Mailing Address:
ADAP Advocacy
PO Box 846
Nags Head, NC 27959

Office Address:
1630 Connecticut Ave, NW
Suite 500
Washington, DC 20009

CEO:
Brandon M. Macsata
Washington, D.C.

adapadvocacy.org

September 5, 2025

Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD

RE: CMS Proposed Exclusion of 340B Drug Units from Medicare Inflation Rebate Calculations [CMS-1832-P; RIN 0938-AV50]

Dear Administrator Oz:

ADAP Advocacy is writing to you to urge you to modify your proposal to identify Medicare Part D-related 340B Drug Pricing Program duplicates by mandating the use of 340B identifiers and aligning the policies of the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) around the permissibility (and, indeed, *the necessity*) of using retrospective claims-based systems in addressing the serious and pervasive problem of 340B duplicates.

About ADAP Advocacy

ADAP Advocacy is a national 501(c)(3) non-profit organization whose mission is to promote and enhance the AIDS Drug Assistance Program (ADAP) and improve access to care for PLWHA. ADAP Advocacy is the only national grassroots organization dedicated exclusively to ADAP, ensuring that there are adequate resources nationwide to eliminate or prevent waiting lists for services. Our purpose is to better engage people living with HIV/AIDS by providing a platform whereby they can offer their personal experiences, challenges, knowledge, insight, and solutions to solving this perpetual problem. ADAP Advocacy has worked tirelessly to ensure that PLWHA in the U.S. can access the medications they need to achieve and sustain viral suppression, undetectability, and untransmissability (more commonly known as "U equals U").

We are strong supporters of the 340B program, a significant source of funding to ADAPs. ADAPs participate in the 340B program through a claims-based rebate mechanism, which provides the systems, data, and structure necessary to ensure that the 340B program's prohibitions on diversion and duplicate discounts are respected. The retrospective mechanism that ADAPs use is the gold standard, and our experience with that system informs our comments here.

Scale of the Duplicate-Pricing Problem

The Proposed Rule, quite significantly, states that CMS's own estimates suggest that 340B duplicates are expected to be between 10–35% of all Medicare Part D units subject to inflation rebates. That is an alarming estimate that underscores the need to implement substantial safeguards.

By all accounts and all estimates, the 340B program is enormous and growing rapidly. The wholesale acquisition cost value of 340B purchases in 2024, an estimated reimbursement value, was $148 billion.[1] The program grew an astonishing 1,000% from 2010 to 2023.[2]

Although ADAPs and many smaller covered entities utilize the 340B program to assist the uninsured and the underinsured, reflecting the original intent of the program, many 340B hospitals, which receive 80% of the benefits of the program, have profited from the program while providing abysmally low levels of charity care. In 2002, for instance, the last year for which data is available, 340B hospitals devoted just 2.15% of their spending to charity care.[3] ADAP Advocacy's 340B map shows the disturbing pattern of 340B hospitals growing their 340B programs larger *and larger.* At the same time, their charity care commitments erode, and their chief executive officer's compensation increases, often dramatically.[4]

Multiple government reports have demonstrated that non-ADAP 340B program claims are riddled with duplicate discounts and diversion issues, as well as vulnerabilities. *See, e.g.*, GAO-20-212: "340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement" (Jan. 2020); GAO-18-480: "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement" (June 2016); Office of Inspector General (OIG) Report: "State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates" (Dec. 2016); OIG Report: "Contract Pharmacy Arrangements in the 340B Program" (July 2014).

Against this backdrop, CMS' estimate of the prevalence of 340B Part D duplicates is quite disturbing. CMS' estimate (10-35%) is likely to exceed, perhaps very substantially, all current estimates of the share of 340B program as a percentage of the U.S. drug market. Those current estimates are 13.5% to 15.45%. Please refer to the table below, which uses wholesale acquisition cost data.

U.S. Drug Market vs. 340B (WAC Dollars)

Year	Total U.S. Drug Spending (WAC, IQVIA)	340B Program Size (WAC, IQVIA)	340B Share of U.S. Market (Computed)	Sources
2023	~$917B	$124.1B	**13.5%**	IQVIA *Use of Medicines in the U.S. 2024*; IQVIA *340B White Paper 2024*
2024	~$963–$990B (estimated, based on 5–8% growth from 2023)	$147.8B	**~15.0% (range: 14.9–15.4%)**	IQVIA *340B Market 2024* white paper; IQVIA growth projections

[1] R. Martin, *et al*., "IQVIA 340B Dynamics Dashboard" (2025)
[2] *Id.*
[3] Pioneer, 340B Abuse, Hospital Charity Care, available at https://pioneerinstitute.org/340babuse/
[4] ADAP Advocacy, 340b Map, available at https://340bmap.org/

Even the midpoint of CMS' estimated range (22.5%) is substantially more than prior estimates. At the high end of CMS' estimated range, 35%, that figure is more than double all other prior estimates.

Whether CMS' estimates are correct or not, the size of that estimate, the massive difference in the upper and the lower ends of that estimate, and the substantial delta between CMS' estimated range and prior estimates all underscore the need for CMS to bring much greater transparency to 340B utilization. This is essential if CMS is to have any basis to conclude that it has met its statutory obligation to ensure that Medicare Part D inflation rebates exclude 340B units and that it has collected the Medicare inflation rebates it should.
Importantly, the 340B program's ills, discussed above, can themselves only be addressed by dramatically improved transparency, like that which we call for here. The public should know how the billions in 340B profits that flow to 340B hospitals are being used and whether program protections against duplicate discounts and diversion are being honored. Patients in need, the very people that the 340B program was designed to help, should understand when large hospitals profiting from the program are sharing 340B pricing with them—and when 340B hospitals refuse to share that pricing.

