October 28, 2020

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5600 Fishers Lane
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Submitted via www.regulations.gov

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,

As the national organization representing our country's 1,400 Federally Qualified Health Center (FQHC) organizations and the nearly 30 million medically-underserved patients they treat, we 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." ***In short, we strongly urge the Administration to <u>not</u> issue a final version of this regulation, as it is based on fundamental misunderstandings of how FQHCs and 340B operate, and if implemented would do significantly more harm than good. However, if HHS insists on finalizing this regulation, we strongly urge you to make several important adjustments to the regulatory text.***

This letter begins by summarizing our comments, and then discusses each in depth.

SUMMARY OF NACHC COMMENTS

A. Major concerns underlying our request that this regulation not be finalized

FQHCs and NACHC share the Administration's goal of ensuring that all individuals can 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 such as FQHCs and the 340B Drug Pricing Program. Regardless of the EO'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:

1. 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.

2. The Executive Order reflects a fundamental misunderstanding of the 340B program, and – if implemented as written – would decrease some patients' access to affordable drugs.

3. To avoid the harm that the EO would do if implemented as written, the NPRM must diverge significantly from the EO's text.

4. Defining "low-income" individuals (who are eligible for 340B-or-less-pricing on insulin and injectable epinephrine) 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 injectable epinephrine dispensed to privately-insured patients, significantly reducing FQHCs' <u>total</u> 340B savings.

For these reasons, we strongly urge the Administration not to finalize this misguided regulation.

B. Necessary adjustments to regulatory text if the Administration insists on finalizing this regulation

While NACHC strongly urges HHS to <u>not</u> finalize this regulation, if HHS insists on doing so, we strongly urge you to make the following changes to the regulatory text:

1. Align the definition of "low-income" individual who is eligible for discounts under this regulation with the definition that has been in place throughout the FQHC program for over 50 years– 200% FPL.

2. Clarify in the regulatory language that only those patients who meet the 340B patient definition are eligible for the 340B (or lower) price.

3. 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.

4. Clarify the definition of "high cost sharing requirement."

5. Recognize that, as a result of this regulation, the "minimal administration fee" for insulin and injectable epinephrine will differ from the fees (if any) associated with dispensing other pharmaceuticals.

DETAILED COMMENTS

A. Major concerns underlying our request that this regulation not be finalized

As stated above, FQHCs and NACHC share the Administration's goal of ensuring that all individuals can afford their prescribed medications, regardless of their ability to pay. Indeed, ensuring that low-income patients can afford their prescribed medications -- as well as medical, dental, and behavioral health services – is *the reason that FQHCs exist*.

Given the complexities of the US health care system – and pharmaceutical issues in particular – any effort to expand access to affordable drugs must be grounded in a thorough understanding of how the drug market works, including the important roles currently played by key actors such as FQHCs and the 340B Drug Pricing Program. Regardless of the EO's intentions, it clearly was not based on an adequate understanding of these critical factors -- and will end up doing much more harm than good in terms of ensuring access to care for underserved populations. For these reasons, ***we strongly urge the Administration not to finalize this misguided regulation.***

1. 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.

When announcing the Executive Order (EO) on which this NPRM is based, President Trump suggested that CHCs are "receiving discounts for themselves while charging their poorest patients massive, full prices." This statement, and the EO, reflect a fundamental misunderstanding of what FQHCs are, how they operate, and the important role they currently play in ensuring access to affordable pharmaceuticals for medically-vulnerable populations.

The core mission shared by every FQHC is ensuring that all persons can access high-quality, affordable health care, regardless of their ability to pay. This includes access to primary care, preventive care, dental care, mental health services, substance use disorder services – and

pharmaceuticals. Ensuring that low-income uninsured and underinsured patients can afford their prescribed medications is one of the central reasons why FQHCs exist. It's why, when COVID-19 hit, FQHCs across the country rapidly converted their in-house pharmacies to drive-through and home delivery structures. It's why FQHCs devote significant staff time to applying to drug manufacturers' Patient Assistance Programs on behalf of their patients. It's why state governments are turning to FQHCs to implement their affordable insulin initiatives. And it's why FQHCs have been so successful in managing chronic conditions -- such as diabetes, HIV/AIDS, depression, SUD, and heart disease – among their medically vulnerable patients.

