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September 8, 2025

Chantelle Britton
Director, Office of Pharmacy Affairs, HRSA
5600 Fishers Lane, Mail Stop 14W52,
Rockville, MD 20857
VIA Email: 340Bpricing@hrsa.gov

RE: 340B Rebate Model Pilot [HHS Docket No. HRSA–2025–14619]

Dear Ms. Britton:

ADAP Advocacy is writing to you to urge you to modify the Health Resources and Services Administration (HRSA) proposed rebate pilot. The HRSA proposal, as it currently stands, is deeply flawed and invites challenge under the Administrative Procedure Act.

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 People Living with HIV and AIDS (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 largely 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 and the statutory intent of both the 340B program and ADAPs are achieved by providing direct access to medications at no-cost to patients. This retrospective mechanism that ADAPs use is the gold standard, and our experience with that system informs our comments here.

HRSA Misstates Its Own Authority—and Its Limits

The premise of HRSA's Proposal is that it has statutory authority to prevent manufacturers from implementing a rebate model, notwithstanding the fact that the plain language of the statute repeatedly refers to "rebates". HRSA's false premise is based on a clearly errant and tortured reading of language. Where the statute gives HRSA only limited authority to determine the "amount" of a rebate that has been paid, HRSA attempts to create, out of whole cloth, a limitless authority to write "rebates" out of the program entirely--save only if the agency choose to "pre-approve" the choice of a rebate mechanism. HRSA sees this entirely atextual and ahistorical assertion of an authority to negate rebate payments actually made without any limitation on its purported "discretion" to "pre-approve" a rebate.

We will not belabor here the many reasons why HRSA's position is arbitrary and capricious, contrary to law, and ultra vires. We fully incorporate here our amicus brief in the related federal litigation. We have attached that brief to this comment letter.

The balance of our comments assumes what we know to be incorrect—that HRSA has a "pre-approval" authority over rebates.

No Pilot Is Needed

Even if HRSA has a pre-approval authority, there is no need to conduct a pilot. The ADAP experience has already demonstrated that retrospective rebates work *without* causing delay or undue administrative burdens.

For 27 years, ADAPs have operated by way of rebate mechanism, providing a gold standard for wider implementation of that well-established system. State Drug Assistance Programs show how rebates operate in the best interest of **all** 340B stakeholders. Using a rebate model, ADAPs have been able to dramatically grow their drug and non-drug services for HIV/AIDS patients, while providing financial assistance to patients and funding for non-drug HIV/AIDS support services. Significantly, 340B ADAP drug rebates provided just 5% of ADAP funding for HIV/AIDS patients in 1997, the year before the rebate system started. By 2022, those rebates successfully and efficiently funded 47% of programs, an increase of more than 800%, including direct financial assistance to drug patients in need.[1] 340B rebates, which in 2025 are estimated to fund a full 55% of these programs, work.[2] Further, much larger, better-resourced 340B hospitals are in an even better position to operate effectively under a rebate model than the pharmacies that participate in ADAPs. ADAPs are predicated on annual, means-based, federal funding awards to each state program which are significantly smaller than most moderate – or large-scale hospital systems' annual revenue.

[1] M. Hopkins, "NASTAD Releases 2024 Monitoring Project Annual Report", *The ADAP Blog* (May 2024), available at https://adapadvocacyassociation.blogspot.com/2024/05/nastad-releases-2024-monitoring-project.html.

[2] B. Macsata, "Is the 340B Drug Rebate Program the Next 'Too Big to Fail'?", *ADAP Advocacy* (Feb. 2025), available at https://www.adapadvocacy.org/pdf-docs/2025_ADAP_Project_RW_340B_Asset_16_Too_Big_To_Fail_03-07-25.pdf.

The critics of rebates contend that they would impede the growth of the program and undermine its funding of covered entities, but those contentions, unsupported by any evidence, have already been disproved by almost three decades of ADAP experience.

Scale of the Duplicate-Pricing Problem

The recent Proposed Rule by the Centers for Medicare and Medicaid Services (CMS), quite significantly, states 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 for HRSA to act much more broadly and much more decisively than reflected in the pilot.

