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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 <https://www.regulations.gov/commenton/HRSA-2021-0003-0002>

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

Dear Dr. Joseph,

Bi-State Primary Care Association (Bi-State) strongly supports HHS’ proposal to rescind the Final Rule entitled “Implementation of Executive Order on Access to Affordable Life-Saving Medications.” This rescission will retract the related requirements for awarding new grants under section 330(e) of the Public Health Service Act. We thank you for the opportunity to comment on the rescission of this regulation.

Established in 1986, Bi-State is a nonpartisan, nonprofit 501(c)(3) charitable organization promoting access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State’s combined Vermont and New Hampshire membership includes 21 Federally Qualified Health Centers, one Look-Alike, one Rural Health Clinic, Planned Parenthood of Northern New England, Vermont Coalition of Clinics for the Uninsured, North Country Health Consortium, Community Health Access Network, and the Area Health Education Centers in both Vermont and New Hampshire.

Bi-State’s 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.

Bi-State also urges the Biden Administration to revoke the “Executive Order on Access to Affordable Lifesaving Medications”, on which this Final Rule was based.

Below, please find additional detail on the reasons outlined above:

- 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.**

Bi-State 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 injectable epinephrine 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. Bi-State believes 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.

- 2. 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.**

Bi-State 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 as it 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 will 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.

Additionally, this definition would reduce the amount of 340B savings that health centers could retain on insulin and injectable epinephrine, which would impact critical services that all patients, including those who use insulin and injectable epinephrine, 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 not their U&C, as very few patients would not qualify for the 340B price. As a result, this would transfer the benefit of the 340B savings from the health center to the insurers.

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

Bi-State 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 and are 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 6.5 million COVID-19 vaccinations and over 11 million COVID-19 tests, responding to the needs of their underserved communities and patients. In several of our New Hampshire and Vermont communities our health centers are using mobile units to reach into their communities rather than relying on patients to come to them.

4. 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.

Bi-State is concerned about the on-going confusion and misinformation around how the health center and 340B programs 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, by some estimates, 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 no 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 injectable epinephrine (along with all other pharmaceuticals plus the full range of primary, dental, and behavioral health care services.)

Bi-State shares the Administration's goal to increase access to affordable medications around the country, and health centers while living 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.

Bi-State 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 a primary 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 pricing¹, 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.

Bi-State 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.

Thank you for your consideration of our comments, and we again strongly urge you to rescind the Final Rule. We would be happy to work with you on alternative ways to meet our mutual goal of reducing prescription drug costs for patients. Please contact Georgia Maheras, Vice President of Policy and Strategy with any questions (gmaheras@bistatepca.org).

Sincerely,

Tess Kuening

Tess Stack Kuening, CNS, MS, RN
President and Chief Executive Officer