NATIONAL ASSOCIATION OF Community Health Centers

Main Office
7501 Wisconsin Ave.
Suite 1100W
Bethesda, MD 20814
301.347.0400 Tel
301.347.0459 Fax

Division of Federal, State and Public Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
202.296.3800 Tel
202.296.3526 FAX

July 16, 2020

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

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

Dear Director Joseph:

The National Association of Community Health Centers (NACHC) is the national membership organization for federally qualified health centers (also known as FQHCs or health centers). Health centers are federally-funded or federally-supported nonprofit, community-directed provider clinics that serve as the health home for over 30 million people, including 1 in 5 Medicaid beneficiaries and 1 in 3 people living in poverty nationwide. It is the collective mission and mandate of over 1,400 health centers around the country to provide access to high-quality, cost-effective primary and preventative medical care as well as dental, behavioral health, and pharmacy services and other "enabling" or support services that facilitate access to care to individuals and families located in medically underserved areas, regardless of insurance status or ability to pay.

In the fight against COVID-19, the community health center mission of advancing equity in the nation's pandemic response is now more critical than ever. Health centers have been on the ground in force for over a year, fighting the spread of the virus in hard-to-reach communities, including communities of color and among special populations – the elderly, homeless and agricultural workers. They have tested, vaccinated, diverted non-acute cases from overwhelmed hospitals, connected affected patients with housing, food and critical services. To this date, health centers have delivered over 6.7 million COVID-19 vaccinations and over 11 million COVID-19 tests. With the continued support of this Administration, NACHC is confident health centers will help bring the pandemic to an end.

NACHC strongly supports HHS' proposal to rescind the Final Rule entitled "Implementation of Executive Order on Access to Affordable Life-Saving Medications", and retract the related requirements for awarding new grants under section 330(e) of the Public Health Service Act. We appreciate the opportunity to comment on rescinding this regulation, and to highlight health centers' existing and continued commitment to provide affordable medications to underserved populations.

In brief, NACHC supports HHS's proposal to rescind the final rule for the following reasons:

1. **The Final Rule would reduce access to care for underserved populations, which is contrary to the intentions of the health center program. Implementing the rule would lead to significant administrative burdens and costs for health centers, reducing available resources to support critical services for all their patients – including those who use insulin and injectable epinephrine.**
2. **The Final Rule's definition of "low income" as persons below 350% Federal Poverty Guidelines (FPG) is inconsistent with every known Federal program, and this new definition significantly increases the administrative burden on health center staff and reduces the resources health centers devote to general patient care.**
3. **If implemented, the Final Rule would require health centers to divert critical resources away from vital COVID-19 pandemic response efforts across the country.**
4. **If implemented, the Final Rule would only improve access for a small population of patients, and health center services would drastically be reduced given the increase in administrative costs and loss of 340B savings.**

In addition, NACHC urges the Biden Administration to revoke the "Executive Order on Access to Affordable Lifesaving Medications," on which this Final Rule was based.

Below is more detailed information on each of these topics.

The Final Rule would reduce access to care for underserved populations, which is contrary to the intentions of the health center program. Implementing the rule would lead to significant administrative burdens and costs for health centers, reducing available resources to support critical services for all their patients – including those who use insulin and injectable epinephrine.

NACHC commends the Biden Administration for recognizing the valuable role health centers play in ensuring access to affordable primary, preventive, dental, behavioral health, and pharmaceutical services for medically vulnerable populations. We support HHS's proposal to rescind the final rule because, as stated in the NPRM, health centers would need to "absorb significant additional cost, time, and ongoing support staff to create and maintain new reporting, monitoring, technical and administrative re-engineering, staff training, and workflow re-designs to assess eligibility for patients to receive insulin and injectable epinephrine consistent with the final rule". Examples of this added administrative burden include:

- Determining 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
- Adjusting the charge for qualifying patients for every form of insulin and EpiPen every quarter, when the 340B price changes
- Keeping Third Party Administrators, contract pharmacies, and other pharmacy partners abreast of and compliant with new charges, eligibility rules, etc.