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.[3] The program grew an astonishing 1,000% from 2010 to 2023.[4]

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 87% of the benefits of the program,[5] 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.[6] 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.[7]

Multiple government reports have demonstrated that non-ADAP 340B program claims are riddled with duplicate discounts and diversion issues, as well as other 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, likely 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%, as discussed below in Table 1.

[3] R. Martin, *et al*., "IQVIA 340B Dynamics Dashboard" (2025)
[4] *Id.*
[5] https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases
[6] Pioneer, 340B Abuse, Hospital Charity Care, available at https://pioneerinstitute.org/340babuse/
[7] ADAP Advocacy, 340b Map, available at https://340bmap.org/

Table 1:

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

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 HRSA to bring much greater transparency to 340B utilization. Importantly, the 340B program's many ills, discussed above, can only be addressed by dramatically improved transparency, like that which we call for here in a broad and thoroughly transparent rebate model.

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. Failing to strictly prohibit duplicate discounts across other discount drug programs encourages abuse and dramatically increases wasteful spending for states and the federal government. 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.

Modifications to the Pilot

HRSA requested comment on its pilot design. We have several suggestions, beyond the fundamental point made above, that HRSA should acknowledge that it lacks the authority to restrict manufacturers from implementing rebate models. Even assuming that HRSA has the authority to pre-approve a rebate model, which, as a factual matter, it did not do in connection with ADAPs, the proposal advanced by HRSA must be modified to reflect the interests of 340B patients and the Administration's priority in preventing waste, fraud, and abuse.

It is deeply concerning that in posing its questions about "pilot design"—and indeed throughout its notice—HRSA neglects to mention 340B patients and their interests, even once. Congress, in speaking to the purpose of the 340B program, referenced its intent that the program would benefit "eligible patients" and that covered entities serving those patients would provide more comprehensive services.[8]

[8] Some 340B interest groups cynically claim that Congress, in creating the 340B program, only intended it to benefit providers, not patients. That's untrue. When Congress enacted 340B it specifically tied the program to federally-funded clinics and public hospitals precisely because they "*serve* large numbers of *low-income and uninsured patients*". Though Congress' legislative history also referenced "stretching … resources" in creating the program, it did so specifically in a context that stressed the underlying purpose of

However, HRSA's proposal fails to reflect the interests of eligible 340B patients who receive drugs but are provided no access to 340B pricing at the pharmacy counter. Research demonstrates that 340B hospitals, which receive more than 80% of the program's benefits, allocate an average of just 2.15% of their expenditures to charity care. Similarly, 340B contract pharmacy branded drug transactions result in no more than 4.7%, and as low as 1.7%, of patients receiving any demonstrable support from covered entities with their medication needs.[9]

Although we support HRSA's call for manufacturer rebate models to include platforms that are transparent to covered entities and to HRSA itself, it is unthinkable that that transparency would not also be required to extend to the patients who generate billions in profits to 340B hospitals. Patients must be permitted access to rebate platforms to determine whether they are being provided access to 340B pricing. In addition, state Medicaid agencies should be provided access to the platforms so that they can better administer the Medicaid program, including by better identifying duplicate Medicaid rebates and reconciling any wasteful expenditures as it relates to any duplicate discount.

Any rebate model worth its salt will provide **everyone**—covered entities, patients, manufacturers, HRSA, and state Medicaid agencies—with transparency into how the program is operating.

HRSA Should Clarify Its Proposal

Some 340B stakeholders have misunderstood HRSA's reference to its proposal for a "voluntary 340B Rebate Model Pilot Program". Those stakeholders have incorrectly stated that covered entities may decline to participate in the pilot even when the manufacturer's proposal has been accepted by HRSA. That is both inconsistent with the plain language of HRSA's proposal and nonsensical, as it would effectively give covered entities a veto power over an approved pilot. It would, in fact, render the pilot a nullity. HRSA should address this misunderstanding promptly.

HRSA Is Obligated to Respond to Comments

To the extent that HRSA has the authority it purports to assert, HRSA is fundamentally incorrect in simultaneously asserting that it "is under no obligation to respond to or act on the comments."