Depending on the drug, FQHCs do much more than pass on the 340B discount to their low-income patients. For many drugs (including insulin and injectable epinephrine, depending on the form, manufacturer, and calendar quarter), the 340B price is out of reach for many low-income patients, so FQHCs discount it further to ensure it is affordable. In fact, discounting drugs below the 340B price is generally the first purpose for which FQHCs use their 340B savings.

Besides suggesting that FQHCs fail to make drugs affordable for their low-income patients, the EO also implied that FQHCs are benefitting inappropriately from the 340B program. In contrast to this implication, Federal law and regulation – as well as their mission – require FQHCs to invest every penny of 340B savings in activities that expand access to care for low-income populations. FQHCs are widely praised for their strong track record of compliance with both the letter and the spirit of the 340B statute. Members of Congress from both parties have repeatedly highlighted health centers as excellent stewards of the 340B program, using the savings it generated as Congress intended — "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Even Dr. Adam Fein, the CEO of Drug Channels Institute and a well-known critic of the 340B program stated that the EO was "surprising" because "I generally consider [FQHCs] to be the good guys of 340B."[1]

Given their focus on 340 compliance and the commitment to enabling their low-income patients to access the drugs they are prescribed, FQHCs were shocked and disappointed to hear the President suggest that they are somehow profiting off 340B at the expense of their vulnerable patients. As front-line health care providers committed to ensuring access to affordable medications, FQHCs are already part of the solution to unaffordable drug prices – not part of the problem.

2. The Executive Order on which this NPRM is based reflects a fundamental misunderstanding of the 340B program, and – if implemented as written – would decrease some patients' access to affordable drugs.

[1] https://www.drugchannels.net/2020/07/trumps-executive-orders-on-drug-pricing.html

The EO states that FQHCs pay only one penny for a month's supply of insulin or injectable epinephrine. While this statement is true in a very limited sense – i.e., for *specific forms of insulin and epinephrine during specific calendar quarters* -- it is far from universally true. Rather, depending on the form of the drug, the manufacturer's past pricing decisions, and the calendar quarter, the 340B price for these drugs can often be in the range of $100 to $450 per month. Also, 340B prices are very volatile; for example, it is not unusual for the 340B price for a one-month supply of a particular brand of insulin to be one penny during one quarter, and over $100 in another quarter. Thus, ***to imply that FQHCs consistently pay only a penny for insulin and injectable epinephrine reflects a very narrow understanding of 340B pricing[2], and drug pricing more generally.***

Due to this basic misunderstanding of 340B pricing, the EO – if implemented as written – would have many negative impacts on patients, both in terms of how much they would need to pay for life-savings medications, and the consistency of their medical care. For example:

- Many diabetic patients would end up paying <u>more</u> for their insulin. Depending on the type of insulin a patient needs, the 340B price could be far above what health centers currently charge low-income patients. For example, the 340B price for inhaled insulin is hundreds of dollars. Health centers currently discount this price for their low-income patients, but would be prohibited from doing so under the EO.
- Many diabetic patients would face dramatic fluctuations in how much they pay for insulin from one calendar quarter to the next. As stated above, it is not unusual for the 340B price for a one-month supply of a particular brand of insulin to be one penny during one quarter, and over $100 in another quarter. Thus, under the EO a low-income patient's cost for insulin could switch from 3 cents to over $300 in just 3 months.
- To keep charges affordable for low-income patients, health centers would seek to put them on the type of insulin with the lowest 340B price. As 340B prices change quarterly, this could require changing patients' insulin prescriptions quarterly. This would create a significant administrative burden for health center staff, and potential clinical complications for patients.

