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August 6, 2026

Via CM/ECF

Anastasia Dubrovsky
Clerk of Court
United States Court of Appeals for the First Circuit
John Joseph Moakley U.S. Courthouse
1 Courthouse Way, Suite 2500
Boston, MA 02210

Re: *American Hospital Association, et al. v. AbbVie Inc., et al.*, No. 25-2237, Notice of Supplemental Authority

Dear Clerk Dubrovsky:

Appellants submit this letter regarding the Health Resources and Services Administration's (HRSA) announcement of a revised 340B Rebate Model Pilot Program, 91 Fed. Reg. 48,883 (Aug. 3, 2026), which further confirms that this appeal is not moot because the intervention dispute here is likely to imminently recur in expedited litigation that will directly affect Appellants' interests.

Each manufacturer Appellant is eligible to participate in the revised Pilot Program, for the same reasons each was eligible to participate in the initial Pilot Program. *See id.* at 48,901-48,902; Reply.Br.31. Each manufacturer Appellant intends to apply to participate in the revised Pilot Program. If and when such applications are granted, Appellants will have the same direct, concrete legal interests that were at issue in the underlying litigation here. In response to HRSA's announcement, Appellee the American Hospital Association (AHA) stated that it is "considering all available options to prevent" the revised Pilot Program "from going into effect." Rick Pollack, AHA Statement on 340B Rebate Model (July 31, 2026), https://tinyurl.com/bdfxxfxv.

A suit by Appellees to prevent the revised Pilot Program from going into effect will threaten Appellants' concrete legal interests. Pursuant to the settlement in this case, Appellees and HRSA plan to litigate the validity of the revised Pilot Program in ninety days, if not fewer. JA558(¶9). That expedited timeline threatens to replicate the situation that already once deprived Appellants of review: should Appellants again be erroneously denied intervention, the contemplated rushed merits proceedings would very likely conclude before the appellate process could fully play out. Opening.Br.63-64.

This appeal is not moot, so this Court should reach the merits and reverse the district court's denial of Appellants' motions to intervene. Alternatively, this Court should vacate the intervention denial under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), as other courts of appeals have done in similar circumstances, *see* Opening.Br.64-65, and as Appellees agree is appropriate, Response.Br.33 n.10.

Respectfully submitted,

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Cc: All counsel of record (*via CM/ECF*)

and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936, *Susan.Levine@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry titled ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' This guidance revises the draft guidance of the same name that was published in the **Federal Register** on April 13, 2023 (83 FR 50945).

The components and composition of a TDS formulation, including the nature of the drug substance and/or the occlusivity of the TDS materials, in conjunction with other factors such as the environmental humidity or the condition of the skin, may have the potential to irritate the skin or lead to a sensitization reaction. Such reactions can be unpleasant to the patient and may affect patient compliance, skin permeability, and/or adhesion of the TDS to the skin. The collective consequence of these potential effects could create uncertainty about the resulting drug delivery profile and the rate and extent of drug absorption from the TDS. Therefore, when appropriate, applicants should perform a comparative assessment of the test (T) and reference (R) TDS products using an appropriately designed skin irritation (or combined irritation and sensitization) study with human subjects to demonstrate that the potential for a skin irritation or sensitization reaction with the T TDS is no worse than the reaction observed with the R TDS.

This revised draft guidance (Revision 2) provides the following updates to the last revised draft guidance (Revision 1) from April 2023:

(1) Clarifies recommendations for the design and conduct of studies to evaluate the in vivo skin irritation (and sensitization, if applicable) potential of a proposed TDS.

(2) Clarifies when an in vivo study to assess the sensitization potential of a TDS product may not be needed.

The recommendations in this revised draft guidance relate to studies submitted in support of an ANDA. The Agency is seeking comments on the recommendations reflected in the revised draft guidance announced in this notice. In addition, FDA invites comments on the scoring scales and any alternative approaches, including those recommended by international regulatory agencies, that may have been used for the comparative assessment of the irritation/sensitization potential for proposed generic TDS products. FDA also specifically invites comments regarding the comparative assessment of sensitization itself, *i.e.,* whether there are clinical scenarios where a comparative sensitization assessment may be uninformative when conducted in addition to a comparative irritation assessment.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 relating to the submission of abbreviated new drug applications, including the design and conduct of studies and the submission of study data, as well as the collections of information relating to good clinical practice, have been approved under OMB control number 0910–0001. The collections of information for controlled correspondence and meetings related to generic drug development are approved under OMB control number 0910–0727.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15612 Filed 7–31–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding 340B Rebate Model Pilot Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA), which administers the 340B Drug Pricing Program (340B Program), is issuing this Notice to announce the availability of a revised 340B Rebate Model Pilot Program (Pilot). The Pilot provides a rebate mechanism through which qualifying drug manufacturers may effectuate the 340B ceiling price for certain drugs sold to covered entities. Consistent with HRSA's longstanding statutory authority, rebates will be used instead of upfront discounts.

HRSA issued a Request for Information (RFI) [1] to gather input from interested parties regarding the potential use of rebates to effectuate the ceiling price under the 340B Program, including the standards and procedures that should govern the approval of manufacturer rebate plans and the impacts on all stakeholders. After carefully considering all comments from interested parties and different policy alternatives, HRSA is announcing this Pilot, which will implement a rebate approach for a limited set of drugs, and which builds on established and successful rebate programs.

This Notice is effective immediately as published, unless revised by a future notice. HRSA reserves the right to issue revisions or addenda to this Notice at a later date.

[1] *Request for Information* (91 FR 7287) (Feb. 17, 2026), available at *https://www.federalregister.gov/documents/2026/02/17/2026-03042/request-for-information-340b-rebate-model-pilot-program.*

DATES: Eligible manufacturers seeking to participate in the 340B Rebate Model Pilot Program must submit plans to *340BPricing@hrsa.gov* no later than August 24, 2026, for an effective date of January 1, 2027, for selected drugs for initial price applicability year 2026 and 2027 during their price applicability periods.

FOR FURTHER INFORMATION CONTACT: Chantelle Britton, Director, Office of Pharmacy Affairs, HRSA, 5600 Fishers Lane, Mail Stop 10W29, Rockville, MD 20857; email: *340Bpricing@hrsa.gov;* telephone 301–594–4353.

SUPPLEMENTARY INFORMATION:

I. Background

Section 340B of the Public Health Service Act entitled ''Limitation on Prices of Drugs Purchased by Covered Entities,'' was created under section 602 of Public Law 102–585, 106 Stat. 4943, 4967, the ''Veterans Health Care Act of 1992,'' and codified at section 340B of the Public Health Services Act (PHSA) [2] (hereinafter ''the 340B statute'' or otherwise referred to herein as ''section 340B''). Section 340B requires pharmaceutical manufacturers participating in Medicare Part B (which covers physician-administered drugs) and Medicaid to sell drugs at reduced prices to certain healthcare providers known as ''covered entities.'' While the 340B Program ''was intended to enable certain hospitals and clinics 'to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services, *Am. Hosp. Ass'n* v. *Hargan,* 289 F. Supp. 3d 45, 47 (D.D.C. 2017) (quoting H.R. Rep. No. 102–384, pt. 2, at 12 (1992)), participation is not limited to small hospitals that traditionally serve a low-income population, such as community disproportionate share hospitals. Rather, large academic medical centers and integrated health systems may also qualify if they meet certain criteria. As of April 1, 2026, the 340B Program includes 15,249 covered entities [3] and 49,214 associated sites [4] and reached $100 billion in purchases at discounted 340B pricing in 2025.

