

March 14, 2021

Dr. 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

Submitted on-line at www.federalregister.gov/d/2021-05165

RE: Comments on HHS Docket No. HRSA-2021-000 -- Proposal to delay effective date of regulation entitled "Implementation of Executive Order on Access to Affordable Life-saving Medications" until July 20, 2021

Dear Dr. Joseph,

Howard Brown Health is the largest LGBTQ health center in the Midwest, serving over 38,000 patients across twelve clinic locations in Chicago. As a federally qualified health center (FQHC), Howard Brown provides primary care, behavioral and mental health services, HIV/STI prevention, social services, and community support initiatives to our patients regardless of insurance coverage or ability to pay. We are writing today to express our strong support for delaying the effective date of the regulation entitled "Implementation of Executive Order on Access to Affordable Life-saving Medications" (hereafter, "the regulation") until at least July 20, 2021, as proposed at www.federalregister.gov/d/2021-05165.

First, extending the delay is consistent with the "Regulatory Freeze Pending Review" issued by the White House Chief of Staff on January 20, 2021. The Regulatory Freeze memo states that "where necessary to continue to review these questions of fact, law, and policy" agencies should "consider further delaying, or publishing for notice and comment proposed rules further delaying, such rules beyond the 60-day period." As indicated by the large volume and range of comments submitted last fall in response to the proposed rule implementing this Executive Order, the regulation raises significant questions of "fact, law, and policy." Given the critical role that HRSA's Bureau of Primary Health Care (BPHC) is playing in national efforts to provide COVID vaccinations to medically underserved populations, it is understandable that BPHC was unable to address all the questions raised in the public comment period during the initial 60-day delay. Per the Regulatory Freeze memo, the delay should be extended in order to fully address and investigate these questions.

The Regulatory Freeze memo also states that pending rules should be reviewed and approved by “a department or agency head appointed or designated by the President after noon on January 20, 2021.” Neither an HHS Secretary nor a HRSA Administrator have been appointed yet under the current Administration, so there has not been an opportunity for an individual in either of these positions to review this regulation, or to delegate their authority to another individual. As a result, the regulation’s effective date must be delayed at least until a HHS Secretary or HRSA Administrator has been appointed and is able to review it.

In addition to the questions of fact, law, and policy raised during the public comment period, HRSA must also now consider how the administrative and operational burdens involved in implementing the regulation will impact Community Health Centers’ (CHCs’) role as national leaders in the effort to vaccinate hard-to-reach populations against COVID-19.

As HRSA and Congress are well aware, CHCs like Howard Brown have been on the frontlines fighting COVID—especially among underserved and marginalized communities—for over a year now. At Howard Brown, we’ve increased our workforce, implemented new workflows, and developed and expanded our community partnerships in order to ensure that we are able to provide care for the communities that we serve throughout the pandemic. Last year we provided over 64,000 COVID tests, and this year we have so far administered over 10,000 vaccine doses, with an emphasis on providing easy and no cost vaccinations in communities hardest hit by the pandemic. We readily accept this responsibility to keep underserved communities healthy and safe, but it requires significant staff time and resources. Staff from all departments are being called on to support vaccination efforts. Implementing this regulation as written would be highly burdensome and disruptive for our staff who are busy providing COVID testing, treatment, and vaccination. Under the best of circumstances, it would take many months and substantial expense for a CHC to come into compliance with the regulation—and the middle of a pandemic is far from the best of circumstances.

For these reasons, we strongly urge HRSA to delay this rule through at least July 20, 2021, and to give serious consideration to extending the delay for the duration of the Public Health Emergency.

In closing, I would like to highlight the significant concerns that we raised about this regulation during the initial comment period:

- The regulation, and the underlying Executive Order, are based on fundamental misunderstandings of how both CHCs and 340B operate.
- CHCs are nonprofit providers whose mission is to make insulin, other medications, and a wide range of other health services affordable for low-income patients.

- 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 CHCs by imposing burdensome new requirements and reducing their ability to support discounts on medications and other services.

For these reasons, we urge the Administration to undertake a fresh review of the previously submitted comments and ultimately rescind this regulation. Thank you for your consideration of these comments, and we look forward to continuing to work with you to expand access to affordable, high-quality care for underserved communities.

Sincerely,

David Ernesto Munar
President and CEO