3. To avoid the harm that the EO would do if implemented as written, the NPRM must diverge significantly from the EO's text.

The EO text clearly states that eligible patients must be charged the 340B price (plus a minimal administration fee) for insulin and injectable epinephrine – not more, and not less. As described above, this would lead to a range of negative outcomes for patients (e.g., dramatic

[2] 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.

fluctuations in charges from one calendar quarter to the next, the need to change insulin prescriptions quarterly to keep the drug affordable.) For this reason, NACHC appreciates that the NPRM strays from a strict reading of the EO to allow FQHCs to charge eligible patients *less than* the 340B price. Nonetheless, ***the fact that an Administration that values strict textualism needs to stray from that approach to avoid harming patients further demonstrates the inappropriateness of this EO and the resulting NPRM.***

4. **Defining "low-income" individuals (who are eligible for 340B-or-less-pricing on insulin and injectable epinephrine) 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 injectable epinephrine dispensed to privately-insured patients, significantly reducing FQHCs' <u>total</u> 340B savings.**

Each of these points is discussed below.

- ***Defining "low-income" as less than 350% FPL is inconsistent with any known Federal definition of "low-income."***

To the best of our knowledge, nowhere in the Federal government is there any precedent for defining a "low-income" individual as someone whose income is as high as 350% of the Federal Poverty Level (FPL.)

For research purposes, "low-income" is generally defined as individuals whose family income is at or below 200% of the Federal Poverty Level (FPL.) This definition is widely used by private groups[3] as well as Federal officials in HHS and the Census Bureau[4].

In terms of Federally-mandated benefits, HHS' Assistant Secretary for Planning and Evaluation (ASPE) has published a list of over 40 Federal programs for which eligibility is based on income. Of these 40 programs, only the ACA's Advanced Premium Tax Credits provide benefits to persons at or above 350% FPL[5] -- and these tax credits were explicitly designed to support middle-class individuals[6]. ***For every program in which the Federal government determines eligibility thresholds, "low-income" is defined as 250% FPL or less***. For example, the following

[3] For example, see The Wharton School, The Kaiser Family Foundation, and The Urban Institute.
[4] https://www.census.gov/content/dam/Census/library/publications/2019/demo/p60-266.pdf
[5] Advance Premium Tax Credits are available to persons who family incomes are at or below 400% FPL.
[6] For example, the popular health insurance sales site eHealth states "In general, subsidized enrollees are also shielded from rising premiums as ACA subsidies usually increase along with the price of premiums. This helps keep health insurance affordable for the lower and ***middle classes***." *(emphasis added)*

list shows the maximum income level associated with various Federal programs designed to support "low-income" individuals:

- ACA cost sharing reductions -- 250% FPL
- Head Start -- 100% FPL
- Federal Transit Administration -- 150% FPL
- Federal TRIO programs through the Department of Education -- 150% FPL
- Head Start -- 100% FPL
- Low-Income Home Energy Assistance Program -- 175% FPL
- National School Lunch Program – 130% FPL for free meals, 185% FPL for reduced price
- Section 330 Consolidated Health Centers program – 200% FPL
- Supplemental Nutrition Assistance Program (SNAP) -- 200% FPL
- Titles III, VII, and VIII of the Public Health Service Act (all programs) – 200% FPL
- Title X of the Public Health Service Act -- 250% FPL

It is inappropriate for a proposed rule to establish a definition of "low-income" that varies so significantly from the definition used in any other Federal program, or from the common understanding of that term.

- ***Defining "low-income" as less than 350% FPL will impose enormous administrative burdens on FQHCs.***

As you know well, the health center program requires FQHCs to provide discounts on in-scope services provided to all uninsured and underinsured persons with incomes at or below 200% FPL. Every FQHC in the country has policies and procedures in place to determine which patients are eligible for discounts, and which discount pay class they qualify for. This 200% threshold is applied to discounts for pharmaceutical services as well as medical services.

