March 11, 2021

Honorable Norris Cochran
Acting Secretary
Office of the Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Proposed Delay of Effective Date for Implementation of Executive Order on 340B Drug Pricing Program Discounts [RIN 0906-AB25, HRSA-2021-0002]

Dear Acting Secretary Cochran:

On behalf of OCHIN and our members, we respectfully urge that you rescind the Final Rule implementing President Trump’s Executive Order 13937 (Executive Order) of July 24, 2020, concerning changes to the 340B Drug Pricing Program (340B Program) as applied to all participating health centers; or, in the alternative, OCHIN supports delaying implementation until the Final Rule can be adequately considered and substantive shortcomings under the Administrative Procedures Act (APA) addressed. The Final Rule will not achieve the stated goal, was procedurally and substantively defective under the APA, and, if implemented, would further de-stabilize community health clinics as they grapple with addressing the COVID-19 public health emergency and the extreme adverse impact on people of color, the deepening of the opioid use disorder epidemic, and the rapid rise in mental and behavioral health needs, particularly among the pediatric population.

OCHIN is a national nonprofit health information, innovation, and research network with two decades of experience transforming health care delivery and provides leading-edge technology, data analytics, research. We support services to more than 500 community health care sites, reaching nearly 6 million patients. OCHIN’s 340B Program eligible network members treat patients regardless of ability to pay, charge a sliding fee scale based on income and would not have been able to remain open to serve their patients, particularly due to the impact of the COVID-19 public health emergency, without a myriad of support structures, including the 340B Program.
Recommendations:

- Rescind the Final Rule as neither a rational basis nor legal authority was offered to target community health clinics for differential treatment nor to establish different policies for insulin and injectable epinephrine.
- Rescind the Final Rule as it does not provide a rational basis for the methods to implement the new policy, including failure to address comments concerning the complexity and administrative impossibility of implementation.
- In the alternative, delay implementation of the rule entitled “Implementation of Executive Order on Access to Affordable Life-saving Medications” until steps can be taken to comply with the APA to rescind this Final Rule.

OCHIN and our members support policies that ensure affordable access to healthcare services and treatment for individuals with qualifying low-incomes who face barriers to all affordable medication, including insulin and injectable epinephrine, due to either lack of insurance or high-cost sharing requirements. The 340B Program serves as a critical lifeline in advancing this goal and the mission of community clinics by supporting affordable access to quality care and medication. The 340B Program ensures health center patients obtain the prescriptions and the care they need, regardless of their ability to pay. The savings afforded to health centers through 340B Program help them remain open, utilize technology to reach patients where they are, and keep enough staff on hand to meet community care needs.

The requirements of this Final Rule, much like the additional onerous reporting requirements that several drug manufacturers have attempted to impose unilaterally on participating 340B Program community clinics, creates a whole new set of reporting, monitoring, technical and administrative re-engineering, staff training, and workflow re-design obligations. In short, this Final Rule would:

- Increase burden on community clinics already stretched thin to serve their expanding patient population as a result of COVID-19 and other growing public health emergencies.
- Arbitrarily single out and strip health centers of the benefit of the 340B Program savings mandated by Congress, undermining their ability to provide affordable pharmaceuticals and other services to their safety net patients.

The Final Rule will further undermine community health clinics’ ability to sustain current operations to meet multiple public health emergencies and preclude altogether efforts to prepare for new, more sustainable payment and delivery models that would improve access to the communities hardest hit by COVID-19 and longstanding structural inequality in healthcare.

In contrast, drug manufacturers continue to report significant profits. Instead of directly addressing the high cost of these drugs, the Trump Administration focused on providing access to two drugs by requiring participating community clinics with limited resources to “pass” through 340B Program discounts. Yet,
the Final Rule would not improve access because it would unravel the current operations of community health clinics. The Final Rule imposes an administratively complex, costly, and inexact method for providing such discounts to patients that require both prospective and retrospective calculations that cannot be easily and accurately reconciled. The impact of the Final Rule in tandem with the refusal earlier this year by several drug manufactures to allow drugs purchased at the 340B price by 340B-eligible providers to be delivered to “contract pharmacies” and the unilateral imposition of onerous reporting requirements on contract pharmacies and community health clinics by certain manufacturers could be permanently debilitating.

OCHIN appreciates your consideration of our comments and would welcome working with the Biden Administration to identify solutions that would improve equitable access to prescription medication and long-term sustainable programmatic changes that strengthen community-based care and public health. Please contact me at stollj@ochin.org should you have any questions.

Sincerely,

Jennifer Stoll
Executive Vice President
Government Relations and Public Affairs