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March 14, 2021

Dr. Jennifer Joseph
Director
Office of Policy and Program Development
Bureau of Primary Health Care
Health Resources and Services Administration
5600 Fishers Lane
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Submitted on-line at www.federalregister.gov/d/2021-05165

RE: Comments on HHS Docket No. HRSA-2021-000 -- Proposal to delay effective date of regulation entitled "Implementation of Executive Order on Access to Affordable Life-Saving Medications" until July 20, 2021

Dear Dr. Joseph,

Bi-State Primary Care Association (Bi-State) appreciates the opportunity to provide input on the proposal to delay the effective date of the regulation entitled "Implementation of Executive Order on Access to Affordable Life-Saving Medications" until July 20, 2021. We write to express our strong support for delaying the effective date of the regulation until at least July 20, 2021, as proposed at ***www.federalregister.gov/d/2021-05165*.**

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.

We strongly support the proposed delay as it:

1. is consistent with the "Regulatory Freeze Pending Review" issued by the White House Chief of Staff on January 20, 2021; and
2. will allow for consideration of new policy questions that have arisen since the regulation was initially delayed.

Each of these is discussed in more detail below.

1. Extending the delay is consistent with the "Regulatory Freeze Pending Review" issued by the White House Chief of Staff on January 20, 2021.

On January 20, White House Chief of Staff established a Regulatory Freeze Pending Review, addressing regulations that had been finalized by the previous Administration but not yet finalized. Pursuant to that Regulatory Freeze policy, on January 21, HHS delayed the effective date of this regulation for 60 days, until March 22, 2021, stating that the delay was "necessary to give Department officials the opportunity for further review and consideration… consistent with" the Regulatory Freeze. A further extension of the effective date, until July 20, is also consistent with Regulatory Freeze memo for the following reasons:

- As indicated by the volume and range of comments submitted last fall in response to the proposed rule[1], this regulation raises significant questions of "fact, law, and policy." Given the critical role that HRSA's Bureau of Primary Health Care (BPHC) is playing in national efforts to provide COVID vaccinations to medically underserved and disproportionately impacted populations, it is understandable that the BPHC was unable to address all these questions during the initial 60-day delay. The Regulatory Freeze memo states that "where necessary to continue to review these questions of fact, law, and policy" agencies should "consider further delaying, or publishing for notice and comment proposed rules further delaying, such rules beyond the 60-day period." Thus, given the number of questions raised about the regulation, and the effort required to address them, the Regulatory Freeze indicates that a further delay is appropriate.
- The Regulatory Freeze memo states that pending rules should be reviewed and approved by "a department or agency head appointed or designated by the President after noon on January 20, 2021." As neither an HHS Secretary nor a HRSA Administrator have yet to be appointed under the current Administration, there has not yet been an opportunity for an individual in either of these positions to review this regulation, or to delegate their authority to another individual. As a result, the regulation's effective date must be delayed at least until an HHS Secretary or HRSA Administrator has been appointed and is able to review it.

2. A new issue of "fact, law, and policy" must be considered: the impact of implementing this regulation on Federally Qualified Health Centers' efforts to vaccinate hard-to-reach populations against COVID-19.

In addition to the questions of fact, law, and policy raised during the NPRM comment period, there is a new – and time-sensitive – issue that HRSA must consider when determining whether and when to make this regulation effective. Federally Qualified Health Centers (FQHCs) are serving as national leaders in the effort to vaccinate hard-to-reach populations against COVID-19. The administrative and operational burdens involved in implementing this regulation will adversely impact the FQHCs abilities for COVID-19 response and vaccination.

As discussed in our NPRM comments, implementing this regulation as written would be highly burdensome and disruptive for FQHCs' registration staff, I.T. departments, in-house pharmacy staff, and contract pharmacy arrangements; it will also lead to reduced financial resources for the FQHC (see Attachment A for details). Under the best of circumstances, it would take many months and substantial expense for an FQHC to come into compliance with the regulation – and the middle of a pandemic is far from the best of circumstances.

