

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,

Fenway Health is a federally qualified community health center (FQHC) whose mission is to enhance the well-being of the LGBTQIA+ community and all people in our neighborhoods and beyond through access to the highest quality health care, education, research and advocacy. Fenway Health advocates for legislation and budget priorities that align with its mission to serve the LGBTQIA+ community, those living with HIV/AIDS, and those who are vulnerable to healthcare access inequities. Healthcare inequity is a racial justice issue, affecting people who are LGBTQIA+, people who inject drugs, people experiencing homelessness, and other marginalized communities. We are committed to breaking down barriers, and work towards the principle that healthcare is a right, not a privilege, particularly for low-income and vulnerable populations. Of the 35,000 patients that Fenway Health serves, 7% are uninsured altogether, and 36% are at or below 200% of the federal poverty level (FPL), which makes them eligible for our sliding fee discount program.

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 proposed SUNSET rule would undermine Medicaid, Medicare, and the health insurance marketplaces, as well as other core functions of government, such as the critically important health and safety work of the Food and Drug Administration and the Centers for Disease Control and Prevention. The rule is totally unnecessary for these programs’ proper administration. If finalized, the rule would require substantial agency staff time to implement, diverting key resources from responding to the COVID-19 crisis, other priorities, and day-to-day program administration, and it has the potential to wreak havoc on HHS programs and harm the people who rely on them.

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

¹ 85 Fed. Reg. 70104.

the COVID-19 pandemic. HHS itself estimates that the proposed rule would cost nearly \$26 million over 10 years, needing 90 full-time staff positions to undertake the required reviews.² Within the first two years, HHS estimates a 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 Rule would adversely affect HHS's ability to focus on the administration of current programs, to issue new regulations, and to appropriately review current regulations that legitimately 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.

As a community health center, we serve as a healthcare safety net for the most vulnerable in our communities. For the approximately 12,600 Fenway patients who access our services by paying only what they can afford, this proposed rule change has the potential to severely disrupt the systems that make healthcare available to them, putting their care in jeopardy, and exacerbating the public health crisis we are navigating. 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.

Regulations play an important role in implementing HHS policies and programs, including safety net programs. A strong regulatory framework provides states the clarity they need to run these programs on a day-to-day basis, gives providers 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.

The rule is unnecessary. HHS already periodically reviews and updates its regulations. HHS annually reviews and updates the Notice of Benefits and Payment Parameters for insurance exchanges and issuers. It also reviews the Basic Health Program's funding methodology, updating requirements based on new information and data. HHS annually reviews and updates certain Medicare regulations to reflect policy and technical changes and new program parameters. In 2016, HHS revised the 2002 regulations governing Medicaid managed care, modernizing the regulations to reflect updated practices.

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.*

The Regulations Rule is simply an attempt to sabotage and destroy duly promulgated regulations, by retroactively imposing an arbitrary end date. In its coverage of the proposed rule, S&P Global reported that “Trump may be laying land mines for Biden with proposal to nix health rules.”⁴ This rule is unnecessary, and would wreak havoc in our health care system—the last thing we need in the middle of raging pandemic. Worse yet, it will tie the hands of the incoming Administration by detracting from critical issues like the COVID-19 pandemic and the economic recession in order to undertake this onerously 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 issue.

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⁴ <https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/trump-may-be-laying-land-mines-for-biden-with-proposal-to-nix-health-rules-61117416>