

October 28, 2020

Director Jennifer Joseph, PhD
Office of Policy and Program Development
Bureau of Primary Health Care
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland, 20857

RE: Notice of Proposed Rulemaking: Implementation of Executive Order 13937, “Executive Order on Access to Affordable Lifesaving Medications.” (HHS Docket No. HRSA-2020-0004 RIN 0906-AB25)

Dear Dr. Joseph,

We at Howard Brown Health appreciate the opportunity to provide input on the Notice of Proposed Rulemaking: Implementation of Executive Order 13937, “Executive Order on Access to Affordable Lifesaving Medications.”

Howard Brown is the largest LGBTQ health center in the Midwest, serving more than 38,000 patients across twelve clinic locations in Chicago. As a Federally Qualified Health Center (FQHC), Howard Brown provides comprehensive, high quality and affordable care—including primary care, behavioral health, mental health services, HIV/STI prevention, elder services and community outreach initiatives—to patients regardless of ability to pay. Through these programs, Howard Brown fulfills its mission of eliminating health disparities and improving health outcomes experienced by LGBTQ individuals and area residents.

Howard Brown shares the Administration’s goal of ensuring that all individuals have access to healthcare and their prescribed medications, regardless of their ability to pay. However, policies intended to advance this goal must consider the impact of fluctuating drug pricing, understand FQHCs’ pivotal role in providing access to medications to under-served patients, and acknowledge the importance of the 340B Program to increase scarce resources to safety net providers such as FQHCs.

We strongly urge the Administration to not issue a final version of this regulation, as it is based on fundamental misunderstandings of how FQHCs and 340B operate, and if implemented would do significantly more harm than good in terms of ensuring access to care for underserved populations. Specifically:

- 1. The Executive Order (EO) reflects fundamental misunderstandings about FQHCs’ mission and operations – and fails to recognize that FQHCs are already part of the solution to unaffordable drug prices, not part of the problem.*

The underlying rationale of the EO is that FQHCs are not passing along savings from the 340B program to our patients. President Trump asserted that community health centers are “receiving discounts for themselves while charging their poorest patients massive, full prices.” This is not the case, and it is a fundamental misunderstanding about the mission and operation of FQHCs. Our mission at Howard Brown, and the mission of all FQHCs across the country, is to ensure that all people can receive high quality and comprehensive care, regardless of their ability to pay.

The EO asserts that FQHCs are benefitting inappropriately from 340B savings rather than passing the savings along to our patients. In reality, FQHCs are subject to intense oversight and have been found to be good stewards of the 340B program.

At Howard Brown, we extend 100% of the 340B Program discount to our uninsured patients so they can afford the vital therapies they need to survive. The vast majority of these patients live with chronic medical conditions that would otherwise become health emergencies without uninterrupted maintenance medications. Where the 340B Program generates savings, Howard Brown reinvests it in patient care to improve health outcomes for our vulnerable patient population in many different ways. This includes expanding our clinical capacity; offering comprehensive and holistic wrap-around support services; providing affordable medications to our under and uninsured patients; and offering a full continuum of care—including primary care, behavioral care, dental care, preventative care, and social support services—to all of our patients.

The 340B Program is especially important to our mission at Howard Brown to eliminate health disparities experienced by LGBTQ people because the savings from the program allows us to provide a full suite of innovative services and programs to LGBTQ patients in a safe, affirming, and nondiscriminatory environment. This EO, especially in concert with recent attacks on the 340B Program by pharmaceutical companies, which in fact DO limit access to life saving medications to our patients, could negatively impact our ability to continue to provide many of these services to our patients.

2. The Executive Order reflects a fundamental misunderstanding of the relationship between drug pricing and the 340B program, and if implemented as written would decrease some patients’ access to affordable drugs.

The EO states that FQHCs pay only one penny for a month's supply of insulin or epipens. This statement is only true in a very limited sense—i.e., for *specific forms of insulin and epipens during specific calendar quarters*—it is far from universally true and does not capture the full picture. 340B pricing has the potential to change the following quarter and these changes can be volatile. Furthermore, depending on the form of the drug, the manufacturer's past pricing decisions, and the calendar quarter, the 340B price for these drugs can often be in the range of \$100 to \$450 per month. In addition, it is not unusual for the 340B price for a one-month supply of a particular brand of insulin to be one penny during one quarter, and over \$100 in another quarter. Thus, it is inaccurate to assume that FQHCs consistently pay only a penny for insulin and epipens. It reflects a very narrow understanding of 340B pricing, and drug pricing more generally. Because the EO requires patients be charged exactly the 340B price, this could lead to situations where our low-income diabetic patients are paying more for their insulin than they normally would because of normal fluctuations in 340B pricing.

While Howard Brown appreciates that the proposed rule diverges from the EO in allowing FQHCs to charge patients less than the 340B price, the fact that the EO cannot be implemented as originally written without harming patients demonstrates the fundamental misunderstandings about drug pricing and FQHCs that the EO was built upon.

3. Defining “low-income” individuals (who are eligible for 340B-or-less-pricing on insulin and epipens) as those with incomes at or below 350% of the Federal Poverty Level:
 - Is inconsistent with any known Federal definition of “low income,”
 - Will impose enormous administrative burdens on FQHCs, and
 - Will eliminate FQHCs' ability to retain 340B savings on insulin and epipens dispensed to privately-insured patients, significantly reducing FQHCs' total 340B savings. The unintended consequence is that savings will be transferred from safety net providers to for-profit private insurers.

HHS' determination that this proposed rule will not have significant impact on FQHC operations is not true. For this proposed rule to establish a definition of “low income” that varies so significantly from the definition used in any other Federal program or from the common understanding of that term will require a change in operation and resources and adds another layer of complexity. For example, adding a new discount requirement with a much different income threshold that applies only to certain patients (those needing insulin or epipens) and only for certain items (insulin and epipens) would create enormous administrative burdens for FQHCs.

For the above stated reasons, Howard Brown strongly opposes the finalization of this proposed rule. While we **strongly urge HHS not to finalize this regulation**, if HHS insists on doing so, we join our colleagues at the National Association of Community Health Centers in strongly urging HHS at least to make the following changes to the regulatory text:

1. With regards to the definition for “low income”, we oppose administratively burdensome and arbitrary differential eligibility requirements for one category of medications, which will be confusing, difficult to administer, and challenging for patients. We therefore recommend deferring to the 200% FPL definition, which has been the definition in place throughout the FQHC program for over 50 years.
2. Add regulatory language to ensure that FQHCs are not forced to provide discounts to underinsured patients if doing so would violate the terms of their insurance contracts.
3. Clarify the definition of “high cost-sharing requirement.”
4. Recognize that, as a result of this regulation, the “minimal administration fee” for insulin and epipens will differ from the fees (if any) associated with dispensing other pharmaceuticals.

Thank you for your consideration of our comment, and we again urge you not to finalize this misguided proposed rule. If you have any questions, please feel free to contact Tim Wang, Director of Policy and Advocacy, at timothyw@howardbrown.org.

Sincerely,



David Ernesto Munar
President and CEO