



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 National Adult Day Services Association (NADSA) represents 5,600 centers serving over one-quarter million aged and/or adults with disabilities. We appreciate the opportunity to provide comments to the Department of Health and Human Services (HHS) proposed rule, “Securing Updated and Necessary Statutory Evaluations Timely” (hereinafter referred to as the “Regulations Rule”). 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. The Regulations Rule is an ill-conceived proposal that would create tremendous administrative burden for HHS and would wreak havoc across a broad swath of Department programs and regulated entities from Medicaid and Medicare to Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). We also strongly object to and believe the truncated 30-day comment period is insufficient for a rule of this broad scope with potentially harmful effects. We urge HHS to immediately withdraw this proposed rule.

The proposed rule would create tremendous administrative burden for HHS

HHS asserts that the Regulations Rule will promote “accountability, administrative simplification [and] transparency. . . .”¹ In fact, the proposed rule would create a significant administrative burden 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

¹ 85 Fed. Reg. 70104.

² 85 Fed. Reg. 70116.

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.

The Regulations Rule would adversely affect HHS's ability to focus on the administration of current programs, to issue new regulations, and appropriately review current regulations that need modification. In addition, several regulations implementing important parts of the Affordable Care Act are approaching their ten-year anniversary, like the Medicaid cost-sharing rule. Regulations like these would need to be reviewed within the next two years, or they would expire. However, the underlying law still exists, even if the regulations expire. Without the cost-sharing rule, states would not have clear guidance on how to implement cost-sharing amounts.

Many regulations relating to Long-term Supports and Services (LTSS) and Home and Community Based Services (HCBS) will be caught in this dragnet of expiration leaving many of our most vulnerable citizens in limbo without adequate services. Especially during crisis situations like COVID-19, it is critically important that HHS have the flexibility and bandwidth to shift focus and respond quickly to immediate needs.

The current rule would wreak havoc across all HHS programs

Regulations play an important role in implementing HHS policies and programs including 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. Medicare Advantage plans, which at this very time are enrolling consumers, will be threatened with losing some regulations but not others making functional integration next to impossible. The Regulations Rule would create legal uncertainty regarding the validity and enforceability of regulations throughout the review process.

The bigger danger posed by the Regulations 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 summarily expire, potentially leaving vast, gaping holes in the regulatory framework implementing HHS programs and policies.

For example, multiple insurance affordability programs including Medicaid and CHIP rely on regulations at 42 C.F.R. § 435.603 to determine financial eligibility using Modified Adjusted Gross Income (MAGI) methodologies. If this regulation were to simply disappear, programs would be free to redefine MAGI household and income counting rules, with no standards, consistency, or accountability. Arbitrarily rescinding large swaths of regulations would wreak havoc in HHS programs, leading to untold harm to the millions of people who rely on those programs.

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.*

The proposed rule is unnecessary and HHS does not have the authority to propose automatic expiration dates on almost all regulations.

The Regulations Rule claims that automatic expiration dates give HHS the incentive necessary to conduct regular assessments of existing regulations and comply with the Regulatory Flexibility Act (RFA). First, 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 In 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations.⁵ CMS 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 CMS spent nearly a decade constructing the HCBS settings rule it published in 2014 and has since reviewed and extended implementation dates twice. HHS’ contention 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.

In fact, this proposal is contrary to 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

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-medicaid-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-medicaid-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).

process to revise or rescind a rule as they would for a new rule, with public notice and the opportunity to comment.¹⁰

HHS states it has authority under the APA to add end dates, or conditions whereby a previously promulgated rule would expire.¹¹ We do not dispute that federal agencies can later amend existing regulations. However, the Regulations Rule would modify thousands of separate, distinct rules across HHS in a single stroke, in violation of the APA. HHS' attempt 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,

Conclusion

This Regulations Rule appears to be nothing more than a last-minute attempt by an out-going administration to roll back and destroy duly promulgated regulations by retroactively imposing an arbitrary end date. In short, this rule is both unnecessary and will wreak havoc upon current HHS programs. Furthermore, the very immensity of it will divert staff from addressing critical issues like the COVID-19 pandemic. We strongly oppose this rule, and urge HHS to withdraw it immediately.

Thank you for the opportunity to comment on this important issue. If you have further questions, please contact me at your convenience.

Sincerely,



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¹⁰ 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).

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