Section 340B(a)(1) of the PHSA instructs HHS to enter into pharmaceutical pricing agreements with manufacturers of covered outpatient drugs [5]. Under section 1927(a)(1) and (5)(A) of the Social Security Act, a manufacturer must enter into an agreement with the Secretary that complies with section 340B ''[i]n order for payment to be available under section 1903(a) or under part B of title XVIII of the Social Security Act for covered outpatient drugs of a manufacturer.'' These ''are not transactional, bargained-for contracts'' but rather ''simply incorporate statutory obligations and record the manufacturers' agreement to abide by them.'' *Astra USA, Inc.* v. *Santa Clara Cnty.* 563 U.S. 110, 113, 118 (2011). When a drug manufacturer signs a pharmaceutical pricing agreement, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. 340B ceiling prices are based on quarterly pricing reports that manufacturers provide to the Secretary through the Centers for Medicare & Medicaid Services (CMS) and are calculated by HRSA.

Section 340B imposes two core prohibitions on covered entities: (1) duplicate discounts, and (2) diversion of drugs purchased under the 340B Program. 42 U.S.C. 256b(a)(5). To prevent duplicate discounts, the statute specifies that a covered entity shall not request a discount for a drug that is already subject to a separate Medicaid rebate requirement. *Id.* § 256b(a)(5)(A); *see also* Social Security Act § 1927(a)(5)(C) (creating a default mechanism for enforcing duplicate discount prohibition if HRSA fails to implement a mechanism to enforce the prohibition). And to prevent diversion, the statute specifies that ''a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.'' *Id.* § 256b(a)(5)(B).

The landscape governing 340B pricing obligations has also been shaped by more recent legislation with direct implications for how 340B ceiling prices interact with other federal drug pricing programs. In the Inflation Reduction Act of 2022, Public Law 117–169, 136 Stat. 1818, Congress gave the Secretary authority to negotiate the prices that Medicare pays for certain pharmaceutical products that lack generic competition and that account for a disproportionate share of Medicare's expenses (''selected drugs''). 42 U.S.C. 1320f(a), 1320f–1(b), (d), (e) (hereinafter ''the Medicare Drug Price Negotiation Program'' or ''MDPNP''). The MDPNP [6] applies only to manufacturers that choose to participate in Medicare and Medicaid and applies only to the prices that Medicare pays for the selected drugs. *Id.* § 1320f–1(b), (d). If negotiations for a selected drug are successful, the manufacturer memorializes its agreement to make the drug available to Medicare beneficiaries at the negotiated price, which is called the maximum fair price (MFP). *Id.* § 1320f–2(a).

The negotiated price of drugs and biologics in the MDPNP and the 340B Program are not cumulative. 42 U.S.C. 1320f-2(d). If a manufacturer provides a drug to a Medicare beneficiary at the MFP established by the MDPNP and if the negotiated price is lower than the 340B ceiling price, then the manufacturer need not also provide a 340B discount to the covered entity. *Id.; see* Ctrs. for Medicare & Medicaid Servs. (CMS), *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028,* at 253–256 (Sept. 30, 2025), *https://perma.cc/37EL-GRUW.* Negotiated prices for the first year of the MDPNP took effect on January 1, 2026. *Id.* at 154.

II. Statutory Framework and Early Implementation of the 340B Program

A. Statutory Flexibility in Pricing Mechanisms

Since its beginning, the 340B price reductions were to be ''implemented, at the discretion of the Secretary, either by a point-of-purchase discount, a rebate, or other mechanism.'' H.R. Rep. No. 102–384, pt. 2, at 12 (1992); *id.* (stating manufacturers ''would have to enter into an agreement with the Secretary of HHS to provide price reductions (whether through a discount, rebate, or other mechanism) to these 'covered entities' on covered outpatient drugs''); *see also* Guidance Regarding Section 602 of the Veterans Health Care Act of 1992; Limitation on Prices of Drugs Purchased by Covered Entities, 58 FR 27289, 27290 (May 7, 1993) (stating that the act creating the 340B Program is ''an attempt to provide federal purchasers with a process whereby they will receive drug discounts or rebates''). As the House Report stated:

The Committee bill does not specify whether ''*covered entities*'' *would receive*

[2] 42 U.S.C. 256b.

[3] A ''covered entity'' is an entity that is listed within section 340B(a)(4) of the PHSA, meets the requirements under section 340B(a)(5) of the PHSA, and is registered and listed in the 340B database. 42 CFR 10.3.

[4] Associated sites include offsite outpatient facilities integral to a parent 340B hospital or a site that shares a grant number or designation number for community health centers or Federally Qualified Health Center Look-alikes.

[5] OMB Control Number 0915–0327.

[6] *https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program.*

these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of ''covered entity,'' such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs. The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of ''covered entity.''

H.R. Rep. No. 102–384, pt. 2, at 16 (1992).

B. Early Reliance on Upfront Discounts and Replenishment Models

During the 340B Program's early stages, covered entities maintained separate physical inventories of 340B drugs for eligible patients and drugs purchased at a higher commercial price for ineligible patients. Over time the replenishment (or virtual inventory) model emerged as the standard approach. Under a replenishment model, a pharmacy first dispenses drugs to patients from one commercial inventory, also referred to as its neutral inventory. Specialized software then evaluates each dispense to determine whether the patient qualifies as a 340B-eligible patient of the covered entity. Once a sufficient quantity of eligible dispenses has accumulated, the covered entity is authorized to purchase a matching replenishment quantity of that drug at the discounted 340B price through its wholesaler account, which is then shipped to the pharmacy to restock its neutral inventory. In this way, the covered entity effectively captures the 340B discount retroactively on drugs already dispensed to eligible patients, allowing it to realize the cost savings the program is designed to provide.

After several years of experience with this system, HRSA identified limitations for certain covered entities. In particular, it found that State AIDS Drug Assistance Programs (ADAPs) ''have drug purchasing systems that have prevented their participation in the section 340B discount program.'' 62 FR 45824 (Aug. 27, 1997). To address this constraint, unlike other 340B entities, ADAPs can choose to participate as a direct purchase entity (*i.e.* receive the 340B discount upfront) and/or through a rebate mechanism. In the ADAP rebate model, ADAPs pay retail prices to dispensing pharmacies on behalf of their clients. The Secretary subsequently recognized this approach, permitted ADAPs to obtain 340B pricing through rebates from manufacturers equal to the difference between the retail price paid and the 340B ceiling price, and required manufacturers to offer such rebates to ADAPs, emphasizing that the agency was ''recogniz[ing] a rebate option'' for these providers.

C. Emergence of Rebate Proposals and Recent Agency Actions

Following passage of the MDPNP, a number of pharmaceutical manufacturers approached HRSA in 2024 with proposals to implement a new rebate model for complying with 340B pricing requirements. Each proposal for a rebate model worked in a similar way: covered entities (or contract pharmacies acting on their behalf) would initially purchase drugs at commercial prices and then, after dispensing the drugs to 340B patients, would submit claims to the manufacturers for a cash rebate ''equal to the difference between the acquisition cost and the 340B ceiling price.''

In the fall of 2024, several pharmaceutical manufacturers informed HRSA that they intended to roll out rebate models irrespective of the Secretary's approval. HRSA responded to these proposals with similar letters and expressed concern that ''[s]hifting to the rebate model would disrupt how the 340B Program has operated for over thirty years'' and sought clarification on how rebates would affect providers and patients. To that end, HRSA requested responses to a detailed list of questions to enable it to better evaluate the manufacturers' proposals. The letters sought additional information about how the manufacturers would process and approve or reject claims; inquired into data privacy practices; and sought assurances that in implementing the rebates, the manufacturers would comply with their obligations under section 340B. Each manufacturer responded to these questions, and covered entities expressed concerns that the proposed models would fundamentally shift how the 340B Program has operated for over 30 years. At the time, HRSA considered information from a variety of stakeholders, including manufacturers, covered entities, trade organizations representing the interests of covered entities and manufacturers, information technology (IT) companies, and other supply chain trade organizations.

HRSA concluded its deliberations by determining manufacturer-imposed rebate approaches violate a manufacturer's obligations under Section 340B(a)(1) of the Public Health Service Act because the 340B statute requires Secretarial pre-approval of any rebate mechanism and that no manufacturer may unilaterally shift from upfront discounts to a rebate structure without HHS authorization. The court in *Eli Lilly & Co.* v. *Kennedy,* No. 24–cv–03220, 2025 WL 1423630 (D.D.C. May 15, 2025) agreed, holding that HRSA does have authority to require pre-approval of rebate models and that manufacturers may not implement such models unilaterally.[7] *Id.* at *14.

