



**CONSORTIUM FOR CITIZENS
WITH DISABILITIES**

December 28, 2021

The Hon. Xavier Becerra, 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, Proposal to Withdraw or Repeal

Dear Secretary Becerra:

On behalf of the Consortium for Citizens with Disabilities' (CCD) Long Term Services and Supports and Health Task Forces, we write in support of the Department of Health and Human Services' (HHS) proposal (hereinafter "Repeal Rule") to withdraw or repeal the Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) final rule.¹ 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 free from racism, ableism, sexism, and xenophobia, as well as LGBTQ+ based discrimination and religious intolerance.

We appreciate the opportunity to comment on the HHS's proposed rule to withdraw or repeal the SUNSET final rule. If implemented, the SUNSET final rule would wreak havoc in HHS programs and activities by imposing a retroactive expiration date on an estimated 18,000 duly promulgated regulations.² We support its withdrawal or repeal.

¹ U.S. Department of Health and Human Srvs., Securing Updated and Necessary Statutory Evaluations Timely, Proposal to Withdraw or Repeal RIN 0991-AC24 (Notice of Proposed Rulemaking), 85 Fed. Reg. 59906-59931 (Oct. 29, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-10-29/pdf/2021-23472.pdf> (proposing to withdraw or repeal U.S. Department of Health and Human Srvs., Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5694 (Jan. 19, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-01-19/pdf/2021-00597.pdf>).

² 86 Fed. Reg. 5737.

The rule would create significant administrative burden for HHS

HHS now recognizes that the assessment and review process mandated by the SUNSET final rule “would be a colossal undertaking.”³ The data collection and analysis required for assessing and reviewing thousands of regulations would be, according to the Repeals Rule, “infeasible.”⁴ We agree. As we explained in our earlier comments, if implemented, the SUNSET final rule would create a significant administrative burden that would divert resources from critical work, including efforts to address the COVID-19 pandemic.⁵

HHS previously estimated that the SUNSET rule would cost nearly \$26 million dollars over 10 years, representing 90 full-time staff positions.⁶ However, these estimates were likely a minimum assessment of the time and money involved in the review process, and did not accurately account for complications that may arise. HHS also did not account for the costs that would be passed along to states, providers, and beneficiaries who rely on regulations that are arbitrarily rescinded if they are not properly assessed and reviewed.

For example, the first six parts alone of the regulations implementing the Medicaid program -- 42 CFR §§ 430 to 436 -- contain over 450 separate CFR sections. Most of those sections are at least ten years old, which would require each to be “Assessed” and if necessary, “Reviewed” before 2026, or they would expire. The remaining eight parts of Medicaid regulations contain hundreds more sections. CHIP regulations span over 155 separate sections, the majority of which were promulgated over ten years ago.⁷ In short, if implemented, the SUNSET rule would require that, over the next five 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 SUNSET 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 five 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.

³ 86 Fed. Reg. 59912.

⁴ *Id.*

⁵ Ltr. From Consortium for Citizens with Disabilities, to Alex Azar II, Sec’y, U.S. Dep’t Health & Hum. Servs., NHeLP Comments on RIN 0991–AC24 Securing Updated and Necessary Statutory Evaluations Timely (Dec. 4, 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0222> .

⁶ 85 Fed. Reg. 70116.

⁷ 42 CFR § 457.

HHS now recognizes that “[t]he proposed withdrawal or repeal rule would generate cost savings to the Department from reductions in staff time spent on assessments and reviews, and on related activities. It would also generate cost savings to the general public by reducing time spent on public comments related to these assessments and reviews, and on other activities, such as monitoring potentially expiring regulations.”⁸ 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 SUNSET rule would wreak havoc on 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. Roughly 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 SUNSET rule, if implemented, would create legal uncertainty regarding the validity and enforceability of regulations throughout the review process.