Adding a new discount requirement with a much different income threshold that applies only to certain patients (those needing insulin or injectable epinephrine) and only for certain items (insulin and injectable epinephrine) would create enormous administrative burdens for FQHCs. Because of the narrow nature of the discount, it would be very burdensome and ineffective for FQHCs to screen every patient for eligibility; rather, the screening should focus on those individuals who are – or are likely to be -- prescribed insulin and injectable epinephrine. However, to target the screening in this manner, the staff who conduct income assessments would need to know which patients have diabetes or need injectable epinephrine – which is Personal Health Information to which they generally do not and should not have access. Also, staff who do income assessments often have very limited medical training and would not necessarily be competent at determining who currently takes insulin or might need it in the near future.

Theoretically, the FQHCs' in-house pharmacy staff could be asked to conduct the eligibility screenings for insulin and injectable epinephrine discounts, as they know which patients receive

these medications. However, pharmacy staff are rarely familiar with the details of assessing income, and adding this role would be very time-consuming and burdensome -- particularly in the age of COVID-19 when pharmacy staff is already stretched thin doing curbside deliveries and maintaining appropriate safety precautions.

It is even less likely that staff at a contract pharmacy would be willing to determine eligibility for these discounts. Income-based eligibility determinations are completely outside of their regular duties, and not something they have any experience with. The administrative burden associated with determining and documenting eligibility would far exceed the value of the dispensing and administrative fees that they receive from the FQHC. Rather than agreeing to conduct these determinations (even for an increased fee), it is much more likely that the contract pharmacy would opt out of its contract with the FQHC entirely.

- ***Defining "low-income" as 350% FPL or less will eliminate FQHCs' ability to retain 340B savings on insulin and injectable epinephrine dispensed to privately-insured patients, significantly reducing FQHCs' <u>total</u> 340B savings.***

Increasingly, private insurance contracts prohibit FQHCs from billing the insurer 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 a FQHC charges to its patients below 200% FPL qualify as the FQHC's U&C rate, and therefore should be the maximum they bill to the private insurer. Fortunately, FQHCs 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% FPL.

If this NPRM were finalized as written, it would be very difficult for FQHCs 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, they would soon be forced to bill insurers only the 340B price – thereby transferring the benefit of the 340B savings from themselves to the private insurers. The impact of losing 340B savings on injectable epinephrine would be relatively small, as FQHCs dispense relatively few of these devices. However, being forced to give up 340B savings on insulin would have a significant impact on FQHC finances, as insulin is currently one of the most important sources of FQHCs' 340B savings. Therefore, defining "low-income" as 350% FPL or less in regulation will lead directly FQHCs retaining significantly less in 340B savings, which in turn will lead to fewer services supported by those savings.

B. Necessary adjustments to regulatory text if the Administration insists on finalizing this regulation

As discussed above, NACHC strongly urges HHS to <u>not</u> issue a final version of this regulation, as it is based on fundamental misunderstandings of how FQHCs and 340B operate, and if

implemented would do significantly more harm than good. However, if HHS insists on finalizing this regulation, we strongly urge you to make the following changes before doing so:

1. **Align the definition of "low-income" individual who is eligible for discounts under this regulation with the definition that has been in place throughout the FQHC program since its inception – 200% FPL.**

   As previously discussed, defining "low-income" individuals (who are eligible for 340B-or-less-pricing on insulin and injectable epinephrine) 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 injectable epinephrine dispensed to privately-insured patients, significantly reducing FQHCs' <u>total</u> 340B savings.

   For all these reasons, ***if HHS proceeds with finalizing this regulation, it is essential that the definition of "low-income" be aligned with the definition that has been in place for all FQHC services since the program's inception – 200% FPL.*** Failure to make this change will lead to massive administrative burdens and significant losses of 340B savings for health centers throughout the country.