HRSA's call for comments is itself a tacit admission that the Administrative Procedure Act, 5 U.S.C. § 553(c), applies here. Without question, the APA obligates HRSA to respond to those comments. *See, e.g., Home Box Office, Inc. v. FCC*, 567 F.2d 9 (D.C. Cir. 1977); *Portland Cement Ass'n v. Ruckelhaus*, 488 F.2d 375 (D.C. Cir 1973); *Automotive Parts &Accessories Ass'n v. Boyd*, 407 F.2d 330 (D.C. Cir. 1968). HRSA's proposal would alter the pre-existing rights and obligations of stakeholders, and it, therefore, is a "substantive rule". *See Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92 (2015). Your position will unnecessarily expose your policy to attack under the APA. You would be prudent to respond to comments, including ours.

"reaching more *eligible* patients". "Eligible" patients are, by definition, those who use 340B drugs. Congress absolutely intended that needy drug patients at the pharmacy counter would receive assistance from 340B covered entities.

[9] R. Martin, *et al*., "Are Discounts in the 340B Drug Discount program Being Shared with Patients at the Contract Pharmacy?", *IQVIA* (Sept. 27, 2022); R. Martin, *et al*., "Do Patients Receive 340B Drug Discounts at the Contract Pharmacy Counter?", *IQVIA* (July 2, 2025).

HRSA's 2026 Only Proposal Is an Invitation to Disaster

Even assuming that HRSA does not broaden the proposal as we set forth above, HRSA should, at an absolute minimum, permit manufacturers now to submit applications for years 2027 and 2028, in addition to 2026. In addition, HRSA should act quickly on those applications.

Though we have enormous respect for HRSA and its dedicated personnel, we feel obligated to speak bluntly here. HRSA has been repeatedly asked to support a rebate model as a means of addressing the program's many ills (and the well-documented failings in the oversight of it). Those requests have been made for over five years. Despite those many requests and the five years that HRSA had to address those requests, HRSA failed to take any action until this pilot was announced, just a few months short of the initial implementation of Medicare Fair Prices (MFP). HRSA's delay has been a disservice to the 340B program and has imperiled the MFP policy.

HRSA should not repeat its previous mistake and push off applications for pilot participation and decisions on those pilots until we, once again, are within a few months of another MFP implementation for 2027 or 2028. That would put both those pilots and MFP implementation for those years at entirely unnecessary risk.

HRSA should permit manufacturers to apply now for at least 2027 and 2028 to give them and all 340B stakeholders a reasonable runway to implement rebates for those years. It would be entirely unreasonable for HRSA to engage further in the kind of delays that have undermined the 340B program and placed MFP at risk. Patients deserve better than that.

HRSA's Factual Premise Is Factually Incorrect

In framing its proposal, HRSA states that "the 340B Program has traditionally operated as an upfront discount program". That entirely unqualified statement is factually incorrect, and HRSA should correct its error immediately.

HRSA's statement is manifestly false for multiple reasons. First, because the program has grown by more than 1,000% since 2010, covered entities have routinely had to support that incredible rate of growth by purchasing products at commercial prices. Growth like that simply cannot be achieved through "replenishment". It requires the regular purchase of a massive number of units beyond the prior rate of utilization. All of those commercial purchases have in no way impeded the program's explosive growth.

But HRSA's statement is untrue for multiple other reasons as well. HRSA's position is also false because it ignores that a hefty percentage of the program as a whole operates through contract pharmacies, where the dispensed product is typically purchased at commercial prices. HRSA's position also overlooks the fact that ADAPs operate entirely on a rebate model. It also ignores that, under the replenishment model, the need to accumulate complete units necessarily means that, in the interim, covered entities must purchase product at commercial prices. It also fails to acknowledge that, since it is frequently unclear whether a particular patient will or will not be 340B eligible, covered entities must regularly purchase units at commercial prices for those dispenses they make to persons that are not 340B eligible.

It is disappointing to see HRSA premise its approach to such an important issue on inaccurate premises.

HRSA's Application Procedures Need Revision

In addition to the unnecessary time crunch that HRSA has created, having failed to act for five years on rebate requests, HRSA states that all proposed plans submitted by manufacturers "should not exceed 1,000 words". This incredibly short word limit applies even though those manufacturers must "address all of the criteria" HRSA has set out.

