Howard Brown Health

July 16, 2021

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

RE: Comments on Proposed Rescission of Executive Order 13937, "Executive Order on Access to Affordable Life-Saving Medications" (RIN 0906-AB25)

Dear Director Joseph,

Howard Brown Health 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 to patients regardless of ability to pay. It is through our many programs—including primary care, behavioral health, mental health services, HIV/STI prevention, elder services and community outreach initiatives—that Howard Brown fulfills its mission of eliminating health disparities and improving health outcomes experienced by LGBTQ individuals and residents of the Chicago area and beyond. In order to ensure that we are able to continue to provide comprehensive and affordable care to all of our patients, we strongly support this proposed rule by the Department of Health and Human Services to rescind the Final Rule implementing Executive Order 13937.

While the Final Rule implementing EO 13937 was intended to increase access to affordable insulin and epinephrine, it did not fully understand FQHC operations and 340B Program mechanics, nor did it consider the possible negative consequences. **If the Final Rule is implemented, it will do more harm than good in terms of ensuring access to care and medications for underserved populations**

Both the Final Rule and EO 13937 had a flawed understanding of the 340B program requirements and the crucial role that FQHCs play in bridging low-income patients to essential resources including medications. FQHCs like Howard Brown are nonprofit providers whose mission is to make insulin and other medications affordable for low-income patients, and we are able to do this in large part because of the 340B program. The EO incorrectly asserts that FQHCs are benefitting inappropriately from 340B savings, when in reality, 100% of our 340B savings are used to increase access and services for our unique patient population. For example, many of our patients live with chronic medical

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conditions that would otherwise become health emergencies without uninterrupted maintenance medications. 340B program savings have helped us to expand our clinical capacity, provide affordable medications and offer holistic wrap-around services to ensure our patients have access to the resources they need to stay healthy, especially during the pandemic.

If the Final Rule is implemented, it could threaten to undermine the services that we are able to provide to our low-income and uninsured patients, both by decreasing 340B savings and also by increasing financial and administrative burden on health centers. Examples of this added administrative burden include:

- Creating new work flow processes, and policies and procedures which would include how to
  - Determine in real time whether a patient has a high remaining deductible – a process that is particularly complicated given delays in medical billing and claims processing.
  - Adjust the charge for qualifying patients for every form of insulin and injectable epinephrine every quarter, when the 340B price changes.
  - Keep Third Party Administrators, contract pharmacies, and other pharmacy partners abreast of and compliant with new charges, eligibility rules, etc.

The Final Rule is also problematic because it would redefine "low income" as people with income below 350% of the Federal Poverty Level (FPL), which is inconsistent with the definition of low income for every other Federal program. Because this change to the definition of "low income" is not broadly applicable across federal programs, it could create significant logistical and administrative burden for health centers and other federal grantees to navigate different poverty thresholds for different programs. For example, FQHCs are required to offer sliding scale fee discounts for uninsured patients with incomes below 200% FPL, but would have to create and implement new eligibility screening and billing procedures just for patients with incomes below 350% FPL that need access to insulin and epinephrine for the purpose of implementing this Final Rule.

Based on HRSA's estimate, implementing the Final Rule would require each health center organization to hire one additional full-time equivalent (FTE) worker at approximately $50,000 annually just to help with all of the administrative work required to determine eligibility under the Final Rule. This money and staff time would be better spent on our already existing efforts to help patients access affordable medication and treatment. This undue administrative burden is also particularly harmful as FQHCs have been working tirelessly over the course of the pandemic to care for underserved communities who have been hit hardest by COVID-19.

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Additionally, this Final Rule does not address the rising cost of insulin and epinephrine nor the source of issue. Drug prices are set by the drug manufacturing companies, and they have caused the price of insulin to skyrocket over the last decade. This regulation would do nothing to change the price that drug companies charge for insulin. Instead of helping more people afford insulin, this regulation would harm FQHCs by imposing burdensome new requirements and reducing their ability to support discounts on medications and other services.

We are concerned that if this Final Rule is not rescinded, it would in fact decrease patients' access to affordable drugs. For these reasons, we support the rule to rescind the Final Rule, and we also urge the Administration to revoke the "Executive Order on Access to Affordable Lifesaving Medications" on which the Final Rule was based.

Thank you for your consideration of these comments.

Sincerely,

David Ernesto Munar, President and CEO
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