2. **Clarify in the regulatory language that only those patients who meet the "340B patient definition" are eligible for the 340B (or lower) price.** The regulatory language must clearly state that the FQHC is required to charge the 340B price (or less) only to those low-income individuals who meet the definition of "FQHC patient" under the 340B program. Without such language, FQHC could be forced to provide 340B pricing (or less) to individuals who are not eligible to receive 340B-priced drugs from the FQHC. For example, low-income patients could demand that the FQHC provide them with discounted insulin, without permitting the FQHC to assume responsibility for the patient's care (a necessary step for 340B eligibility.) In those situations, 340B compliance would require the FQHC to purchase the insulin at the regular price, while this regulation would require that the patient be charged the 340B price – an outcome that would be both expensive and administratively burdensome for the FQHC.

   To avoid this outcome, we recommend the following addition to the regulatory text:

   > "(w)(1) *Provision*. To the extent that an applicant has indicated that it plans to distribute, either directly, or through a written agreement, drugs purchased through the 340B Drug Discount Program (42 U.S.C. 256b), and to the extent that such applicant plans to make insulin and/or injectable epinephrine available to its

patients, the applicant shall provide an assurance that it has established practices provide insulin and injectable epinephrine at or below the discounted price paid by the health center grantee or sub-grantee under the 340B Drug Pricing Program (plus a minimal administration fee) to individuals ***who meet the eligibility requirements to receive a drug purchased under 340B from the health center and who have*** ~~with~~ low incomes, as determined by the Secretary, who have a high cost sharing requirement for either insulin or injectable epinephrine; have a high unmet deductible; or have no health insurance."

3. **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.** As you are aware, many insurers prohibit providers from charging a patient less for a supply or service than the amount due under their deductible or cost sharing requirements. This is why Chapter 9 of the Compliance Manual states that "Such discounts *[for underinsured patients]* are subject to potential legal and contractual restrictions."

   If HHS decides to finalize this regulation, we request that the regulatory text explicitly waive the requirement to offer the 340B (or lower) price to underinsured patients if doing so would violate the FQHC's contract with their insurer. While we appreciate that the Compliance Manual currently contains this "exception language," the sub-regulatory guidance might not provide adequate protection.

4. **Clarify the definition of "high cost sharing requirement.**" We are having difficulty understanding the proposed definition of "high cost sharing requirement." We think the intention is to say that a low-income patient with insurance should be charged the lesser of their cost sharing amount (either copay or deductible) or the amount that they would be charged under this regulation if they were uninsured. We recommend that this language be clarified.

5. **Recognize that, as a result of this regulation, the "minimal administration fee" for insulin and injectable epinephrine will differ from the fees (if any) associated with dispensing other pharmaceuticals.**

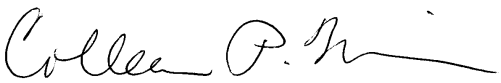
   The proposed regulatory language states that "The minimal administration fee includes any dispensing fee, counseling costs, and ***any other charges associated with the patient receiving the medication.***" *(emphasis added.)* It is important to note that this regulation will create a significant amount of additional administrative work for FQHCs, beyond the costs regularly associated with dispensing, counseling, and 340B compliance. These additional costs will include:

- Establishing and implementing new eligibility determination systems – particularly if the threshold for eligibility under this regulation is different from the 200% FPL threshold already in effect throughout FQHCs.
- Adjusting pricing systems on a quarterly basis to reflect changes in 340B prices.
- Educating non-FQHC patients about the need to become an FQHC patient in order to be automatically eligible for the 340B price or lower.
- Monitoring and reporting on compliance with the new regulation.

Given these additional costs associated with patients "receiving the medication" under this regulation, it is likely that the "minimal administrative fee" for insulin and injectable epinephrine will differ from the fees (if any) charged for other pharmaceuticals.

In closing, thank you for your consideration of our comments, and we again urge you not to finalize this misguided regulation. If you have any questions, please contact me at cmeiman@nachc.org or 301-906-5958.

Sincerely,



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