Consistent with these developments, after considering the information received, on August 1, 2025, HRSA published a **Federal Register** Notice (''2025 Notice'') inviting manufacturers with MDPNP Agreements with CMS for initial price applicability year 2026 to participate in a voluntary rebate model pilot program. 90 FR 36163 (Aug. 1, 2025); *see also* HRSA Announces Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment (July 31, 2025), *https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program.* The pilot program was intended to launch a rebate model across a limited set of drugs that were subject to the MDPNP in 2026 to ensure a fair and transparent 340B rebate model process for all stakeholders involved.

HRSA received 1,243 public comments from stakeholders in response to the 2025 Notice, including from covered entity and manufacturer trade organizations, individual covered entities, and drug manufacturers. HRSA's review of the public comments helped to inform the Agency's review of and decision on whether to approve the manufacturer applications, and the conditions of approval.

On October 30, 2025, HRSA announced the approval of eight manufacturer applications for participation in the pilot program, with an effective date of January 1, 2026. HRSA later approved a ninth manufacturer application for participation in the pilot program with an effective date of April 1, 2026.

On December 1, 2025, covered entity stakeholders filed suit under the Administrative Procedure Act in the U.S. District Court for the District of Maine to enjoin implementation of the 2025 340B Rebate Model Pilot Program. *See Am. Hosp. Ass'n* v. *Kennedy,* 820 F. Supp. 3d 30 (D. Me. 2025). On December 29, 2025, the District Court granted the Plaintiffs' request for a preliminary injunction, thus triggering a nationwide pause of the Pilot, while

[7] On July 21, 2026, the D.C. Circuit affirmed the district court's ruling upholding HHS's position that Section 340B permits rebate models and manufacturers may not unilaterally implement such models without HHS Secretarial approval. *Novartis Pharms. Corp.* v. *Kennedy,* No. 25–5177 (D.C. Cir. July 21, 2026).

confirming that in establishing and implementing the 2025 340B Rebate Model Pilot Program, HRSA was not required to respond to public comments. *Id.* at 45. HHS appealed the preliminary injunction to the U.S. Court of Appeals for the First Circuit, which denied a stay of the District Court's order, thus keeping in place a nationwide pause of the 2025 Pilot. *Am. Hosp. Ass'n* v. *Kennedy,* 164 F.4th 28 (1st Cir. 2026).

HHS later voluntarily dismissed its appeal of the preliminary injunction, which was granted by the First Circuit on January 20, 2026, and opted to withdraw the 2025 Pilot. On February 10, 2026, the District Court formally vacated and remanded to HHS the ''340B Rebate Model Pilot Program Application Notice,'' 90 FR 36163 (Aug. 1, 2025), the ''Corrected 340B Rebate Model Pilot Program Application Notice,'' 90 FR 38165 (Aug. 7, 2025), and the approvals of applications from drug manufacturers submitted pursuant to those notices (announced between October 30 and November 14, 2025).

III. Expansion and Transformation of the 340B Program

At its inception, the 340B Program operated as a relatively simple pricing requirement. Covered entities were few in number, and the statutory scheme contemplated a straightforward transactional model in which manufacturers would provide drugs at discounted prices at the point of sale. Program administration reflected those assumptions: entities dispensed drugs directly, often from segregated inventories, and the application of the ceiling price occurred in a largely contemporaneous and verifiable manner. This structure aligned with the program's scale. With limited participants and relatively simple distribution arrangements, an upfront discount model provided a practical and administrable means of ensuring compliance with the ceiling price requirement.

Over time, however, the program expanded significantly. Administrative guidance permitted covered entities to rely on contract pharmacies and to utilize replenishment inventory systems rather than maintaining separate physical inventories.[8] Congress further expanded the program through the Patient Protection and Affordable Care Act, which increased the number and types of eligible covered entities.[9] Public Law 111–148, § 7101(a), 124 Stat. 119, 821–22 (2010). As a result of these developments, the 340B Program has evolved into a large and economically significant component of the pharmaceutical marketplace.

That growth has been substantial. In 2022, total 340B program sales reached $53.7 billion when measured at the discounted 340B price by 2023, covered entities purchased $66.3 billion in covered outpatient drugs under the program, representing approximately 23.4% growth in just 1 year. Comparatively, in 2023, prescription drug spending in the U.S. grew 10.1%. By 2024, covered entities purchased $81.4 billion in covered outpatient drugs under the program, representing approximately 50% growth in just 2 years.

Over a longer horizon, there was a 174% increase in the number of covered entities between 2013 and 2023. As the market has shifted, covered entities now include large hospital systems and extensive networks of affiliated hospital outpatient sites, often operating through numerous arrangements with contract pharmacies.

A 340B contract pharmacy is a retail or specialty pharmacy that has entered into a formal agreement with a covered entity to dispense drugs on the covered entity's behalf. Because many covered entities, such as federally qualified health centers, lack the ability to operate their own in-house pharmacy, contract pharmacy arrangements provide a mechanism to extend their 340B Program benefits to eligible patients by leveraging existing pharmacy infrastructure. Under this arrangement, a contract pharmacy dispenses drugs to the covered entity's eligible patients, while the covered entity retains ultimate responsibility for ensuring compliance with 340B Program requirements, including proper tracking of eligible dispenses and accurate replenishment ordering.

As the 340B Program has grown, so too has its operational complexity. Transactions now frequently occur through multi-step distribution channels involving contract pharmacies and retrospective eligibility determinations. Because 340B transactions often flow through multi-step distribution channels, including contract pharmacies that serve multiple covered entities, real-time eligibility verification at the point of sale is not always feasible, leaving eligibility determinations to be made after the fact based on claims data that may be incomplete or inconsistently documented. This retrospective approach creates a gap between when a drug is dispensed and when eligibility is confirmed, making it difficult to ensure that discounted purchases are accurately matched to qualifying patients (*i.e.,* raising the risk of diversion) and raising the risk that the same transaction could be counted toward both a 340B discount and a Medicaid rebate, a duplicate discount that the statute expressly prohibits. In this environment, administrative and program integrity challenges, including difficulties in verifying patient eligibility at the point of sale and preventing statutorily prohibited diversion and duplicate discounts, present challenges as the 340B Program has evolved over time.

The progression of the 340B Program from a narrow pricing safeguard to a complex, multi-billion-dollar system thus underscores the importance of flexibility in determining how statutory pricing obligations are implemented. The 340B statute itself contemplates such flexibility, directing that the ceiling price be determined ''taking into account any rebate or discount, as provided by the Secretary.'' 42 U.S.C. 256b(a)(1). Accordingly, the method by which that price is effectuated must be capable of adapting to the Program's current scale and operational realities.

While HRSA initially administered the Program as primarily an upfront discount drug purchasing model, the size and complexity of the 340B Program and the pharmaceutical distribution chain, together with the MDPNP framework and nonduplication requirements,[10] warrant reconsideration of whether the upfront discount model remains the most effective means of

[8] *See, e.g.,* 61 FR 43549 (Aug. 23, 1996) (permitting one contract pharmacy per covered entity); 75 FR 10272 (March 5, 2010) (permitting covered entities to use multiple contract pharmacies).

[9] The ACA added five additional categories of hospital covered entities: Pediatric Hospitals, Rural Referral Centers, Critical Access Hospitals, Cancer Hospitals, and Sole Community Hospitals.

[10] As stated in Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026, ''in accordance with section 1193(d)(1) of the Social Security Act, the Primary Manufacturer of a selected drug is not required to provide access to the Maximum Fair Price (MFP) for a selected drug to MFP-eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the (Public Health Service (PHS)) Act if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHSA and the 340B ceiling price (defined in section 340B(a)(1) of the PHSA is lower than the MFP for such selected drug. Under section 1193(d)(2) of the Social Security Act, the Primary Manufacturer is required to provide access to the MFP to 340B covered entities in a deduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug.''

carrying out statutory objectives. In exercising its stewardship role, HRSA must balance covered entities' longstanding reliance on the upfront discount model against the need to ensure effective program oversight, safeguard the benefits of 340B pricing, and maintain program integrity and accountability in a rapidly evolving landscape, as it has done in the past.