Based on HRSA's estimate, implementing the Final Rule would require each health center organization to hire one additional full-time equivalent (FTE) eligibility assistance worker at approximately $50,000 annually. NACHC strongly maintains that a full-time FTE would have a more meaningful positive impact on patient access by focusing on existing efforts, such as helping patients apply to pharmaceutical manufacturers' Patient Assistance Programs, and connecting them enabling services in the community.

The Final Rule's definition of "low income" as persons below 350% FPG is inconsistent with every known Federal program, and this new definition significantly increases the administrative burden on health center staff and reduces the resources health centers devote to general patient care.

NACHC supports rescinding the Final Rule because of multiple issues resulting from the definition of "low income" as individuals with incomes at or below 350% FPG:

This definition further exacerbates the administrative burdens that the Final Rule would create.

Health center program rules require providing sliding fee discounts to all uninsured and underinsured patients with incomes below 200% FPG. By defining low income as below 350% FPG, significantly higher than any other Federal program, every health center in the country would have to implement new policies and procedures to establish "new, distinct, and higher 'low income' thresholds" applicable to only two types of drugs, and then create new billing procedures for these drugs. Due to this narrow focus, it would be extremely burdensome for health centers to determine eligibility before a visit without an in-depth medical assessment. Instead of health center staff screening every patient for income eligibility, staff would have to focus on if the patient will need insulin or injectable epinephrine before assessing income status. Traditionally, the health center staff that determine income eligibility have limited medical training and usually do not have access to patients' Personal Health Information. HHS should not require health centers to implement new policies and procedures that would require patients to share more personal information than necessary with non-clinicians.

This definition would reduce the amount of 340B savings that health centers could retain on insulin and EpiPens, which would impact critical services that all patients, including those who use insulin and EpiPens, receive at their local health center.

Altering the definition of "low income" would also jeopardize health centers' ability to retain 340B savings. This is because insurance contracts generally prohibit health centers from billing them any more than their "usual and customary" (U&C) rate for each specific drug. To date, several insurers have argued that the discounted rates that health center charge an uninsured or underinsured patient below 200% FPG should qualify as their U&C rate, and therefore should be the maximum they bill the private insurer. Fortunately, health centers have been largely successful in pushing back against these claims, by pointing out that long-standing program rules requires them to provide discounts off their regular rates to persons below 200% FPG.

If HHS does not rescind this Final Rule, it would be very difficult for health centers to argue that the 340B price is <u>not</u> their U&C, as very few cash patients would <u>not</u> qualify for the 340B price.

As a result, this would transfer the benefit of the 340B savings from the health center to the insurers. If health centers are forced to give up 340B savings on insulin, that would have a significant impact on their finances, and ultimately their ability to provide comprehensive primary and preventive care for all patients, regardless of a patient's ability to pay.

The Final Rule would require health centers to divert critical resources away from vital COVID-19 pandemic response efforts across the country.

NACHC appreciates HHS acknowledging the countless hours health centers have devoted to responding to the COVID-19 pandemic and the undue burden the final rule would place on health centers**.** Health centers have been on the ground in force for over a year, fighting the spread of the virus in hard-to-reach communities, including communities of color and among special populations. While mass COVID-19 vaccination sites continue and vaccinations are being incorporated into routine or other clinic visits, health centers are reaching deep and wide into their communities to ensure they are equitably distributing vaccines. In each of their communities, health centers are working to ensure medically underserved and uninsured populations have access to testing, and that COVID-19 patients receive follow-up services. To this date, health centers have delivered over 6.7 million COVID-19 vaccinations and over 11 million COVID-19 tests, responding to the needs of their underserved communities and patients. When COVID-19 hit, health centers across the country rapidly converted their in-house pharmacies to drive-through and home delivery structures, to serve their patients as safely and efficiently as possible. Health centers staff from the C-suite to the front desk are all doing their part to educate their patients, build confidence in the vaccine, and create innovative solutions to bring more patients in the door. Rescinding this Final Rule will enable health centers to continue to their vital work without having critical financial and administrative resources diverted to activities with significantly less positive impact.

The Final Rule would only improve access for a small population of patients, and health center services would drastically be reduced given the increase in administrative costs and loss of 340B savings.