Such a strict limitation on such important applications projects, whether intended or not, a limited interest in exploring the critical issues raised, a disinterest in discussing and addressing implementation details, and in the obligation of the agency to engage with stakeholders as a regulatory partner. HRSA should make the application process a meaningful one, consistent with the importance of the implementation of a robust rebate model.

Support for Data-Driven Analysis

We greatly appreciate HRSA's admonition that commenters should provide data to support any contentions they advance.

In that regard, we wish to offer our analysis of the 340B Health "survey" that we were disappointed to see HRSA tacitly adopt in the federal litigation. That survey presents the case that the rebate model is too "costly". Unfortunately, this survey is junk data science.

First, the survey was deeply flawed in its design from the start. The survey report shows, on its face, that a randomized sample was **not** used and indicates that only "347 respondents" participated in the survey. This represents a small fraction of the 50,000 340B covered entities, less than 1%. Given 340B Health's advocacy efforts, its non-randomized, small set of "respondents" necessarily biases the results towards that group's established anti-rebate advocacy position.

Second, the survey report fails to provide a copy of the survey instrument, which makes it impossible to assess the substantial risk of bias communicated in the survey form or other communications related to the survey. This failure to disclose the survey instrument is inconsistent with the most basic data practices expected in conducting or reporting on a survey.

Third, the survey was premised in a manner that shows bias. The survey was based on the assumption that drug makers would use "a 30-day payment period" for rebates. That assumption was more than twice the maximum period most manufacturers had committed to previously and is three times the time period required now in the HRSA pilot. The survey addresses a program that neither manufacturers nor HRSA have proposed--rendering it both irrelevant and useless.

Fourth, the survey results fail to consider multiple factors that must be taken into account to have any bearing on the issues posed. The results fail to acknowledge, for instance, the fact that 340B hospitals and other covered entities do not pay their distributors and wholesalers for their drug purchases before or even when those products are delivered to them. In the normal course, distributors and wholesalers provide a "float" **to** covered entities. A standard float, as publicly documented, is 30 days,[10] three times the payment period HRSA will require of manufacturers.

It is true that some covered entities do choose a shorter distributor or wholesaler "float". They do this often because the covered entities are **paid** for their voluntary decision to pay earlier in the form of an additional discount in addition to the 340B price. The distributor and wholesaler "float," and those payments from them to covered entities are wholly absent from 340B Health's analysis.

Further, the survey fails to consider how quickly covered entities, particularly 340B hospitals "turn" their inventory, and how quickly those "turns" occur relative to the payment terms offered by distributors and wholesalers. In many cases, the undeniable fact is that rebate payments would be made **before** the 340B entity pays for the drug.

We decided to undertake our own analysis given the fundamental defects present in the 340B Health survey results. Prior research, discussed above, establishes that the reimbursement value of the 340B program to covered entities is $148 billion, using wholesale acquisition cost as an estimate of that reimbursement value. The actual acquisition cost for 340B drugs is $68 billion. The delta between those two numbers is $80 billion.[11]

We determined, that 340B hospitals "turn" their inventories between 12 and 15 times each year. We developed this information by speaking with multiple individuals at 340B hospitals and other industry experts. That rate of "turns" means that product is held on average only between 24 and 30 days. Speaking with these same sources and experts, we determined that a standard cost of funds to 340B hospitals is 7% per annum.

Based on these inputs, the cost of a rebate model is no more than 0.31% of the value of the 340B program ($80 billion x 0.07% /12 /$148 billion). Further, this analysis is likely a substantial overestimate of the actual cost. It fails to consider the positive impact of rebate payments made before covered entities pay for their medications, the value of payment terms extended by distributors and wholesalers, the value of the payments that those distributors and wholesalers make to covered entities for earlier payments, and the fact many covered entities would purchase upfront at a low group purchasing price if they did not purchase initially at a 340B price. Even without considering any of those and other factors, the cost of a rebate program is substantially less than a credit card transaction.

HRSA Misunderstands the Administrative "Costs" Question

HRSA's notice seems to adopt some rebate critics' argument that the normal costs of providing data should be characterized as "administrative burdens" and attributed to a rebate model in analyzing that model. That is fundamentally incorrect as both a practical and a legal matter.

