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December 16, 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:

The National Health Law Program (NHeLP) has worked to improve health access and quality through education, advocacy and litigation on behalf of low-income and underserved individuals for over 50 years. We appreciate the opportunity to provide comments on the Department of Health and Human Services' (HHS) proposed rule to withdraw or repeal the Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) rule.¹ 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 welcome HHS's recognition that, before finalizing the SUNSET rule, "the Department should have engaged in a more robust consideration of the comments, should have more thoroughly examined the factual and legal basis of the rule, and should have given greater weight to the potential harms to stakeholders and the public health."³ We strongly support HHS's proposal (hereinafter "Repeal Rule") to withdraw or repeal the SUNSET final rule.

**Retroactively imposing blanket expiration date on duly
promulgated regulations is unlawful**

The SUNSET rule retroactively imposes a mandatory expiration date on an estimated 18,000 regulations.⁴ Even long-standing

rules would be automatically rescinded unless they survive a complex process of assessment and review.

When it originally promulgated the SUNSET rule, HHS cited to authority under the Regulatory Flexibility Act (RFA), which requires executive agencies to periodically review current rules.⁵ 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.”⁶ However, nothing in this forty year-old law authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations. As HHS notes in the proposed Repeal Rule, the “SUNSET final rule imposes requirements beyond the requirements of the RFA.”⁷ We agree.

Additionally, 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.⁸ 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.⁹ We do not dispute that federal agencies can amend

¹ U.S. Department of Health and Human Svcs., 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 Svcs., 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.

³ 86 Fed. Reg. 59909.

⁴ 86 Fed. Reg. 5737.

⁵ See 86 Fed. Reg. 5695, citing to the Regulatory Flexibility Act (RFA), Pub. Law 96–354, 94 Stat. 1164 (Sept. 19, 1980), <https://www.govinfo.gov/content/pkg/STATUTE-94/pdf/STATUTE-94-Pg1164.pdf>; 5 U.S.C. § 610(a).

⁶ 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).

⁷ 86 Fed. Reg. 59917.

⁸ 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/sqp/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).

⁹ 86 Fed. Reg. 5703, fn 104 & 105, citing to separate, specific rulemakings modifying interim final rules implementing mental health parity and foreign quarantine provisions, respectively.

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.

Under the plain language of the APA and affirmed in well-established case law, a final agency rule promulgated through notice and comment can only be revised or rescinded through an additional notice and comment rulemaking process.¹⁰ The plain language of the APA states that notice and comment rulemaking is required for “amending, or repealing a rule.”¹¹ In addition, the case law clearly anticipates that amending an existing rule take place on an individual basis, requiring specific fact-finding relevant to the individual rule that the agency wants to amend, and not as HHS proposes, via universal, wholesale revisions.

When an agency seeks to change an existing policy promulgated by notice and comment rulemaking, that agency must “at least ‘display awareness that it is changing position’ and ‘show that there are good reasons for the new policy.’”¹² In addition, agency action is arbitrary and capricious, in violation of the APA, if the agency fails to “examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choices made.’”¹³ The Supreme Court has made clear that “[i]t would be arbitrary and capricious to ignore” factual findings which underlay a prior policy.¹⁴ 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.

Even more troubling, in the SUNSET final rule, HHS rejected the APA’s definition of regulation and instead claims that “for the purposes of this rule” regulation is defined as “a section of the Code of Federal Regulations.”¹⁵ HHS sought to justify this by claiming that the APA’s definition could create confusion “in certain circumstances about what needs to be reviewed.”¹⁶ HHS provided no further explanation regarding why it rejects the well-established definitions and procedures from the APA. Moreover, HHS provided no statutory basis for redefining “regulation” here.

¹⁰ See *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 101 (2015) (“agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance”).

¹¹ 5 U.S.C. §§ 553(a)(2); 551(5).

¹² *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2126 (2016) (citations omitted).

¹³ *State Farm*, 462 U.S. at 42 (quoting *Burlington Truck Lines v. U.S.*, 371 U.S. 156, 68 (1962)).

