HEALTH CENTER PARTNERS
of Southern California

October 28, 2020

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

RE: **HHS Docket No. HRSA-2020-0004 - RIN 0906-AB25**
Notice of Proposed Rulemaking: Implementation of Executive Order 13937
"Executive Order on Access to Affordable Lifesaving Medications"

Dear Dr. Joseph:

On behalf of Health Center Partners of Southern California and its 16 member primary care organizations, which together serve more than 850,000 patients each year, for 3.6 million patient visits each year, at 160 practice sites across San Diego, Riverside, and Imperial counties, I 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".

Health Center Partners of Southern California's comments mirror those submitted by the National Association of Community Health Centers (NACHC) and I refer you to their full comments for further details. ***In short, I strongly urge the Administration not to issue a final version of this regulation, as it is based on fundamental misunderstandings of how Federally Qualified Health Centers (FQHCs) and the 340B Drug Pricing Program operate, and if implemented would do significantly more harm than good. However, if HHS insists on finalizing this regulation, I strongly urge you to make several important adjustments to the regulatory text.*** Please, let me explain.

Major concerns underlying why this regulation should not be finalized:
Health Center Partners of Southern California shares the Administration's goal of ensuring all individuals access their prescribed medications regardless of their ability to pay. However, policies intended to advance this goal must be grounded in a thorough understanding of how the drug market works, and the important roles already played by key actors like FQHCs and the 340B Drug Pricing Program.

Regardless of the Executive Order's intentions, it clearly was not based on an adequate understanding of these important factors, and if implemented would do significantly more harm than good in terms of ensuring access to care for underserved populations. Specifically:

- The Executive Order 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.

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- The Executive Order reflects a fundamental misunderstanding of the 340B program, and – if implemented as written – would decrease some patients' access to affordable drugs.
- To avoid the harm that the Executive Order would do if implemented as written, the NPRM must diverge significantly from the Executive Order's text.
- 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.

For these reasons, Health Center Partners of Southern California strongly urges the Administration not to finalize this misguided regulation.

While Health Center Partners of Southern California strongly urges HHS not to finalize this regulation, if HHS insists on doing so, I strongly urge you to make the following changes to the regulatory text:

- Align the definition of a "low-income" individual eligible for discounts under this regulation with the definition that has been in place throughout the FQHC program for more than 50 years – 200% FPL.
- Clarify in the regulatory language that only those patients who meet the 340B patient definition are eligible for the 340B (or lower) price.
- 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.
- Clarify the definition of a "high cost-sharing requirement".
- 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.

I welcome the opportunity to speak with you further on this important matter. Please let me know how Health Center Partners may be of assistance to you as you consider this request. Thank you.

Sincerely,

Henry N. Tuttle
President and Chief Executive Officer
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Health Center Partners of Southern California, a family of companies, includes a 16-membership organization of federally qualified health centers, Indian Health Services Organizations, both urban and sovereign, and Planned Parenthood of the Pacific Southwest, collectively serving 850,000+ patients each year, for 3.6 million patient visits each year, at 160 practice sites across San Diego, Riverside, Imperial counties, with the seventh largest provider group in the region. Read our award winning 2018/2019 Impact Report.