



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:

We are writing on behalf of the Ryan White Working Group (RWWG) and the HIV Health Care Access Working Group (HHCAWG) – coalitions with over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV- and hepatitis C-related health care and support services. RWWG and HHCAWG have served as resources to you and your staff on issues pertaining to people living with HIV, in particular on the ambitious initiative to End the HIV Epidemic you have worked to advance. We appreciate the opportunity to engage with you again as we provide comments on the Department of Health and Human Services (HHS) proposed rule, “Securing Updated and Necessary Statutory Evaluations Timely” (SUNSET Rule).

The proposed rule would retroactively impose an expiration provision on most HHS regulations, and establish new procedures to assess and review to determine which, if any, regulations should be retained or revised. We are very concerned that the SUNSET Rule would not only create tremendous administrative burden for HHS but would cause disruptions to programs across a broad swath of the Department on which the HIV community rely heavily, such as the Ryan White HIV/AIDS Program through the Health Resources and Services Administration (HRSA), and regulated entities like Medicaid and Medicare, the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). HHCAWG and RWWG feel the 30-day comment period does not allow for proper review for a rule of this broad scope with potentially harmful effects. We strongly urge HHS to withdraw this proposed rule.

Unnecessary Administrative Burden for HHS

While asserting that the SUNSET Rule will promote “accountability, administrative simplification [and] transparency” HHS simultaneously 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.^{1,2} 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 total time and money involved in the new review process, and do not accurately account for complications that may arise. The proposed rule would create a significant administrative burden that would divert resources from critical work, including efforts to address the COVID-19 pandemic and Ending the HIV Epidemic initiative, which is counter to the stated intention of the rule.

Not only is it critically important that HHS have the flexibility and bandwidth to pivot quickly to respond to immediate needs during crisis situations like COVID-19, but it is also important that every regulation due for review receive the proper attention and not be subjected to an arbitrary expiration date. Finalizing the SUNSET Rule could stretch already thin federal resources beyond their capacity.

Regulations serve as the guiding directives for how laws should be implemented. Several regulations implementing important parts of the Affordable Care Act are approaching their ten-year anniversary, such as 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 these rules, states would not have clear guidance on how to implement cost-sharing amounts or whether issuers must accept premium and cost sharing payments from third parties including the Ryan White Program. The proposed rule creates an unnecessary burden at all levels, and would cause more disruption to the administration and operation of HHS programs than simplification.

Disruptions to all HHS Programs

Regulations play an important role in implementing HHS policies and programs including safety net programs such as Medicaid, which is the largest provider of health insurance for people living with HIV, covering 42% of the adult population in care.⁴ Approximately 40 percent of Ryan White HIV/AIDS Program clients also have Medicaid coverage. A strong regulatory framework provides the Medicaid program the clarity it needs 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 would create legal uncertainty regarding the validity and enforceability of regulations for Medicaid throughout the review process, which could destabilize the Ryan White Program. State officials and program administrators could delay services to avoid conflicts with federal regulations; any lapse in

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.*

⁴ Kaiser Family Foundation. October 1, 2019. [Medicaid and HIV](#).

coverage, disruption to care, or barrier to treatment for people with HIV can be detrimental, causing irreversible disease progression and prescription drug resistance.

The bigger danger posed by the SUNSET 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, there are multiple civil rights and health information regulations within the Health Insurance Portability and Accountability Act Privacy Rule that clarify and strengthen privacy protections people with HIV at 45 C.F.R. § 164.502.⁵ If this regulation were to simply disappear, insurers, providers, and programs would not be on notice of their obligations to not disclose protected health information such as an HIV diagnosis to unauthorized individuals. Arbitrarily rescinding large swaths of regulations would destroy the foundations of many HHS programs, leading to untold harm to the millions of people living with HIV who rely on those programs to protect their health and information.

Redundancy of Existing Regulations

The proposed rule seems to establish an unnecessary, burdensome, and bureaucratic process on top of processes that already exist under the Regulatory Flexibility Act (RFA).⁶ As directed by the RFA, HHS agencies already update regulations when needed based on their plan to periodically review regulations issued. Most importantly, the RFA does not provide for regulations to automatically expire if a review is not conducted.

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.⁷ The SUNSET Rule would modify thousands of separate, distinct rules across HHS in a single stroke, violating of 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

⁵ HHS. *HIV and HIPAA*. Retrieved December 1, 2020 hhs.gov

⁶ 5 U.S.C. §610. Periodic review of rules

⁷ 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).

The SUNSET Rule will create unnecessary burden and wreak havoc in current HHS programs, diverting resources from current program operations and detracting from critical issues like the COVID-19 pandemic. We have seen the dedication this Administration has shown to the HIV and hepatitis communities through the Ending the HIV Epidemic and other initiatives, and believe there are better ways leave a lasting legacy than this rule will do. 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 feel free to reach out to any of the co-chairs of HHCAWG or RWWG: Merylyn Francis with AIDS United, mfrancis@aidsunited.org; Stephanie Hengst with The AIDS Institute, shengst@taimail.org; Aisha Davis with the AIDS Foundation of Chicago , adavis@aidschicago.org; Rachel Klein with The AIDS Institute, rklein@taimail.org; Emily McCloskey with the National Alliance of State and Territorial AIDS Directors, emccloskey@nastad.org; Phil Waters with the Center for Health Law and Policy Innovation, pwaters@law.harvard.edu.

Respectfully submitted by:

ADAP Educational Initiative	HIV Medicine Association
AIDS Alabama	Housing Works
AIDS Action Baltimore	JustUs Health
AIDS Alliance for Women, Infants, Children, Youth & Families	Legal Council for Health Justice
AIDS Foundation of Chicago	Michigan Positive Action Coalition
AIDS Research Consortium of Atlanta	National Alliance of State and Territorial AIDS Directors
AIDS United	National Latino AIDS Action Network
American Academy of HIV Medicine	National Working Positive Coalition
APLA Health	NMAC
Black AIDS Institute	Positive Health Solutions of the University of Illinois
Cascade AIDS Project (CAP)	Positive Women's Network – USA
Center for Health Law and Policy Innovation	Ryan White Medical Providers Coalition
Communities Advocating Emergency AIDS Relief (CAEAR)	San Francisco AIDS Foundation
Community Access National Network (CANN)	Silver State Equality-Nevada
Equality California	SisterLove
Georgia AIDS Coalition	Southern AIDS Coalition
Harm Reduction Coalition	The AIDS Institute
HealthHIV	Thrive Alabama
HIV+Hepatitis Policy Institute	Treatment Action Group
	Vivent Health