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 hospitals 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 member hospitals rely upon their 340B savings to provide vital care and services to their patients and communities. Therefore, we support CMS' proposal to implement the provisions in a way that would preserve hospitals' ability to use 340B drugs for Medicare Part D beneficiaries and would not place a tremendous and unreasonable burden on 340B hospitals. More specifically, we support CMS' decision not to pursue a policy of modifiers for 340B Part D claim identification at this time and the agency's proposed methodology to estimate what portion of Part D rebatable units are 340B. 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.

In the proposed rule, CMS said it is no longer pursuing a policy of modifiers for 340B Part D claim identification at this time but may consider it in future. We support CMS' decision not to pursue modifiers and urge that the agency not revisit the idea. The overwhelming majority of 340B pharmacies are unable to apply modifiers because they do not know at the point of sale if a claim is 340B. This is because most 340B patient eligibility determinations are made after the point of sale. Modifiers would simply be unworkable for most 340B pharmacies.

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 hospitals' ability to use 340B drugs for Medicare Part D beneficiaries and would not place a tremendous and unreasonable burden on 340B hospitals. 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 pharmacies determining 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. It would also be inappropriate for the manufacturer to use that information to police 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.

Additionally, the IRA does not require CMS to share 340B claims data with manufacturers, and manufacturers' inflation rebate obligation does not apply to 340B claims. Therefore, sharing 340B claims data with manufacturers is not needed for the agency and manufacturers to meet their statutory obligations. Furthermore, Oregon does not share 340B claims data with manufacturers. The state removes 340B claims data from the information provided to manufacturers.

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.

Thank you for considering our comments.

Sincerely,

Catholic Health Association of the United States
Association of American Medical Colleges
America's Essential Hospitals
American Society of Health-System Pharmacists
340B Health