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:

On behalf of the National Council for Behavioral Health (National Council), we appreciate the opportunity to provide comments on 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 National Council serves as the unifying voice of America’s health care organizations that deliver mental health and addiction treatment services. Together with our 3,326 member organizations serving over 10 million adults, children and families living with mental illnesses and addictions, the National Council is committed to all Americans having access to comprehensive, high-quality care that affords every opportunity for recovery.

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 proposal would create tremendous administrative burden for HHS and would result in significant disruption across a broad swath of Department programs and regulated entities that individuals living with mental health and substance use disorders rely upon, from Medicaid and Medicare to Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). We urge HHS to 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]](#footnote-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]](#footnote-2) Within the first two years, HHS estimates the need to assess at least 12,400 regulations that are over 10 years old.[[3]](#footnote-3) However, these figures likely underestimate the time and money required to conduct 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. Several regulations implementing important parts of the Affordable Care Act are approaching their ten-year anniversary, such as the Patient Protection and Affordable Care Act, Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Rule, which would need to be reviewed in the two years. The rule established HHS’ belief that the benchmark approach to the statutorily required Essential Health Benefits, which include mental health and substance use disorder services best struck the balance between comprehensiveness, affordability, and state flexibility. In addition, without regulations prohibiting health insurance carriers from discriminating against individuals with pre-existing conditions, millions of Americans could be left without access to affordable coverage. 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 rule could significantly disrupt current HHS programs/requirements**

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. For example, the Medicare Program: Conditions of Participation for Community Mental Health Centers (CMHCs) Rule, provided for the conditions of participation – conditions that prioritized client care, staff and provider operations, and client/provider collaboration in care planning - that CMHCs must meet in order to participate in Medicare, allowing for standardization and reliability across CMHCs. 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.

Regulations implementing the 2008 Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act have provided important protections for individuals experiencing mental illness or substance use disorders. HHS, in collaboration with the Departments of Labor and Treasury, went through a lengthy rulemaking process to establish extensive final regulations ensuring that individuals with these conditions will be assured of health coverage in commercial plans and Medicaid managed care that is comparable to, and no more restrictive than, coverage provided for medical/surgical conditions. If these regulations were to sunset, the Departments would have to spend time and energy repeating their extensive rulemaking. Without clarity for plans and consumers on if or how the regulations would change, millions of Americans could lose access to important – often lifesaving – benefits.

Additionally, 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 disrupt HHS programs/requirements, leading to untold harm to the millions of people who rely on those programs.

**The proposed rule is unnecessary as evidenced by the regulatory history and HHS lacks the authority to propose automatic expiration dates when it would impact nearly 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]](#footnote-4) In 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations.[[5]](#footnote-5) CMS took nearly a year to review and consider the 875 comments submitted, publishing the final rulemaking in May 2016.[[6]](#footnote-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]](#footnote-7) HHS’ contention that it needs to “incentivize” regulation review by imposing a mandatory rescission is simply not supported by the regulatory history.[[8]](#footnote-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]](#footnote-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 process to revise or rescind a rule as they would for a new rule, with public notice and the opportunity to comment.[[10]](#footnote-10)

HHS states it has authority under the APA to add end dates, or conditions whereby a previously promulgated rule would expire.[[11]](#footnote-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 seeks to amend.

**Conclusion**

The Regulations Rule proposal would create tremendous administrative burden for HHS and would result in significant disruption across a broad swath of Department programs and regulated entities that individuals living with mental health and/or substance use disorders rely upon, from Medicaid and Medicare to the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). We strongly oppose this rule and urge HHS to withdraw it immediately. The National Council appreciates the opportunity to provide these comments. We welcome any questions or further discussion about the recommendations described here. Please contact Reyna Taylor at [ReynaT@thenationalcouncil.org](mailto:ReynaT@thenationalcouncil.org). Thank you for your time and consideration.

Sincerely,

1. 85 Fed. Reg. 70104. [↑](#footnote-ref-1)
2. 85 Fed. Reg. 70116. [↑](#footnote-ref-2)
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.* [↑](#footnote-ref-3)
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>. [↑](#footnote-ref-4)
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>. [↑](#footnote-ref-5)
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>. [↑](#footnote-ref-6)
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>. [↑](#footnote-ref-7)
8. 85 Fed. Reg. 70099, 70106. [↑](#footnote-ref-8)
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). [↑](#footnote-ref-9)
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). [↑](#footnote-ref-10)
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. [↑](#footnote-ref-11)