates give HHS the incentive necessary to conduct regular assessments of existing regulations and ensure compliance with the Regulatory Flexibility Act (RFA), but HHS

³ 85 Fed. Reg 70104

agencies already have the authority to commonly update regulations when needed. For example, in 2002 the Centers for Medicare & Medicaid Services (CMS) promulgated new regulations implementing statutory changes to Medicaid managed care programs.⁴ Then in 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations⁵ and took nearly a year to review and consider the 875 comments submitted, publishing the final rulemaking in May 2016.⁶ This administration undertook further rulemaking to revise Medicaid managed care regulations, to “relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care.”⁷ Thus, HHS’ assertion that it needs to “incentivize” regulation review by imposing a mandatory rescission is simply not supported by the facts.⁸

Further, the RFA 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.”⁹ However, nothing in this forty year-old law authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations. Such a policy would be contrary to the Administrative Procedure Act’s (APA) requirements for rulemaking in which Congress established clear procedures and standards for agencies seeking to modify or rescind a rule.

CDF believes the proposed rule is ill-conceived and designed to significantly disrupt HHS’ ability to effectively implement critical programs and services for children and families and is woefully unnecessary. **CDF strongly urges the Department to immediately withdraw the proposed rule.**

Sincerely yours,



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⁴ CMS, *Medicaid Program; Medicaid Managed Care: New Provisions*, RIN 0938–AK96, 67 Fed. Reg. 40989 – 41116 (June 14, 2002), <https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/cms2104f.pdf>.

⁵ CMS, *Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Proposed Rules*, RIN 0938–AS25, 80 Fed. Reg. 31098–31296 (June 1, 2015), <https://www.federalregister.gov/documents/2015/06/01/2015-12965/medicaid-and-childrens-health-insurance-program-chip-programs-medicicaid-managed-care-chip-delivered>.

⁶ CMS, *Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Final Rule*, RIN 0938–AS25, 80 Fed. Reg. 27498–27901 (May 6, 2016), <https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-health-insurance-program-chip-programs-medicicaid-managed-care-chip-delivered>.

⁷ CMS, *Medicaid Program; Medicaid and Children’s Health Insurance Program (CHIP) Managed Care (Final Rule)*, RIN 0938–AT40, 85 Fed. Reg. 72754–72844, 72754 (Nov. 13, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-11-13/pdf/2020-24758.pdf>.

⁸ 85 Fed. Reg. 70099, 70106.

⁹ 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).