September 9, 2024

Dr. Meena Seshamani, M.D., Ph.D.
Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1807-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Comments on Proposed Rule Relating to the Medicare Prescription Drug Inflation Rebate Program (File Code: CMS-1807-P)

Dear Dr. Seshamani:

We, the undersigned organizations, represent the broad range of providers and programs that participate in the federal 340B drug pricing program. We are writing to provide our input regarding the Centers for Medicare & Medicaid Services' (CMS) July 30, 2024, proposed rule implementing the Inflation Reduction Act's (IRA) Medicare Part D inflation rebate provisions. Our members rely upon their 340B benefit to provide vital care and services to their patients and communities. Accordingly, we support CMS' proposed methodology to estimate what portion of Part D rebatable units are 340B because this approach does not burden covered entities or interfere with their ability to use 340B drugs for Medicare Part D beneficiaries. We also support CMS's consideration of a retrospective methodology for 340B claim identification if the agency were to no longer use the estimation methodology. We strongly encourage CMS to also consider adopting a similar retrospective 340B claim identification methodology for the IRA's maximum fair price (MFP) provisions.

We support CMS' proposal to estimate what portion of Part D rebatable units are 340B, rather than requiring 340B covered entities to use modifiers. This approach would preserve covered entities' ability to use 340B drugs for Medicare Part D beneficiaries and would not burden covered entities. If CMS decided to no longer use the estimation methodology, we encourage the agency to instead use a retrospective methodology of 340B claim identification, as the agency said it is considering.

CMS' retrospective 340B claim methodology, which the agency calls a "repository," would be compatible with the overwhelming majority of 340B pharmacies that determine 340B patient eligibility after the point of sale. A similar approach has been successfully used for a decade by Oregon Medicaid to identify 340B claims. We support CMS' consideration of providing additional time for covered entities to revise claims that were previously identified as 340B or were not identified as 340B. Oregon Medicaid allows entities additional time to modify a claim's status.

If CMS were to move to a repository model, we urge the agency not to share 340B claims data with manufacturers. We are concerned that manufacturers might use the information for purposes outside the scope of the IRA and wholly unrelated to ensuring they do not pay both a 340B discount and inflation rebate on a Part D claim. For example, a manufacturer might use the data to manage its voluntary rebate agreements with Part D plans, including disputing whether it owes rebates to a plan. A manufacturer might also use the information to identify potential concerns about covered entity compliance with 340B requirements. Neither purpose pertains to manufacturers' legal obligations under Part D or 340B. In fact, the latter purpose is

contrary to the 340B program's design. The Health Resources & Services Administration, not manufacturers, are responsible for overseeing covered entities' compliance with 340B program requirements.

We strongly encourage CMS to also consider adopting a similar retrospective 340B claim identification methodology for the IRA's MFP provisions. In May, CMS issued draft guidance regarding implementation of the IRA's MFP provisions. The guidance proposes that covered entities could voluntarily identify 340B claims using modifiers, which, as we explained above, is incompatible with most pharmacies' 340B systems. Additionally, the guidance does not require manufacturers to rely upon the identifiers and permits manufacturers to develop their own methodologies for determining if a claim is 340B. CMS provides no criteria or guidelines for these manufacturer methodologies and offers no other means for covered entities to identify 340B claims. If CMS were to take this approach, the agency would fail to meet its statutory obligation to ensure that 340B covered entities receive the lower of the 340B ceiling price or MFP when purchasing covered outpatient drugs that are subject to the MFP. A retrospective 340B claim identification methodology for the IRA's MFP provisions that is similar to the repository model that the agency is considering for the law's Part D inflation rebate provisions would be a far more workable and significantly less burdensome approach. In fact, CMS could have the Medicare Transaction Facilitator, which the agency already plans to use to implement the IRA's MFP provisions, collect 340B claims retrospectively submitted by covered entities and remove those claims from the data given to manufacturers to pay MFP refunds to pharmacies.

It is critical that CMS preserve covered entities' ability to use 340B drugs for Part D beneficiaries because they use their 340B benefit to fulfill their safety-net missions. Covered entities use their 340B benefit to serve patients in a wide variety of ways:

- Federally qualified health centers use 340B savings for a range of vital care and services, including maternal health care, behavioral health care, and increased access through extended hours and additional staff. Without 340B, health centers would be forced to cut hours, close sites, and lay off staff.

- The 340B benefit is essential to Ryan White HIV/AIDS Program (RWHAP) clinics ability to provide HIV services, allowing them to hire HIV physicians, nurse practitioners, clinical pharmacists, nurses and social workers; expand mental health and substance use services; support oral health care; and fund services critical to maintaining access to care that are not generally covered by health insurance, such as medical transportation, nutritional support and housing assistance. Services provided through 340B savings enable RWHAP clinics to achieve high viral suppression rates for their patients, so they cannot transmit the virus to others. The viral suppression rate in patients receiving care from RWHAP clinics is significantly higher than the national average.

- 340B AIDS Drug Assistance Program rebates and program income are essential to maximize prescription drug formulary options for comorbidities associated with HIV and aging, as well as Medicare Part C and Part D premium and cost-sharing support.

- 340B hospitals offer many specialized services that typically operate at a loss and would otherwise be unavailable, such as trauma care, burn treatment, behavioral health services, and HIV/AIDS care. 340B hospitals provide these services despite experiencing significantly lower operating margins, on average negative, compared to non-340B hospitals. With razor-thin operating margins and little ability to increase their revenue, 340B allows hospitals to increase access to health care services that would

otherwise be unavailable, such as by bringing physicians into the community across a variety of specialties, adding new clinics in new areas, and other services to help individuals access care, such as transportation, translation, and care coordination services.

- The 340B Program is an essential source of discounted outpatient drugs for many rural hospitals serving vulnerable populations who may lack insurance or be low income. For many rural safety-net hospitals operating on thin financial margins, the funds distributed through this program are critical to maintain operations and service lines.

Thank you for considering our comments. Please feel free to reach out to any of the contacts below if you have any questions or if we can provide any additional information.

Sincerely,

Advocates for Community Health
Ryan White Clinics for 340B Access
National Alliance of State & Territorial AIDS Directors
HIV Medicine Association
National Coalition of STD Directors
National Rural Health Association
340B Health

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