¹⁴ *F.C.C. v. Fox Television Stations, Inc.*, 555 U.S. 502, 515-16 (2009).

¹⁵ 86 Fed. Reg. 5751. See also 5 U.S.C. § 551(4) (stating that “ ‘rule’ means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing. . . .”).

¹⁶ 86 Fed. Reg. 5720.

Additionally, HHS agencies 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.¹⁷ In 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations.¹⁸ As CMS noted:

Because the health care delivery landscape has changed substantially [...] this rule proposes to modernize the Medicaid managed care regulatory structure to facilitate and support delivery system reform initiatives to improve health care outcomes and the beneficiary experience while effectively managing costs.¹⁹

CMS took nearly a year to review and consider the 875 comments submitted, publishing the final rulemaking in May 2016.²⁰ CMS 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.”²¹ HHS does not need to “incentivize” regulation review by imposing a mandatory rescission.

When it promulgated the SUNSET rule, HHS opined that imposing a blanket rescission date for regulations would provide relief to consumers and small entities because it would “eliminate or streamline unnecessary regulatory burdens.”²² As we noted in our comments on the proposed SUNSET rule, the APA already provides a mechanism whereby regulated entities, advocacy organizations, and individuals can seek changes to outdated, obsolete, or unnecessary regulations.²³ The APA requires that each “agency shall give an interested

¹⁷ 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>.

¹⁸ 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>.

¹⁹ *Id.* at 31101.

²⁰ 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>.

²¹ 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>.

²² 86 Fed. Reg. 5708.

²³ Ltr. From Wayne Turner, Senior Attorney., Nat’l Health L. Program, to Alex Azar II, Sec’y, U.S. Dep’t Health & Hum. Servs., NHeLP Comments on RIN 0991–AC24 Securing Updated and Necessary



person the right to petition for the issuance, amendment, or repeal of a rule.”²⁴ Although HHS previously argued it needed the SUNSET rule’s assessment and review process, the Repeal Rule now acknowledges the value of more targeted tools to identify obsolete or outdated regulations: “[f]or example, the Department may request information or use other processes to seek input from small entities and the public to identify such rules in a more targeted way, and the public may use already-existing petition processes to ask HHS to issue, amend, or repeal a rule.”²⁵

Finally, the manner in which HHS finalized the SUNSET final rule is legally suspect. As HHS now acknowledges, “the process to promulgate the rule was extremely unusual, if not unprecedented. The rule is expansive in scope and impact, faced considerable opposition from stakeholders (and very little support), and lacked a public health or welfare rationale for expediting rulemaking.”²⁶ HHS also notes that a wide range of stakeholders submitted more than 500 comments on the proposed SUNSET rule, almost all opposed.²⁷ Despite overwhelming opposition, HHS rushed to finalize the SUNSET rule, issuing the rule less than 16 days after comments on certain portions of the rule were submitted, invariably leading to an untenable, slipshod, and harmful result.²⁸

In sum, the SUNSET final rule violates the APA in both its content, and the manner in which it was promulgated. We strongly support full withdrawal or repeal of the rule

The rule would create tremendous administrative burden

HHS now recognizes that the assessment and review process mandated by the SUNSET final rule “would be a colossal undertaking.”²⁹ The data collection and analysis required for

Statutory Evaluations Timely (Dec. 1, 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0054>.

²⁴ 5 U.S.C. § 553(e).

²⁵ 86 Fed. Reg. 59919.

²⁶ 86 Fed. Reg. 59907.

²⁷ 86 Fed. Reg. 59908. Two of the few comments in favor were from a single individual, who also drafted the regulatory impact analysis for the SUNSET rule. *Id.*, citing to 86 Fed. Reg. 5737 n.210, which credits James Broughel, a researcher and adjunct professor at the Antonin Scalia School of Law, for his contribution to HHS’s regulatory impact analysis. However, whatever analysis Mr. Broughel provided is not part of the publicly available administrative record, nor is it included in public comments on the SUNSET rule. See James Broughel and Kofi Ampaageng, Senior Research Fellows, Mercatus Center at George Mason University, Public Interest Comment – HHS’s Innovative New SUNSET Regulation (Dec. 4, 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0267>, and James Broughel, Book chapter submission - Zero-based Regulation (Dec. 4, 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0257>.