Superior Options Are Available to CMS

Although we appreciate CMS' proposed estimation and voluntary repository, we believe that these proposals quite clearly are not the best option available to CMS—given the need for transparency and the potentially enormous level of 340B and Part D duplication. Accordingly, we urge CMS, in the strongest terms possible, to move forward now with a mandate that 340B pharmacy claims, including all Medicare Part D claims, include a 340B identifier. This is the only means to ensure that CMS meets its statutory obligations to both collect Medicare Part D rebates that it is owed and to exclude 340B units.

This, of course, is an entirely workable solution, as evidenced by the fact that the use of a 340B modifier is already required in connection with Medicare Part B claims. *See* CMS, "Medicare Part B Inflation Rebate Guidance, Use of the 340B Modifier", MLN Matters Fact Sheet, MLN4800856 (Nov. 2023).

Indeed, covered entities must, in order to claim a 340B price, ensure that they can link a drug to a 340B patient, an action they typically take using a third-party administrator that uses claims data in that exercise. That claims data is created and maintained by covered entities and their contract pharmacies in the normal course of their operations and is quite independently necessary to bill third-party payers, including Medicare, for 340B drugs.

The only objection that some 340B covered entities offer to the commonsense expectation that 340B claims be labeled as such is their argument that they are unaware of whether a claim is a 340B claim at the time *contract pharmacy* claims are submitted. That issue is limited and is, as we set forth below, easily addressed, in part based on an adaptation of a part of CMS' proposal.

Contract pharmacy transactions account for 25% of the 340B program. Berkely Research Group, "340B Program at a Glance: 2025" (Feb. 2025). In other words, the objection to a 340B identifier mandate relates only to a clear minority of 340B transactions. The fact that a claim is 340B is typically known in the vast majority of cases when the claim is initially filed.

It is an easy matter to provide for 340B contract pharmacy use of 340B identifiers. For contract pharmacy transactions, 340B contract pharmacies could list the identifier (1) when the claim is filed initially (which is, in fact, known at that time for some claims), (2) in a corrected claim thereafter when subsequently identified, or (3) after identification in the repository that CMS proposes.

To claim the 340B price, covered entities, acting through their third-party administrators, must review contract pharmacy claims data and link the relevant claims to 340B patients. Third-party administrators have that data in hand and can and should transmit that data to the repository.

That transmission should be mandatory, and there is no reason to wait to establish that mandate. That action, which should be taken without delay, will both ensure that CMS correctly excludes all identifiable 340B units and that it secures all the Medicare Part D inflation rebates it should. The use of the approximation method that CMS proposes will simply not be as accurate.

No Need for Separate ADAP Reporting

CMS asked in its Proposed Rule whether separate reporting by ADAPs of 340B units that overlap with Part D was needed. It is not. ADAPs primarily operate as a payer of last resort. In other words, ADAPs pay because no one else, including Part D, will. From that perspective, ADAP report of units to Part D would be pointless.

It is true that there are situations where ADAPs pay for patient cost-sharing for patients in need of that assistance. Some portion of those payments may involve Part D drugs. But, even when that is the case, those payments are not made as part of any pharmacy claim process. The mechanisms used are entirely separate from pharmacy claims and pharmacy data.

Further, with respect to any units for which ADAPs pay cost-sharing amounts, our proposal that pharmacies be obligated to use 340B identifiers, submitted with the original claim, a revised claim, or in the repository, would mean that data sufficient to identify those units would already be available to CMS.

The Department Needs to Align its 340B-Related Policies

We are struck at how badly misaligned the Department of Health and Human Services' 340B-related policies are. That misalignment opens the Department to legal challenge that various actions it has taken or will take are arbitrary and capricious within the meaning of the Administrative Procedure Act, 5 U.S.C. § 551 *et seq*. In the context of Part B, the Department has, through CMS, already mandated a retrospective claims-based system to identify Part B 340B duplicates. In the context of Part D, the Department, through CMS, has now proposed to use a claims-based retrospective system to identify Part D 340B duplicates. The Department, through CMS, has authorized manufacturers to use a retrospective claims-based system to identify 340B duplicates in connection with Medicare Fair Price (MFP) drugs. The Department, acting through CMS, permits state Medicaid agencies to identify 340B duplicates through a retrospective claims-based system. The Department, acting through HRSA, has authorized ADAPs to operate on a retrospective claims basis, and the Department, through HRSA, has permitted 340B covered entities to operate on a retrospective basis under the replenishment model. Simultaneously, however, the Department, through HRSA, has refused to allow manufacturers to use a claims-based retrospective system to identify 340B duplicates and diversion in any meaningful manner.

Simultaneously, however, the Department, through the HRSA has refused to allow manufacturers to use a claims-based retrospective system to identify 340B duplicates. Although HRSA has stated that it may approve a limited number of manufacturer MFP retrospective systems on a pilot basis, manufacturers remain unable to deploy the mechanism that CMS, covered entities, ADAPs, state Medicaid agencies, and covered entities are all able to employ. The failure of the Department to align its position on manufacturers' use of retrospective systems to its position on the same question everywhere else is arbitrary and capricious.

The Department should immediately permit manufacturers, as it permits CMS, covered entities, state agencies, and ADAPs, to employ retrospective claims-based systems—without limiting that mechanism to MFP drugs. Such a system would be an additional source of data to CMS in ensuring the accuracy of its collection of manufacturer inflation rebates. More broadly, because manufacturer systems would provide information to *all* stakeholders— the federal government, state agencies, covered entities, patients, and manufacturers — it would bring transparency to the entire 340B ecosystem. This is the only means to fix a 340B program that has been mired in opacity for decades.

Thank you for your service to CMS and to the patients it serves.

Respectfully submitted,

Brandon M. Macsata
CEO

BMM:ws