The bigger danger posed by the SUNSET final rule is that important regulations will likely slip through the cracks of this complicated and time-consuming assessment and review process. Such regulations 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 expired, agencies would have leeway to redefine MAGI household and income counting rules, with few standards, consistency, or accountability. As we emphasized in our earlier comments, arbitrarily rescinding large swaths of

⁸ 86 Fed. Reg. 59924.

regulations would wreak havoc in HHS programs, leading to untold harm to the millions of people who rely on those programs.⁹

Another rule that might “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 integrated in the community and selected by the individual from among setting options, that ensure privacy, dignity, respect and freedom coercion and restraint; optimize autonomy; facilitate choice, and provide 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 for lack of “review” would cause tremendous disruption and potentially waste of all those investments in implementation.

If implemented, the 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.¹⁰ Over 1.8 million individuals are now enrolled in these programs.¹¹ 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.”¹² 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

⁹ See CCD Comments, note 5, *supra*.

¹⁰ 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-medicaidpolicy-changes-long-term-services-and-supports/>

¹¹ 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>.

¹² 42 C.F.R. § 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).

psychiatric crises are not subjected to abuse. Abruptly withdrawing this rule would put thousands of children at immediate risk, with little to no recourse.

When finalizing the SUNSET rule, HHS dismissed concerns raised by commenters that safety net programs could experience disruption, with dire consequences for the people who rely on those programs including persons with disabilities, people of color, LGBTQ+ persons, and other low income people.¹³ We welcome HHS's reevaluation, that "HHS now believes that commenters have raised credible concerns that the SUNSET final rule would likely result in actual expiration of regulations and that these expirations would adversely impact them. Although these comments were raised regarding the SUNSET proposed rule, the SUNSET final rule discounted their seriousness, and did not give them sufficient consideration and weight."¹⁴

The SUNSET final rule would harm not only HHS programs and operations, but states, regulated entities, and millions of people with disabilities who rely on those programs. We strongly support full withdrawal or repeal of the rule.

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

When it originally promulgated the SUNSET rule, HHS claimed that automatic expiration dates gave the agency the incentive necessary to conduct regular assessments of existing regulations and comply with the Regulatory Flexibility Act (RFA). But this incentive already exists. 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.¹⁵ In 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations.¹⁶ CMS took nearly a year to review and consider the 875 comments submitted, publishing the final rulemaking in May 2016.¹⁷ The Trump administration undertook further rulemaking to revise Medicaid managed

¹³ 86 Fed. Reg. 5709.

¹⁴ 86 Fed. Reg. 59916.

¹⁵ 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>.

¹⁶ 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>.

¹⁷ 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),

care regulations, to “relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care.”¹⁸ HHS does not need to “incentivize” regulation review by imposing an arbitrary and mandatory rescission timeline.

Further, though 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,” nothing in this forty year-old law authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations.¹⁹ As HHS notes in the proposed Repeal Rule, the “SUNSET final rule imposes requirements beyond the requirements of the RFA.”²⁰ We agree.

In fact, the framework of the SUNSET final rule runs 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.²¹

The SUNSET final rule claims that HHS has authority under the APA to add end dates, or conditions whereby a previously promulgated rule would expire. We do not dispute that federal agencies can amend existing regulations. However, the SUNSET final rule would modify thousands of separate, distinct rules across HHS in a single stroke, in violation of the APA. The blanket amendment of 18,000 regulations that the SUNSET final rule is currently attempting does not meet the fact-finding requirements mandated by the APA for amendment of existing regulations.

<https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered>.

¹⁸ 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>.

¹⁹ 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).

²⁰ 86 Fed. Reg. 59917.

²¹ 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).

Conclusion

The blanket amendment of 18,000 regulations that the SUNSET final rule is currently attempting does not meet the fact-finding requirements mandated by the APA for amendment of existing regulations. Thank you for the opportunity to comment on this important issue. If you have further questions, please contact David Machledt (machledt@healthlaw.org).

Respectfully Submitted,

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