²⁸ Comments on the SUNSET proposed rule were due December 4, 2020, except for portions of the rule amending 42 CFR parts 400-429 and parts 475-499 (the Medicare program regulations) that were due on January 4, 2020. The SUNSET rule was finalized on January 19, 2020.

²⁹ 86 Fed. Reg. 59912.



assessing and reviewing thousands of regulations would be, according to the Repeals Rule, “infeasible.”³⁰ 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.³¹

HHS previously estimated that the SUNSET rule would cost nearly \$26 million dollars over 10 years, representing 90 full-time staff positions.³² 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.

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.”³³

Moreover, since the onset of the COVID-19 pandemic, Congress has enacted four major pieces of legislation to respond to the emergency.³⁴ With these, and the landmark Build Back Better plan currently pending before Congress, HHS needs to devote its full attention to quickly implementing these laws and bring desperately needed relief.

If implemented, the SUNSET final rule would drain critical resources that are needed to address current challenges in the health care landscape. Especially during crisis situations, like the COVID-19 pandemic, it is important that agencies have the flexibility and resources to shift their focus and respond quickly to immediate needs. The SUNSET final rule would create an administrative burden that makes such a response nearly impossible.

³⁰ *Id.*

³¹ NHeLP comments, note 23, *supra*.

³² 85 Fed. Reg. 70116.

³³ 86 Fed. Reg. 59924.

³⁴ Families First Coronavirus Response Act, Pub. L. No. 116-117 (2021), <https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf>; Coronavirus Aid, Relief, and Economic Security Act (CARES), Pub. Law. No. 116-136 (2020), <https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf>; Consolidated Appropriations Act, 2021, Public Law No: 116-260 (2021), <https://www.congress.gov/bill/116th-congress/house-bill/133/text>; American Rescue Plan of 2021, Public Law No: 117-2 (2021), <https://www.congress.gov/117/plaws/publ2/PLAW-117publ2.pdf>.



The 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 nearly 83 million people, including 39 million children.³⁵ 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 makes clear to beneficiaries what their entitlement means.

The SUNSET final rule, if implemented, would create legal uncertainty regarding the validity and enforceability of regulations and would wreak havoc in HHS programs. The SUNSET final rule would create a kind of regulatory purgatory, in which regulations identified during the review process as needing to be amended or rescinded would continue to be in effect for up to two years. HHS admitted that “enforcing a Regulation deemed to require amendment or rescission in some cases raises concerns about whether such enforcement is arbitrary and capricious. Continuing to enforce the Regulation (or portions thereof) would arguably ‘run [...] counter to the evidence before the agency.’”³⁶ However, when finalizing the SUNSET rule, HHS provided no insight or explanation on how it would address this conundrum.

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 were to simply disappear, agencies would be free to redefine MAGI household and income counting rules, with no standards, consistency, or accountability. As we emphasized in our earlier comments, 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.³⁷

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.³⁸ We welcome HHS’s reevaluation, that “HHS now believes that commenters have raised credible concerns that the SUNSET final rule would likely result in

³⁵ CMS, *May 2021 Medicaid & CHIP Enrollment Data Highlights* (accessed Dec. 9, 2021), <https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html>.

³⁶ 85 Fed. Reg. 70108, quoting *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

³⁷ See NHeLP Comments, note 23, *supra*.

³⁸ 86 Fed. Reg. 5709.



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.”³⁹

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

Conclusion

The SUNSET final rule seems driven not by policy, law, or facts. We welcome HHS reconsideration of the rule, and strongly support full withdrawal or repeal of the rule

Finally, we have included citations to research and other materials, including direct links to those materials. We request that the full text of material cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the APA. If HHS is not planning to consider these citations part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies into the record.

If you have questions, please feel free to contact me at (202) 289-7661 or douglas@healthlaw.org or my colleague Wayne Turner at turner@healthlaw.org.

Yours truly,



Dania Douglas
Senior Attorney

³⁹ 86 Fed. Reg. 59916.