IV. Program Integrity Considerations

When HRSA adopted the rebate option for ADAPs in 1998, commenters asserted that such a model should be limited only to ADAPs and not expanded to other categories of covered entities. HRSA responded that it agreed with those commenters, ''at this time.'' 63 FR 35241, 35241–42 (June 29, 1998). As noted above, however, the Program has changed dramatically in the intervening 28 years. Since 1998, there have been multiple reports by Congress and governmental agencies noting the exponential growth of the Program; [11] the difficulty of enforcing the prohibition on duplicate discounts; [12] and concerns surrounding diversion.[13] The 1998 ADAP guidance predates the adoption of the outpatient prospective payment system in 2000 (which led CMS to codify a regulatory policy on off-campus provider billing), as well as the enactment of Medicare Part D in 2003 (which created a new outpatient drug benefit for Medicare beneficiaries while dramatically expanding the use and understanding of rebates in the pharmaceutical supply chain), the Deficit Reduction Act in 2005 (which added pediatric hospitals as a class of 340B covered entities), the Affordable Care Act in 2010 (which added five additional categories [14] of 340B hospital covered entities), and the Inflation Reduction Act in 2022 (which gave CMS the authority to negotiate drug prices but creating the potential for a new category of duplicate discounts).

The growing complexity of the pharmaceutical supply chain, combined with the enactment of the statutory provisions cited above, makes program integrity a growing risk. For example, the 340B statute is clear that a manufacturer is not required to provide a rebate for a unit of a covered outpatient drug under the Medicaid Drug Rebate Program and provide 340B pricing for that same unit of drug. Yet the growing number of child sites of covered entities and contract pharmacies and the growth in the number of patients who are eligible for insurance coverage for prescription drugs make it more difficult to guard against duplicate discounts with an up-front discount model. Child sites and contract pharmacies introduce complexity because they operate separately from the covered entity itself, often billing under their own identifiers or through intermediary systems that may not be fully integrated with the covered entity's patient eligibility records. When a prescription is dispensed at one of these locations, the covered entity may lack real-time visibility into whether a Medicaid payer is involved, making it difficult to flag the transaction and exclude it from 340B pricing before the discount is applied. Without an ability to verify if a drug is 340B priced, the same drug purchase risks being simultaneously discounted under 340B and submitted for a Medicaid rebate, precisely the duplicate discount the statute is designed to prevent. Moreover, the HHS Office of Inspector General has noted that the prohibition on duplicate discounts is difficult to enforce with respect to drugs dispensed to Medicaid managed care enrollees, especially because the Medicaid Exclusion File, (MEF) [15] which HRSA created in 1993 for fee-for-service Medicaid, is inadequate to capture duplicate discounts with respect to Medicaid managed care enrollees, and that this inadequacy results in both duplicate discounts going unreported as well as excluding some non-340B claims from rebate invoices, thereby resulting in foregone Medicaid rebates to states.[16] The Government Accountability Office (GAO) has identified a similar concern.[17]

While there is no federal estimate of the financial extent of duplicate discounts in 340B, the topic has been evaluated by industry and academia. Manufacturer commenters stated in 2019, when the 340B program was less than half its current size, Medicaid/340B duplicate discounts amounted to as much as $1.5 billion annually. HRSA is using the flexibility granted by the 340B statute and recognized by Congress on the enactment of the program to expand the use of a rebate model in the program. The Pilot will use a rebate approach to mitigate the deficiencies cited by Congress and other governmental entities in enforcing the prohibition on duplicate discounts, by proving a mechanism to avoid duplicate discounts.

V. Summary of Public Comments and HRSA Responses

On February 17, 2026, HRSA published a Request for Information (RFI) (91 FR 7287 (Feb. 17, 2026)) to gather broad stakeholder comments on a wide range of topics having to do with the potential use of rebates to effectuate the ceiling price under the 340B Program. The RFI sought comments on whether HRSA should implement a rebate model under the 340B Program, how best to operationalize any such rebate framework for stakeholders, and the potential operational and financial impacts of transitioning to a rebate model under the 340B Program. The RFI also sought comment on reliance interests in continuing to obtain the 340B ceiling prices through upfront discounts and whether such reliance interests are reasonable in light of the Secretary's express statutory authority to provide for acquisition of covered outpatient drugs at the 340B ceiling price via ''rebate or discount.'' Commenters were invited to provide privileged or confidential information that they believed was necessary to

[11] Comm. on Energy and Com., *Review of the 340B Drug Pricing Program* (2018) (noting that the number of unique covered entities had grown 300% between 2011 and 2017; that the number of child sites had increased by 78% during that period; and that the number of contract pharmacies had increased 158% in that same period). *See also* U.S. Gov't Accountability Off., GAO–26–108784, *340B Drug Discount Program: Agency Oversight Has Improved, but Actions Needed to Address Weaknesses* (2025) (finding a 174% increase in the number of covered entities between 2013 and 2023).

[12] U.S Dep't of Health & Hum. Servs. Off. of Inspector Gen., OEI–05–1300431 at 2, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program* (2014) (noting that ''contract pharmacy arrangements create complications in preventing duplicate discounts''); *see also* U.S Dep't of Health & Hum. Servs. Off. of Inspector Gen., OEI–05–14–00430, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates* at 10 (2016); *see also* U.S. Gov't Accountability Off., GAO 20–212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (2020).

[13] U.S Dep't of Health & Hum. Servs. Off. of Inspector Gen., OEI–05–1300431 at 2, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program* (2014).

[14] The Affordable Care Act added pediatric hospitals; rural referral centers; critical access hospitals; cancer hospitals; and sole community hospitals.

[15] Pursuant to section 340B(a)(5)(A)(ii) of the PHSA, HRSA established the 340B Medicaid Exclusion File (MEF) as the mechanism to assist 340B covered entities and States in the prevention of duplicate discounts for drugs subject to Medicaid rebates. 58 FR 34058, 34058 (June 23, 1993). The 340B MEF is available on 340B Office of Pharmacy Affairs Information System. HRSA publishes the 340B MEF, which lists all of the covered entities that choose to bill Medicaid fee-for-service for the 340B drugs used for their Medicaid patients (carve-in), as the official data source to facilitate the prevention of duplicate discounts.

[16] U.S. Dep't of Health & Hum. Servs. Off. of Inspector Gen., OEI–05–14–00430, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates* (2016).

[17] U.S. Gov't Accountability Off., GAO–26–108784, *Agency Oversight Has Improved, But Actions Needed to Address Weaknesses* (2025).

comment on the RFI. Those comments were not made public and were submitted to a separate email box (*340Bpricing@hrsa.gov*).

HRSA reviewed 2,449 public comments in response to that RFI, including 1,170 identical comments as part of a letter campaign. HRSA also received 26 non-public submissions for a total of 2,475 comments, all of which HRSA considered in the design of the revised Pilot.

This substantial feedback on the RFI came from a broad range of stakeholders across the health care and pharmaceutical sectors, including hospitals, health systems, federally qualified health centers, rural providers, Tribal organizations, manufacturers, pharmacies, technology companies (technology vendors with platforms to receive claims submissions), advocacy groups, and other interested parties. Comments reflect differing perspectives on the potential implementation of a rebate-based approach. Many covered entity stakeholders expressed concerns regarding the financial, operational, and administrative implications of a rebate model, including potential cash flow impacts and implementation burden. Covered entities expressed a high degree of consistency in comments across provider types. While Critical Access Hospitals, rural hospitals, FQHCs, and larger health systems emphasized different operational challenges, there was broad agreement that a rebate model could increase financial and administrative burden. The principal differences in covered entity type comments were in the nature of the risks highlighted: cash flow and liquidity for rural providers, operational complexity for larger systems, and patient access concerns for community-based and specialty safety-net providers. In contrast, manufacturers, technology vendors, some employer and purchaser coalitions, several patient advocacy groups and other stakeholders generally support a rebate model, emphasizing its potential to improve transparency, enhance program integrity, and address manufacturer challenges related to avoiding duplicative price concessions, including those involving the MDPNP and the Medicaid Drug Rebate Program. Across stakeholder groups, HRSA also received input on the importance of minimizing administrative burden and ensuring that any model leverages existing data and operational processes. The comments received on the RFI also provided HRSA with information on the potential advantages and disadvantages that implementation of a rebate model would have on the patients served by different covered entity types.