[10] *See* McKesson, Terms and Conditions of Sale, https://sites.mckesson.com/mscs/images/MSCS_Terms_and_Conditions_102008.pdf (large distributor stating that standard "[p]ayment terms are net 30 [days]").
[11] R. Martin, *et al*., "The Size and Growth of the 340B Program in 2024", *IQVIA* (2025).

At a practical level, it is uncontested that covered entities and their third-party administrators regularly collect and house the very claims data needed for a rebate model. That data is required, entirely separate from any rebate model, in order to secure third-party insurer payment for the drugs and to meet HRSA's existing obligation that covered entities establish that the drugs for which they claim 340B pricing are appropriate for that pricing. A 340B patient cannot be determined to be eligible for 340B pricing without the collection and review of claims data that establishes 340B eligibility.

Thus, the notion of "administrative burden" here is entirely without foundation. Rebate models only ask covered entities to collect the data they already collect. ADAPs and their partners have, for years, operated a rebate model that is dependent on the collection and review of claims data, and that gold standard shows that these arguments against a rebate model are baseless.

The "burden" argument is also legally flawed. The Third Circuit and the D.C. Circuit decisions, binding on HRSA, establish, without question, that manufacturers are permitted to collect claims data completely **independent** of any rebate model. To attribute a claims data condition on sale to the rebate model is flatly inconsistent with manufacturers' court-recognized right to independently collect that data and require its submission.

Indeed, if there is any administrative "cost" associated with the pilot, it is a function of the pilot's design itself. By limiting the pilot to just 10 products, it unnecessarily forces covered entities and manufacturers to run the program without achieving the efficiencies that would otherwise result from the wider application of the model. Unfortunately, HRSA's pilot design biases the pilot in a fashion that minimizes its advantages, to the detriment of all 340B stakeholders.

The Pilot Attempts to Unlawfully Force Pricing in Violation of the Statute

HRSA's notice declares that, under the pilot, 340B rebates are "not [to be] denied based on compliance concerns with diversion or Medicaid duplicate discounts". HRSA purports to mandate that manufacturers provide 340B pricing even where they **know**, based on their review of data that HRSA would have agreed they can collect and review, that 340B pricing is not permitted. That is a clear violation of the APA and the plain language of the statute.

The plain language of the Act states that the Secretary can only compel a price that "does not exceed" the ceiling price. Public Health Service Act, at §340B(a)(1). The Act is explicit that the 340B price does not apply where either a Medicaid duplicate discount is present or the eligible drug has been diverted to any person not a patient of that covered entity. *Id*. at (a)(5).

By attempting to force manufacturers to provide a 340B price when they know that the price does not apply as a statutory matter, the agency is quite clearly asserting a position that is contrary to law, ultra vires, and a violation of the APA. We urge you to abandon this unlawful position.

HRSA's Notice Undermines Its Legal Position

We note that HRSA states that, if a manufacturer were to proceed without agency approval, such action "would violate" the 340B statute. HRSA's position is the federal litigation is that it has not arrived at a final decision with respect to multiple manufacturer and platform rebate models.

This notice shows that HRSA has inaccurately presented its position in the litigation. HRSA has arrived at a final decision—its position is that a manufacturer may not proceed with their rebate models without violating the statute. HRSA should immediately correct the record in the on-going litigation.

The Department Needs to Align its 340B-Related Policies

We are struck at how badly misaligned the Department of Health and Human Services' 340B 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 APA 5 U.S.C. § 551 *et seq*.

We think it is helpful to put the retrospective rebate system in context.

Under 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 rebate system to identify 340B duplicates and diversion. The Secretary, through HRSA, holds out the possibility of permitting a retrospective rebate system for only 10 drugs but only for MFP duplication purposes.

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. Manufacturers should not in any way be limited in implementing such a system to MFP drugs and MFP duplicates when they occur in a single program year.

Manufacturer rebate systems applied broadly would provide desperately needed transparency to ***all*** stakeholders— the federal government, state agencies, covered entities, patients, and manufacturers--and they would, therefore, serve the purposes of the 340B program, not undermine them. This is the only means to fix a 340B program that has been mired in opacity for decades.

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

Respectfully submitted,

Brandon M. Macsata
CEO

BMM:ws