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March 10, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted by email to IRAREbateandNegotiation@cms.hhs.gov

RE: Medicare Part D Inflation Rebate Comments

Dear Dr. Sheshamani,

On behalf of Bi-State Primary Care Association, thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act.

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 (FQHCs), one Look-Alike, Planned Parenthood of Northern New England, Vermont's Free and Referral Clinics, North Country Health Consortium, Community Health Access Network, and the Area Health Education Centers in New Hampshire.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically-underserved patients, regardless of whether they have insurance or their ability to pay. FQHCs serve nearly 1 in 3 Vermonters and 1 in 10 Granite Staters. We serve individuals in all counties within New Hampshire and Vermont providing care to all patients regardless of ability to pay.

Our FQHCs provide comprehensive, whole person care and offer a broad array of services to their patients. FQHCs offer a broad range of services, including primary care, dental, mental health and substance use disorder, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. In New Hampshire and Vermont, the 340B program provides support for numerous services including, but not limited to: patient access to discounted prescriptions, dental programs, transportation services, to support medication assisted treatment, to provide language access services, to support management of chronic conditions, and to support mobile units to go out into the community. Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. FQHCs in NH and VT

endeavor to identify any pharmacy in their service area so that patients can get the prescriptions they need close to home. The 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

- a. Result in data that are highly unreliable.
- b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a “clearinghouse” model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

- a. Produce much more reliable data.
- b. Be significantly less labor-intensive.
- c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
- d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact me at gmaheras@bistatepca.org or 802-229-0002 x 218.

Sincerely,

A handwritten signature in black ink, appearing to be 'gm', followed by a long horizontal line extending to the right.

Georgia J. Maheras, Esq.
SVP, Policy and Strategy