HRSA carefully reviewed and evaluated all comments submitted in response to the RFI. The agency conducted a systematic assessment of stakeholder input and used that feedback to inform the design and policy rationale of this revised Pilot. The following sections describe in greater detail how stakeholder perspectives shaped specific components of this revised Pilot and explain HRSA's responses to the principal issues raised. HRSA's evaluation considered both the substance and the evidentiary support of the comments received, and the agency's responses to the major comment themes are summarized below.

A. Reliance Interests Related To Maintaining Up Front Discounts

Commenters express differing views on the reliance interests of covered entities in the current upfront discount model. Several covered entity organizations express concern that HRSA has not accounted for covered entities' reliance interests in maintaining an upfront discount model. These commenters state that an upfront discount model has been used in the Program for more than 30 years and covered entities have reasonably relied on this consistency when designing their internal operations. They argue that there is no reason to shift to what they view as a costly rebate mechanism given this history. By contrast, manufacturers assert the costs of implementing a rebate mechanism have been overstated and the benefits of a rebate mechanism far outweigh the additional costs. They further assert that a rebate mechanism is not a novel concept as it has been used in a limited capacity in the 340B Program for decades, is widely employed across the drug industry, and the current replenishment system functions in several respects like a rebate mechanism, particularly insofar as post-dispensing determinations and financial true-up already occur outside the point of sale.

HRSA does not agree that exclusive reliance on an upfront discount model is reasonable or that such reliance foreclose consideration of alternative statutory mechanisms. The 340B statute expressly recognizes the authority to provide the 340B ceiling price via ''rebate or discount,'' which provides the Secretary, through HRSA, discretion in how best to operationalize the statutory pricing requirement. Therefore, stakeholders cannot reasonably claim that a rebate model is unforeseeable or outside the range of expected administrative options. Rebates are a common reimbursement mechanism across the pharmaceutical sector and have been recognized by HRSA since 1998 as a valid mechanism for 340B reimbursement for AIDS drug assistance programs. Rebates are also used extensively in Medicare Part D, including with respect to Part D drugs that are dispensed by pharmacies that may have contract pharmacy agreements with 340B Program covered entities. To the extent covered entities structured their operations around a single delivery mechanism, such reliance must be understood in light of the 340B statute's plain language and the 340B Program's evolving administrative framework and the evolution of the pharmaceutical distribution chain over the past 20 years.

The Medicare Part D Program relies extensively on rebates. Manufacturers pay rebates to Part D plans in exchange for formulary placement and other services such as developing a pharmacy network and Part D benefit design. Typically, dispensing a drug for which there is a rebate agreement to a Part D enrollee triggers the payment of a rebate from the manufacturer to the Part D plan, and CMS has a mechanism in place to report the payment of that rebate via its Direct and Indirect Remuneration guidance.[18] HRSA anticipates that a rebate model would work similarly to the operation of rebates in the Part D Program; the 340B covered entity's dispensing of a drug that qualifies for the 340B price reduction would trigger the payment of a rebate by the manufacturer. Over the 20-year history of the Part D Program, a sophisticated rebate mechanism has developed and HRSA anticipates that a rebate model in the 340B Program would work similarly.

The significant growth in size and complexity of the 340B Program has introduced oversight challenges that were less pronounced when the Program was smaller and less complicated. While covered entities have relied on the upfront discount model for three decades, HRSA in its stewardship role must balance these interests against the rapidly changing 340B landscape that requires HRSA to weigh competing policy concerns, including program accessibility, administrative feasibility, statutory compliance, and the prevention of duplicate discounts and diversion.

The Supreme Court has explained that in those instances where an agency

[18] *See https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-indirect-remuneration-dir.*

must consider reliance interests when deciding whether to change a long-standing policy, an agency may consider whether language in the ultimate source of the alleged reliance interests should have warned the public away from relying too heavily on a particular policy. See *Dep't of Homeland Sec.* v. *Regents of Univ. of Cal.,* 591 U.S. 1, 32 (2020) (explaining that it would be permissible for the Department of Homeland Security to ''respond that reliance on forbearance [from removal] and benefits was unjustified in light of the express limitations in the [agency memorandum]'' stating that it conferred no substantive rights). But even if one assumed for the sake of discussion that covered entities' reliance interests in this context are reasonable as a matter of law, such a conclusion does not thereby transform such reliance interests into a categorical prohibition against the Secretary exercising his express statutory discretion to provide for 340B pricing via ''rebate or discount.'' Were it not otherwise, reliance interests would have the impermissible effect of amending statutory language that gives an agency the express discretion to choose between two different implementation methods. As the Supreme Court has explained, ''even if [an agency] ultimately concludes that the reliance interests rank as serious, they are but one factor to consider. [The agency] may determine, in the particular context before it, that other interests and policy concerns outweigh any reliance interests.'' *Regents of Univ. of Cal.,* 591 U.S. at 32.

Such is the case here. As cited throughout this Notice, HRSA recognizes that there are costs associated with a rebate model, and for this reason has incorporated implementation features designed to limit or reduce operational disruption. The 340B statute expressly gives the Secretary the authority to choose between discounts or rebates. HRSA has taken into consideration covered entities' reliance interests and found that, on balance, they do not outweigh the significant benefits of proceeding with the Pilot as described in this Notice.

Moreover, it is true that the 340B statute ''was intended to enable certain hospitals and clinics to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'' *Am. Hosp. Ass'n* v. *Hargan,* 289 F. Supp. 3d 45, 47 (D.D.C. 2017) (internal quotation marks and citation omitted). But as the Supreme Court recently confirmed in rejecting hospitals' reliance on the general purpose of a statute designed to increase certain hospitals' Medicare payments, ''[n]o statute pursues a single policy at all costs, and we are not free to rewrite this statute (or any other) as if it did.'' *Advocate Christ Med. Ctr.* v. *Kennedy,* 605 U.S. 1, 19 (2025) (internal quotation marks and citation omitted). As explained above, the 340B Program has witnessed unprecedented growth recently that has caused certain 340B Program stakeholders to reasonably question whether covered entities are complying with the 340B statute's requirements, including the prohibition against duplicate discounts. The Pilot as described in this Notice exercises the Secretary's express statutory authority to provide for 340B pricing via rebate, applied to a well-defined subset of 340B drugs that represent a relatively modest portion of overall 340B drug discounts.

B. Duplicate Discount Prevention and Program Integrity

Commenters identify duplicate discount prevention and overall program integrity as key considerations in evaluating a potential 340B rebate model. Manufacturers, technology and data intermediaries, certain pharmacy and manufacturer vendor stakeholders and some employer purchaser organizations emphasize that the current 340B framework presents challenges in identifying and preventing duplicate discounts across federal pricing programs, including Medicaid (fee-for-service and managed care) and Medicare, particularly in light of the implementation of the MDPNP and the Medicare Prescription Drug Inflation Rebate Program. These commenters state that existing mechanisms, such as the MEF and claims modifiers, are limited in their ability to ensure accurate, real-time identification of 340B utilization and often require post-hoc audits, manual reconciliation, and dispute resolution. Some commenters cite industry analyses, proprietary data, and government oversight reports suggesting that duplicate discounts may represent a significant source of program inefficiency and financial exposure. These commenters reference government reports identifying challenges in preventing duplicate discounts, particularly within Medicaid managed care, and separately cite industry analyses estimating that duplicate discounts could affect a substantial portion of 340B transactions and represent tens of billions of dollars annually, as well as hundreds of millions of dollars in unresolved disputes. These commenters assert that the implementation of the maximum fair prices under the MDPNP, further increases the likelihood of overlapping price concessions across programs and state that a rebate model, supported by claims-level data validation, could improve transparency and enable more accurate coordination across pricing programs, thereby reducing the incidence of duplicate discounts and related disputes.