As HRSA and Congress are well aware, health centers have been on the front lines of fighting COVID-19 for over a year. Since this rule was initially delayed in January, health centers have been assigned the critical role of leading national efforts to vaccinate hard-to-reach populations- the two NH and VT health centers in Phase I are eagerly delivering vaccine in their communities and the Phase II health centers are getting onboarded. While health centers readily accept this responsibility, their staff and resources are currently stretched to unprecedented levels. At the same time, many health center staff continue to be

[1] As one example, see the comments submitted by the National Association of Community Health Centers, available at https://www.regulations.gov/comment/HRSA-2020-0004-0119.

out on leave, either due to COVID exposure or to family responsibilities related to the pandemic. This raises a new policy question that must be considered before a final decision can be made about the regulation – how the significant administrative and operational burdens created by this regulation should be reconciled with the critical demands placed on health centers to vaccinate hard-to-reach populations against COVID-19.

In closing, I would like to highlight the significant concerns that the health center community raised about this regulation during the initial comment period:

- The regulation, and the underlying Executive Order, are based on fundamental misunderstandings of how both health centers and the 340B program operate.
- Health centers are non-profit providers whose mission is to make insulin, other medications, and a wide range of other health services affordable for low-income patients.
- This regulation would do nothing to change the price that drug companies charge for insulin.
- For the roughly 90% of diabetic patients who aren't CHC patients, this regulation would have no impact on the price they pay for insulin.
- Instead of helping more people afford insulin, this regulation would harm health centers by imposing burdensome new requirements and reducing their ability to support discounts on medications and other services.

Thank you for your consideration of our comments, and we again strongly urge you to delay this rule through at least July 20, 2021, and to undertake a review of the previously submitted comments and rescind this regulation. 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 Kuenning
Tess Stack Kuenning, CNS, MS, RN
President and Chief Executive Officer

Attachment A:
Administrative and Operational Burdens on Health Centers to Implement the Regulation

Registration & IT:

- Case managers will need to start asking every patient – regardless of insurance status -- if they are an insulin-using diabetic or have intense allergic reactions. (Note: these are invasive questions for non-medical personnel to ask and raise potential HIPAA concerns.)
- Patients who are identified as insulin-using diabetics or having intense allergic reactions will have to be screened for incomes up to 350% FPL – when all other patients are screened only for incomes up to 200% FPL.
- Practice management software will need to be updated to indicate qualifying patients, creating further burden on front office workflows.
- Registration staff will likely be inundated by non-patients seeking discounted insulin. Staff will need to explain that the patient must become health center patients in order to qualify.

<u>All Pharmacies:</u>

- 340B Pricing is subject to quarterly changes, potentially causing the following burdens for pharmacists and pharmacy support staff:
  - Out of pocket costs for insulin could vary significantly quarter to quarter, causing patient and provider frustrations.
  - Pharmacy dispensing systems will need to routinely update pricing data to reflect the latest insulin prices. These prices will come as a surprise to pharmacists, pharmacy staff, and patients alike.
  - Patients seeking to move to lower-costs forms of insulin will reach out to their primary care providers (PCPs) for new prescriptions; this will create increased workflows for both PCPs and pharmacy staff.

<u>In-House Pharmacy:</u>

- Every time a pharmacist fills a prescription for insulin or injectable epinephrine, they will need to look up in the practice management software to determine if the patient qualifies for the special (sliding fee) discount, and the exact cost for that drug this quarter. This is very time consuming and labor intensive, as this is a manual process.
- Setting up pharmacy billing software to allow discounted co-pays will be very burdensome and problematic. Again, this will only be for 2 classes of medications. The rest of the meds will be at full co-pay or cost.

<u>Contract Pharmacy:</u>

- Most contract pharmacies – particularly the large chains -- will be unable or unwilling to accommodate the complicated eligibility and pricing determinations required under this rule. Their first priority is to care for the patients from a clinical aspect, any further administrative burden from covered entities like health centers could further damage relationships with these partners. This will further destabilize the contract pharmacy model, which is already under attack from drug makers who are refusing to ship 340B-priced drugs to contract pharmacies, and from PBMs and payers who impose discriminatory contracting terms that discourage participation in 340B.
- For those contract pharmacies that are willing and able to accommodate these new requirements, the health center's Third-Party Administrator (which determines 340B eligibility for prescription claims dispensed by contract pharmacies) may be unable to provide the information needed to determine eligibility and pricing in a timely fashion.
- For those remaining contract pharmacy arrangements where both the pharmacy and the TPA are willing and able to accommodate the new requirements, the contract pharmacy will need substantial time and funding to develop new workflows, train staff, and reprogram point of sale systems.