December 4, 2020

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

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

Dear Secretary Azar:

The Consortium for Citizens with Disabilities (CCD) is the largest coalition of national organizations working together to advocate for federal public policy that ensures the self-determination, independence, empowerment, integration, and inclusion of children and adults with disabilities in all aspects of society. CCD members represent a broad range of stakeholders – people with disabilities and their families, older adults, disability service providers and workers, healthcare professionals, and state systems that provide disability services – who advocate on behalf of adults and children with all types of disabilities, including people with physical, intellectual, developmental, and mental health disabilities, chronic health conditions, and older adults. We are writing on behalf of the Long Term Services and Supports and Health Task Forces.

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 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 the truncated 30-day comment period

820 First Street, NE Suite 740 • Washington, DC 20002 • PH 202-567-3516 • FAX 202-408-9520 •
Info@c-c-d.org • www.c-c-d.org

which 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 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 implementing the Medicaid program are found at 42 CFR Parts 430 to 436, 438, 440-442, 447, and 455-456. The first six parts alone contain over 450 separate CFR sections. Most of those sections are at least ten years old, which means that they would each have to be "Assessed" and if necessary, "Reviewed" before 2023, or they would expire. The remaining eight parts contain hundreds more sections. The regulations implementing the CHIP program are found in 42 CFR Part 457. That part has over 155 separate sections, the majority of which were promulgated over ten years ago. In short, the proposed rule would require that, over the next two years, CMS "Assess" and, if necessary, "Review" well over a thousand Medicaid and CHIP "regulations" in order to avoid or postpone their automatic expiration. This would be a colossal and indefensible waste of resources.

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.

---

[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.*

CMS and other HHS departments must have the flexibility and bandwidth to respond quickly to crises and changing circumstances, yet the sheer breadth of the proposed undertaking would necessarily divert HHS resources away from essential functions. For example, throughout the COVID-19 crisis, CMS had to swiftly approve hundreds of Appendix K waivers and state plan amendments just so people with disabilities could remain safely in their home. If this rule had been in place and CMS staff were hamstrung by unnecessary administrative reviews, they may not have been able to pivot quickly and review and approve states' crucial changes.

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. Medicaid in particular is a lifeline for people with disabilities. One in three adults under age 65 enrolled in Medicaid have a disability, and Medicaid is the primary payer of long term supports and services, including home and community based services, as well as the primary payer for behavioral health services. 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. 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.

Another rule that would potentially "expire" within the next several years is the "Home and Community Based Services (HCBS) Settings Rule," codified in 2014 at 42 C.F.R. 441.301. This rule limits the provision of HCBS funding to settings that are integrated, selected by the individual from among setting options, ensures privacy, dignity, respect and freedom coercion and restraint; optimizes autonomy; facilitates choice, and provides certain additional protections in provider-owned or controlled settings. States, advocates, and other stakeholders have poured countless hours into implementing this rule, and rescinding it would be a tremendous waste of all the resources invested into implementation.

This proposed "SUNSET rule" would also put the Medicaid managed care rule at risk. As of July 2019, 24 states have implemented capitated Medicaid managed long term services and supports (MLTSS) programs, with several more in development.[4] Over 1.8 million individuals are now enrolled in these programs.[5] The Medicaid managed care rule underwent a major update in 2016, as described below, in part to adapt to this increase by improving protections for LTSS users, including people who use Home and Community-Based Services (HCBS). The rule created beneficiary support system, added new federal network adequacy protections for LTSS, and mandated that states implement more performance measures to improve HCBS quality and oversight. But under the SUNSET rule, many of these new protections might be under threat when they reached the 10 year threshold. If resources were not available to "renew" them, they would simply expire.

Other lower profile regulations serve equally important purposes. For example, in 2001, CMS published a rule that protects children in psychiatric residential treatment facilities (PRTFs) from restraint and seclusion used as a means of "coercion, discipline, convenience or retaliation."[6] This rule took ten years to craft, and carefully balances the need for emergency interventions with reasonable limits, evaluation of each child's unique needs, extensive safety monitoring and reporting, and other requirements to ensure that youth experiencing psychiatric crises are not subjected to abuse. Abruptly withdrawing this rule would put thousands of children at immediate risk, with little to no recourse.

---

[4] Kathleen Gifford et al., Kaiser Fam. Found., *A View from the States: Key Medicaid Policy Changes: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2019 and 2020*, 69 (Oct. 2019), https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/;

[5] Elizabeth Lewis et al., Truven Health Analytics, *The Growth of Managed Long-Term Services and Supports Programs: 2017 Update*, 4 (Jan. 2018), https://www.medicaid.gov/media/3406.

[6] 42 C.F.R. Part 483, Subpart G (Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals under Age 21).

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.[7] In 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations, as noted above.[8] CMS took nearly a year to review and consider the 875 comments submitted, publishing the final rulemaking in May 2016.[9] 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."[10] HHS' contention that it needs to "incentivize" regulation review by imposing a mandatory rescission is simply not supported by the facts.[11]

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."[12] However, nothing in this forty year-old law

---

[7] 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.

[8] 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.

[9] 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.

[10] 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.

[11] 85 Fed. Reg. 70099, 70106.

[12] 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).

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.[13]

HHS states it has authority under the APA to add end dates, or conditions whereby a previously promulgated rule would expired.[14] 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

The Regulations Rule is simply an attempt to sabotage and destroy duly promulgated regulations, by retroactively imposing an arbitrary expiration date. This rule is unnecessary, will wreak havoc in current HHS programs, and will tie the hands of the incoming Administration by detracting from critical issues like the COVID-19 pandemic, to undertake this time-consuming process. We strongly oppose this rule, and urge HHS to withdraw it immediately. Thank you for the opportunity to comment on this important

[13] 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).

[14] 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.

issue. If you have further questions, please contact Jennifer Lav (lav@healthlaw.org) or David Machledt (machledt@healthlaw.org)

Sincerely,

Jennifer Lav
National Health Law Program

Sarah Meek
American Network of Community Options and Resources

Nicole Jorwic
The Arc of the United States

Julia Bascom
Autistic Self Advocacy Network

Alison Barkoff
Center for Public Representation

Co-Chairs, CCD Long Term Services and Supports Task Force

David Machledt
National Health Law Program

Rachel Patterson
Epilepsy Foundation

Erin Shea
Center for Public Representation

Natalie Kean
Justice in Aging

Peter Thomas
Brain Injury Association of America

Co-Chairs, CCD Health Task Force