Manufacturers express that existing mechanisms are insufficient to reliably identify and prevent duplicate discounts between the 340B Program and the MDPNP. These commenters emphasize that, under the current framework, manufacturers lack timely access to claims-level data to identify all units subject to 340B pricing for which maximum fair price effectuation is not required. Manufacturers state that current efforts rely on claims modifiers, estimation methodologies, and voluntary data reporting that do not provide the manufacturers with precision they desire to minimize duplication of discounts. Manufacturers further highlight the operational challenges created by timing misalignments, whereby 340B eligibility is often determined after pricing decisions must be made, increasing the risk of duplicate discounts and requiring retrospective reconciliation through resource-intensive ''pay-and-chase'' processes. Based on these limitations, manufacturers contend that a rebate-based model, which links price concessions to validated claims data, would provide a more accurate, transparent, and administratively efficient mechanism to identify and prevent duplicate discounts across federal pricing programs.

Covered entity groups acknowledge the importance of preventing duplicate discounts but contend that the current framework, when properly implemented, is sufficient to meet statutory requirements, including in the context of MDPNP implementation. These commenters state that covered entities already maintain compliance systems, including inventory controls, billing safeguards, and audit processes, to prevent duplicate discounts and diversion, and that existing coordination mechanisms can be adapted to address MDPNP-related requirements.

Many commenters also express concern that a rebate model could shift compliance responsibility and financial risk onto covered entities while introducing additional administrative complexity, particularly given the requirements associated with MDPNP implementation. Commenters also identify alternative approaches to

addressing duplicate discounts within the existing framework, including enhanced use of claims modifiers, improvements to the MEF, standardized data-sharing arrangements, and the potential use of centralized or third-party clearinghouse models that do not require a shift from upfront discounts to a rebate-based pricing mechanism.

In response to these comments, HRSA recognizes the importance of ensuring program integrity and enabling manufacturers to prevent duplicate price concessions across all applicable pricing programs. HRSA believes that a rebate-based approach, which is authorized by the 340B statute, including the use of standardized claims-level data, will improve the identification and prevention of duplicate discounts. HRSA will use data collected through the Pilot, including rebate submissions, denials, and dispute outcomes, to more effectively prevent duplicate discounts relative to existing mechanisms and to inform future policy considerations related to program integrity and compliance. HRSA believes that the manufacturer data collection from covered entities under this Pilot will enable manufacturers to better identify 340B transactions both for purposes of their nonduplication efforts in MDPNP and deduplication in Medicaid Managed Care.

Also, there are many advantages a rebate model has for prospective program integrity measures and overall transparency, including ensuring that stakeholders have transparency into 340B transaction information. Alternatives that would preserve the upfront discount model or rely on clearinghouse mechanisms would not inform whether rebates are an efficient means of effectuating the 340B ceiling price, an option expressly authorized under the 340B statute, and therefore would fail to advance the central purpose of the Pilot. HRSA does not believe that reliance solely on standardized claim identifiers, audits, or improved coordination between government programs would be sufficient to address duplicate discount risks. Retrospective reviews, audits, and dispute resolution processes are inherently reactive, identifying potential duplicate discounts only after they have occurred. Conversely, a rebate model incentivizes covered entity compliance as a prerequisite to receiving 340B discounts.

Improved coordination across government programs is complicated by differences in timing, data availability, and program administration, which limit the ability to reconcile transactions accurately and in real time. As a result, these approaches alone may not provide the level of precision, timeliness, and scalability necessary to ensure compliance with statutory nonduplication requirements. A rebate-based model, which ties price concessions to validated, claims-level data prior to payment, is intended to enhance HRSA's oversight of the 340B Program and improve program integrity by enabling more accurate, prospective identification of eligible transactions.

The Pilot will assist HRSA's evaluation of retrospective, claims-based reconciliation and may offer additional safeguards to assess whether a rebate model can improve transparency and HHS will use information from this Pilot to support compliance with statutory requirements across federal drug pricing programs.

C. Administrative and Implementation Costs to Covered Entities

Several commenters, primarily covered entities and provider organizations, assert that implementation of a rebate model would impose significant additional costs on covered entities across multiple dimensions. These commenters identify increased administrative burden, staffing needs, system modifications, and heightened financial exposure related to cash flow as key areas of concern. Many compare the costs associated with the upfront discount model to projected costs under a rebate-based approach and contend that the latter would be substantially higher.

By contrast, manufacturers and technology company commenters dispute these characterizations, arguing that the cost estimates submitted by covered entities are overstated or unsupported. Manufacturer and technology company commenters emphasize that covered entities are already required to collect and maintain the relevant claims-level data as part of routine billing, compliance, and audit activities. In their view, the data sharing requirements contemplated under a rebate model are materially similar to existing obligations imposed by Medicare, Medicaid, and commercial payers. These commenters further assert that existing infrastructure, including internal systems and third-party administrators (TPAs), can be leveraged to support data submission and rebate processing, thereby mitigating any incremental administrative burden or associated costs.

More specifically, covered entity and provider organizations commenters raise the following concerns regarding the potential costs of implementing a rebate pilot program, which manufacturer and technology company commenters contend are overstated.

1. Comments Concerning Current Administrative Costs Under the Upfront 340B Discount

Covered entities and provider organizations generally describe current administrative costs for the upfront discount replenishment model as manageable and well-integrated into existing operations, noting that their systems, staffing, and workflows have been developed over time to support compliance with 340B requirements, including inventory management, split-billing, duplicate discount prevention, and audit readiness. Covered entities employ third-party administrators (TPA), which are specialized vendors that manage the administrative and operational functions of the 340B Program on behalf of covered entities, including tracking patient eligibility, managing split-billing software, processing claims data, and ensuring compliance with program requirements. These commenters emphasize that while program participation entails ongoing administrative effort, including use of third-party administrators (TPAs), compliance monitoring, and periodic audits, these activities are predictable, standardized, and embedded within existing pharmacy and billing infrastructure.

Manufacturers and technology company commenters offer a contrasting view, asserting that current administrative processes under the upfront discount model are complex, fragmented, and resource-intensive. In particular, they point to challenges in identifying and resolving duplicate discounts, preventing diversion, and avoiding discounts that are not required under the nonduplication provision of the MDPNP. These commenters state that existing mechanisms, such as the MEF, which is the mechanism that HRSA developed pursuant to section 340B(a)(5)(A)(ii) of the PHSA, as well as claims modifiers, are insufficient and often require significant manual reconciliation, audits, and dispute resolution efforts, resulting in ongoing administrative costs across stakeholders. Commenters cited to an Office of Inspector General report [19] that noted that the MEF is not able to identify claims for outpatient prescription drugs paid by Medicaid managed care plans and noted that this is a particular area of vulnerability for duplicate Medicaid discounts. They further emphasize that, under the replenishment model,

[19] *https://oig.hhs.gov/documents/evaluation/2918/OEI-05-14-00430-Complete%20Report.pdf.*

covered entities receive 340B pricing upfront without contemporaneous verification of eligibility, while manufacturers lack access to the claims-level data necessary to confirm compliance with statutory requirements. In their view, this lack of transparency contributes to inefficiencies and necessitates reliance on retrospective oversight mechanisms that are resource-intensive, limited in scope, and ineffective at preventing improper claims in real time.

