



A Passionate Voice for Compassionate Care

December 4, 2020

The Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

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

Dear Secretary Azar,

On behalf of the Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,200 Catholic health care systems, hospitals, long-term care facilities, service providers and organizations, I am writing to share our comments on the Notice of Proposed Rulemaking (NPRM) on Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) published on November 4, 2020 (85 Fed. Reg. 70096). The proposed rule would cause great disruption for Medicare, Medicaid and other federal health programs and have serious consequences for the people who rely on those programs. **We strongly urge the U.S. Department of Health and Human Services (HHS) to withdraw the proposed rule in its entirety.**

Under the proposed rule, all regulations in Titles 21, 42 and 45 of the Code of Federal Regulations (CFR) would automatically expire unless the Department periodically assesses the regulations to determine if they are subject to review, and if they are, performs a review. Following this review, the Department would be able to unilaterally retain, modify, or eliminate the regulation. Unless reviewed, the regulations would expire:

- Two calendar years after the year that this proposed rule first becomes effective,
- Ten calendar years after the year that the regulation first went into effect, or
- Ten calendar years after the last year in which HHS assessed and, if review is required, reviewed the regulation.

In the proposal HHS states its belief that the proposed rule is needed to ensure that periodic evaluation of regulations occurs and establishes assessment procedures for retrospective review. While we appreciate HHS' desire to reduce undue regulatory burdens and streamline the work of federal health programs, the institution of mandatory timelines that would cause significant regulations to automatically expire is extremely problematic. HHS has approximately 18,000 regulations, the vast majority of which would be subject to review under this rule.¹ These regulations

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encompass a massive range of topics and affect a huge number of providers, beneficiaries and citizens. This was indicated by the broad representation of testifiers during the call convened by the Department on November 23, 2020, and shows that robust public input is critical.

The proposed rule would create a significant administrative burden for HHS that would divert resources from critical work, including efforts to address the COVID-19 pandemic. HHS itself 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 However, these estimates likely underestimate the time and money involved in the review process, and do not accurately account for complications that may arise.

Furthermore, the pandemic has shown the importance of health care, public health and human services programs administered by HHS and any additional burdens placed on agency staff should be considered. Complying with the proposed rule is likely to hamper HHS's ability to focus on the administration of current programs, to issue new regulations and appropriately review current regulations that need modification. The Department should instead utilize staff and resources to strategically promote the health and well-being of the American people, providers and communities that rely on program administered by HHS.

Regulations play an important role in implementing HHS policies and programs relied upon by our nation's people. For example, regulations implement safety net programs such as Medicaid and the Children's Health Insurance Program (CHIP), which provide health coverage for over 75.5 million people, 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 beneficiaries what their entitlement means. If regulations were to simply disappear, the programs and millions of people would suffer. In addition, several regulations implementing important parts of the Affordable Care Act approaching their ten-year anniversary would be subject to the proposed rule, including the Medicaid cost-sharing rule.

Older Americans would also be vulnerable were this proposal to be finalized. For instance, many Medicare Advantage (MA) and Part D marketing regulations protect Medicare beneficiaries from misleading and high-pressure marketing tactics that could result in enrollment in an inappropriate or inadequate health plan or result in the purchase of unnecessary ancillary products or services. A substantial number of these regulations were established shortly after the passage of the Medicare Modernization Act with the core marketing regulations finalized in

¹ 5 Federal Register. 70112

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.*

2008, well beyond the 10-year timeline contemplated by this rule, and remain just as vital today as when they were adopted.

The proposed rule would create legal uncertainty regarding the validity and enforceability of these and thousands of other regulations throughout the review process. In many cases, the underlying laws would still exist even if the regulations expire, leaving providers, states, beneficiaries and other stakeholders without clear guidance on how to implement provisions of the underlying laws.

HHS asserts in the proposal that automatic expiration dates give it the incentive necessary to conduct regular assessments of existing regulations and comply with the Regulatory Flexibility Act (RFA). Indeed, HHS agencies already 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.⁴ 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.”⁵ Nothing in the law authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations.

The proposal is also at odds with the Administrative Procedure Act’s (APA) requirements for rulemaking, which include 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 While federal agencies clearly can include sunset dates in regulations and amend existing regulations, the proposed rule seeks to amend thousands of separate, distinct rules across HHS in a single stroke. The proposal is at odds with 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. It does not provide a meaningful opportunity for the public to comment on potential changes to specific regulations. If notice-and-comment rulemaking is necessary to create a regulation, it is also necessary to modify or delete a regulation.

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 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).

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In closing, we strongly urge HHS not to finalize the SUNSET NPRM given its harmful consequences for the agency, the laws HHS is charged with implementing and the millions of people, states and entities that rely on programs established under those laws. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director, Public Policy, at 202-721-6300. Thank you for the opportunity to share our views.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa A. Smith". The signature is fluid and cursive, with the first name "Lisa" being the most prominent.

Lisa A. Smith
Vice President
Advocacy and Public Policy