NACHC continues to be concerned about the on-going confusion and misinformation around how the health center and 340B program operate, and what this final rule would do if implemented. Specifically:

- **If implemented, this Final Rule would have no impact on the price of insulin or EpiPens.** Some recent media reports have claimed the Final Rule, if allowed to go into effect, would lower the price of insulin. That is simply untrue. Drug prices are set by drug manufacturers, who roughly tripled the price of insulin during the last decade. The Mayo Clinic reported that one vial of Humalog, which cost $21 in 1999, cost $332 in 2019, reflecting a price increase of more than 1000%.
- **If implemented, this Final Rule would have no impact on 90% of American diabetic patients**. The Final Rule would apply only to those patients who receive their primary care from a health center, and whose income is below 350% FPG. As 90% of diabetic patients in the US are not health center patients, this Final Rule would have zero impact

on how majority of diabetic patients pay for insulin. For the 10% of diabetic patients who get their care from a health center, the impact would be minimal, as health centers are

already committed to ensuring that their low-income patients can afford insulin and EpiPens (along with all other pharmaceuticals plus the full range of primary, dental, and behavioral health care services.)

NACHC shares the Administration's goal to increase access to affordable medications around the country, and health centers continue living through our mission to ensure access to affordable care for underserved patients. However, the Final Rule fails to address rising drug prices for diabetic Americans.

The Biden Administration should revoke the Executive Order on Access to Affordable Life-Saving Medications because it was founded on a misunderstanding of the 340B program and the health center program.

NACHC has multiple concerns with the previous Administration's Executive Order that led to this Final Rule. First, The Executive Order implies that health centers were benefitting inappropriately from the 340B program by not following federal regulations and the health center mission that require them to reinvest all 340B savings in activities that expand care for low-income populations. Depending on the drug, health centers will discount drugs for patients beyond the minimum requirements. For many drugs, including insulin and injectable epinephrine, the 340B price is still too expensive for many low-income patients. Health centers utilize the existing health center program's regulatory flexibility to provide additional discounts to ensure medication is affordable. In fact, discounting drugs below the 340B price is generally the first purpose for which health centers use their 340B savings.

Second, The Executive Order states that health centers pay only one penny for a month's supply of insulin or injectable epinephrine. This statement represents a very limited understanding of the 340B program because multiple pricing variables impact the 340B price. For example, the form of the drug, the manufacturer's past pricing decisions, and the calendar quarter can be a factor. Depending on the form of insulin, the 340B price can range from $100 to $450 for health centers. Additionally, 340B prices lack consistency, as the 340B price for a one-month supply of a particular brand of insulin could be one penny during a quarter and over $100 in the next quarter. Thus, to imply that FQHCs consistently pay only a penny for insulin and injectable epinephrine reflects a very narrow understanding of 340B pricing[1], and drug pricing more generally. These basic misunderstandings of 340B, drug pricing, and the health center mission led to this Final Rule, which creates more harm than benefits for medically underserved patients.

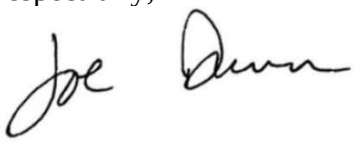
[1] A drug's 340B price is based on two factors, both of which are determined by its manufacturers' pricing decisions. The basic 340B price is either 87% or 77% (for generic and brand, respectively) of the drug's "sticker price." However, if the manufacturer increases the drug's sticker price faster than inflation, the statute requires additional discounts, called an "inflation penalty." If the sticker price is raised particularly fast, the inflation penalty may be large enough that the 340B price drops to one-penny. Thus, when a drug is penny-priced under 340B, it indicates that the manufacturer has increased the sticker price much faster than inflation.

NACHC strongly urges the Biden Administration to revoke the Executive Order on Access to Lifesaving Medications to end the looming threat targeting health centers in the 340B program. Over the last year, health centers have experienced, and continue to daily, attacks on their 340B

savings and ability to participate in the 340B program. If the Biden Administration revokes the underlining Executive Order, health centers can shift their focus from regulatory 340B program threats to defending the external attacks on the 340B program and covered entities, like contract pharmacies.

Thank you for your consideration of these comments and we strongly urge you to rescind the Final Rule. If you have any questions, please contact Vacheria Tutson, Director of Regulatory Affairs at vtutson@nachc.org.

Respectfully,



Joe Dunn
Senior Vice President
Public Policy & Research