2. Comments Concerning Administrative Costs Under a Potential 340B Rebate Model Pilot Program

Commenters also expressed divergent views regarding the administrative costs associated with implementing a 340B rebate model pilot program. Covered entities, provider trade associations, contract pharmacy representatives, third-party administrator consultants and patient advocacy stakeholders, generally assert that a rebate model would introduce substantial new administrative requirements, including claims-level data submission, rebate tracking, reconciliation across multiple systems, and management of denied or disputed claims. They state that implementation would likely require additional staffing and operational changes as well as increased reliance on TPAs or other external vendors, potentially resulting in additional service fees and contractual complexity. Commenters further express concern that, particularly during a transition period or for drugs not included in a pilot, covered entities may be required to maintain both existing upfront discounts processes and new rebate-related workflows, creating duplicative operational burdens. Several commenters also note that variability in manufacturer-specific requirements, such as differing data formats, submission timelines, validation criteria, and dispute processes, combined with a lack of standardized systems, could increase administrative complexity, require the use of multiple platforms, and lead to higher operational costs and inefficiencies.

By contrast, manufacturers and trade organizations assert that the incremental administrative burden associated with a rebate model would be limited or manageable. They emphasize that covered entities already collect and maintain much of the relevant claims-level data as part of routine billing and compliance activities, including data captured in electronic health records and submitted to payers. According to these commenters existing systems and TPAs can be leveraged to support data submission and rebate processing, minimizing the need for new infrastructure. They further contend that a rebate model could, over time, reduce administrative burden by improving data transparency, decreasing reliance on retrospective audits and dispute resolution, and enabling more efficient identification and prevention of duplicate discounts and other compliance issues within the 340B Program.

3. Comments Concerning Staffing Impacts Under a Potential 340B Rebate Model Pilot Program

Commenters provide a range of quantitative estimates regarding potential staffing impacts associated with a 340B rebate model pilot program. Covered entities generally predict that a rebate model would result in the need for additional personnel to support claims-level data submission, rebate tracking, reconciliation, and denial or dispute resolution activities. Several commenters estimate that implementation could require approximately 0.5 to 1 full-time equivalent (FTE) for smaller entities and 1 to 2 or more FTEs for larger organizations or those with higher prescription volumes or extensive contract pharmacy networks. A covered entity trade association commenter cites that over 80% of surveyed entities anticipated needing additional staff, with associated annual personnel costs ranging from approximately $30,000 to over $200,000 per FTE, depending on role and location. In addition, commenters report that existing rebate-related processes can require 10 to 40 or more hours per week of staff time and indicate that a rebate model could increase workload due to expanded reporting, reconciliation, and appeals processes. These commenters provided only estimates of anticipated staffing impacts.

Manufacturers and other groups, on the other hand, assert that staffing impacts would be limited, emphasizing that covered entities already maintain the relevant claims-level data and operational infrastructure necessary to support rebate processing. These commenters state that, in addition to leveraging existing billing systems and TPAs, the administrative workload associated with rebate models may be comparable to or lower than current processes over time, particularly as improved data transparency reduces the need for manual audits and dispute resolution. One manufacturer trade group contends that a rebate model would leverage existing staffing and workflows, rather than necessitating new personnel or fundamentally different operational systems. Manufacturers also question the reliability of specific quantitative estimates submitted by covered entity commenters, citing concerns about survey sample size, response bias, and assumptions regarding rebate payment timelines that differed materially from the Pilot's requirements.

In particular, a manufacturer trade group emphasizes that modern pharmacy and health system infrastructure including automation, batch processing, and TPAs can handle data extraction, formatting, and submission with minimal manual intervention once systems are configured. Accordingly, it maintains that ongoing staffing demands would be limited with most processes becoming automated after initial implementation. Finally, manufacturers assert that over time a rebate model could reduce overall administrative burden, including staffing demands, by improving data transparency and minimizing the need for labor-intensive retrospective activities such as audits, reconciliation, and dispute resolution.

A technology vendor commenter that has developed and deployed a 340B Program rebate processing platform similarly asserts that staffing impacts can be minimized through direct TPA integration. That commenter reports that, as of spring 2026, 53 TPAs are able to submit data directly to its rebate processing platform on behalf of covered entities, which in its view would significantly reduce or eliminate any potential burden of data compilation on the part of covered entities and reduce the need for additional in-house staff. The commenter asserts that for the more than 7,000 covered entities that have previously submitted data to the vendor's existing 340B ESP platform, the incremental work necessary to submit data under a rebate model is very limited because the required data fields are the same. With regard to covered entity concerns of maintaining processes for both existing upfront discounts processes and new rebate-related workflows, the Pilot design seeks to reduce burden in this area by requiring plans to allow covered entities to order the selected drugs under existing distribution mechanisms (*e.g.,* 340B wholesaler accounts with WAC prices loaded) to ensure purchases flow through existing infrastructure, eliminating the need for duplicative operational burdens.

4. Comments Concerning Systems and Infrastructure for Implementation of a Potential 340B Rebate Model Pilot Program

Commenters express differing views regarding the systems and infrastructure required to implement a 340B rebate model pilot program. Most covered entity groups express that their current IT systems, pharmacy management platforms, and TPA arrangements are designed to operate under the existing upfront discount and replenishment model and would require significant modification or replacement to support claims-level rebate submission and reconciliation. These commenters describe potential needs for new data integration across electronic health records, pharmacy systems, billing platforms, and financial systems, as well as the development of new workflows to manage rebate eligibility determination, submission, and tracking. Some commenters estimate that implementation could require tens of thousands of dollars in annual software and reporting costs for smaller entities, with estimates commonly ranging from approximately $30,000 to $50,000 per year for software, tracking functionality, and workflow redesign. Other commenters, particularly larger health systems, project substantially higher costs associated with systems integration, vendor support, and operational implementation, in some cases describing hundreds of thousands of dollars in one-time implementation costs and significant ongoing vendor expenditures. Commenters also express concern that variation in manufacturer-specific data requirements or platform requirements could necessitate the use of multiple systems, increasing complexity, interoperability challenges, and long-term maintenance costs. Manufacturers argue the opposite and assert that existing systems and infrastructure are largely sufficient to support a rebate model, noting that covered entities already maintain and transmit the relevant claims-level data for purposes of billing and reimbursement under Medicare, Medicaid, and commercial payers. These commenters state that current IT systems and TPAs could be leveraged to facilitate data submission and reconciliation and emphasize the availability of centralized or interoperable platforms designed to streamline rebate processing and improve data transparency. They further assert that such systems could reduce fragmentation over time by enabling standardized data exchange and more efficient coordination among stakeholders.

Technology vendors that have developed rebate processing platforms similarly assert that existing systems and infrastructure are sufficient to support implementation. One such commenter, a technology company that has engaged with HRSA since 2019 to develop and operationalize a 340B rebate model, states that its platform is capable of effectuating discounted pricing directly to covered entities as a rebate at the unit level. This commenter reports that multiple manufacturers are already using its platform to collect claims data, that thousands of covered entities have registered on the platform, and that covered entities have reported fully onboarding in less than ten minutes through a self-service process. The commenter further explains that the platform integrates with existing billing, pharmacy, and TPA systems through publicly available application programming interfaces (or APIs), supports near real-time data submission, and incorporates automated validations that check for duplicate discounts before they occur. The commenter also notes that beta testing with covered entities, including health centers, hospitals, and clinics, confirmed that covered entity partners such as TPAs can connect to the platform using existing systems cheaply and quickly, and that standard TPA reports could be leveraged to create dispensation reports matching the format required by the platform. Based on this experience, the commenter contends that the administrative burden on covered entities is minimal once systems are configured, and that a rebate model will simplify the process of identifying when the right discount applies to the right dispense, thereby reducing the costs associated with manufacturer good-faith inquiries, audits, and dispute resolution under the current model.

5. Comments Concerning Other Anticipated Costs or Impacts of a Potential 340B Rebate Model Pilot Program

Commenters identified a range of additional anticipated costs and operational impacts associated with a potential 340B Rebate Model Pilot Program beyond those related to direct administrative, staffing, and systems requirements. Covered entities and provider organizations express concern that a rebate model could result in secondary financial effects, including loss of wholesaler prompt-pay or cost of goods discounts, increased borrowing or financing costs to manage larger working-capital requirements, and potential inventory-related financial risk associated with purchasing drugs at higher upfront prices. While few commenters quantified these secondary effects directly, several quantified the underlying financial exposure, including 20- to 40-fold increases in upfront acquisition costs for affected drugs, approximately $10 million in additional annual working-capital requirements for one large health system, and measurable reductions in liquidity (*e.g.,* a 0.5% reduction in days cash on hand and more than $1 million in cumulative liquidity impacts over 5 years). Some commenters also note the potential for disruptions (or actual disruptions, during the brief period in preparation for the earlier rebate model) to contract pharmacy arrangements, including reduced participation by pharmacy partners due to increased administrative complexity and financial risk, as well as broader impacts on wholesaler relationships, credit limits, and purchasing terms. In addition, commenters indicate that these combined pressures could lead to reductions in patient services, program offerings, or workforce capacity, particularly for smaller or resource-constrained covered entities. Commenters estimates for indirect financial exposures varied and ranged from hundreds of thousands of dollars annually to tens of millions of dollars annually for larger covered entities.

Manufacturer groups did not identify significant additional categories of cost beyond those associated with implementation and administration and instead emphasized potential offsetting benefits. These commenters state that improved claims-level transparency and coordination across pricing programs could reduce inefficiencies, minimize disputes, and improve overall program integrity. Some also suggested that more accurate application of discounts could lead to more predictable financial flows and reduced long-term administrative and compliance costs.

6. Response to Comments Concerning Administrative and Implementation Costs to Covered Entities

HRSA carefully considered the full range of comments while considering a range of policy options to best meet the commenters' varying perspectives. HRSA recognizes that most covered entities currently operate under an upfront discount model that reduces the need for post-purchase reconciliation. HRSA agrees that the upfront discount model limits certain administrative steps. However, the record demonstrates that covered entities and their contract pharmacy partners already perform

extensive administrative functions under the 340B Program, including inventory management, compliance oversight, audit preparation, collection and submission of claims-level data to manufacturers, TPAs, and payers, and reconciliation activities. The record further demonstrates that IT systems and vendors already exist in a competitive marketplace to allow covered entities to shift to a rebate model without significant burden. These existing capabilities reflect a mature operational infrastructure that can be leveraged, rather than replaced, under a rebate model to more effectively prevent duplicate discounts and address the program integrity concerns discussed in this Notice.

HRSA finds that many projections of administrative burden rest on assumptions that do not align with the design of the Pilot or that do not accurately reflect what is needed administratively to implement a rebate approach. For example, several commenters assumed that covered entities would be required to develop and maintain manufacturer-specific data submissions, support multiple proprietary submission platforms, submit purchasing data, encounter-level information, patient-level clinical information, or real-time claims feeds, and manually reconcile claims across multiple systems. Other commenters projected substantial staffing increases, including estimates of six or seven additional full-time employees, more than 12,000 additional annual labor hours, or approximately 240 additional staff hours per week, to support rebate administration, based on assumptions that data would require extensive manual collection, validation, and submission. Similarly, some commenters projected significant one-time system development costs by assuming the need to build new interfaces between electronic health records, split-billing software, third-party administrators, financial systems, and multiple manufacturer portals. These projections generally assumed limited automation, manufacturer-specific reporting requirements, or ongoing parallel workflows that are not contemplated under the Pilot. By contrast, the Pilot requires submission only for the limited universe of drugs included in the Pilot, utilizes standardized pharmacy and medical claims data elements, and relies primarily on information that covered entities already collect, maintain, and retain in the ordinary course of billing, dispensing, audit, and compliance activities. As discussed in Section VIII.D., the Pilot does not require submission of purchasing records, encounter-level clinical documentation, or other patient-level information beyond the standardized claims elements specified by HRSA. HRSA also anticipates that use of standardized submission formats and centralized reporting will substantially reduce the need for the manual reconciliation and customized interfaces assumed by many commenters. HRSA published its estimate of the annual administrative cost in an Information Collection Request [20] to total $523,345,680 for the 15,249 covered entities reporting claims. Based on that estimate, HRSA projects administrative costs of reporting claims data for the Pilot will average approximately $34,320 per entity, but may vary by entity type.

The Pilot is structured to enable covered entities, manufacturers, and vendors to operationalize processes and identify implementation challenges on a limited, manageable scale. Based on 2025 data, the included products represent less than 5.5% of total 340B sales with the remaining 94.5% of drug sales continuing under the upfront 340B discount model in 2027. This approach allows for the evaluation and adjustment of workflows and data exchange mechanisms based on actual experience prior to broader application, generating concrete, practice-based evidence on how the rebate model operates.

Given the limited scope of the Pilot and its reliance on existing data infrastructure and operational processes, HRSA anticipates that any staffing impacts will generally be modest. The record shows that covered entities already collect and maintain relevant claims and purchase data and routinely utilize TPAs and automated systems for billing, compliance, and reconciliation activities. As a result, HRSA expects that, in many cases, additional staffing will be unnecessary because they may be absorbed within existing operational structures or supported through existing third-party arrangements. In limited cases, where operational structures are less sophisticated or TPAs are not utilized, covered entities may need additional staffing to support the Pilot's claims reporting processes.

Several commenters quantified one-time implementation activities associated with a rebate model, including process development, workflow redesign, staff training, IT system configuration, legal review, and early-stage reconciliation. One academic medical center estimated approximately $90,000 in one-time administrative implementation costs and an additional $130,000 for initial IT integration and system configuration. Other commenters estimated approximately 40 hours of initial IT development, 20 hours of legal review, and elevated staffing requirements during the initial implementation period. HRSA recognizes that implementation of a new reporting process may require certain transitional activities. However, many commenters' estimates assumed manufacturer-specific submission requirements, manual reconciliation across multiple proprietary platforms, and customized interfaces that are not contemplated under the Pilot's standardized reporting approach. Consequently, while commenters identified legitimate startup activities, HRSA expects that implementation costs under the Pilot would be substantially reduced through standardized data elements, centralized reporting processes, and reliance on information already maintained by covered entities in the ordinary course of billing and compliance activities and the costs will be transitional. These costs are inherent to the adoption of a new operational approach, which requires that new processes be introduced on a limited scale to allow for calibration and refinement. HRSA expects that, as processes become standardized and integrated into routine operations, these transitional costs will diminish, consistent with ordinary program evolution.

Regarding systems and infrastructure, HRSA recognizes that implementation of a rebate model may require coordination with IT platforms to support the submission and validation of claims data. As an initial matter, the costs of the rebate IT platform must be paid by manufacturers. That is a requirement of participation in this Pilot. Additionally, consistent with comments from manufacturers and technology stakeholders, the record shows that rebate processing platforms have already been developed or are in the process of being operationalized and are designed to integrate with existing billing, pharmacy, and TPA systems. HRSA anticipates that these platforms will leverage existing data flows and automation capabilities, thereby minimizing the need for covered entities to develop new systems. While some covered entity commenters raise concerns that covered entities do not currently submit the data outlined in the Pilot to these IT platforms, HRSA

[20] *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202606-0906-001.*

disagrees as manufacturers have utilized similar platforms and oftentimes the same company for implementation of various contract pharmacy requirements since at least 2021.[21] Moreover, covered entities' data collection and reporting obligations under the current system extend beyond these specific manufacturer systems. HRSA expects that manufacturers and their designated platform vendors will be responsible for the development, operation, and maintenance of rebate processing platforms, including associated system costs for the rebate processing platform, and encourage platform designs that promote interoperability, minimize disruption to existing workflows, and reduce administrative burden on covered entities.

In response to commenter assertions that a rebate model would impose unmanageable costs and complexity, the record includes operational data from a technology vendor that has developed and deployed a rebate processing platform for the 340B Program. That commenter reports that the data fields and utilization data required for rebate submission are the same as those already submitted by more than 7,000 covered entities through the vendor's 340B ESP platform, making the incremental increased effort for those entities very limited. For entities that have not previously submitted data through such platforms, the commenter states that the upload, mapping, and validation steps are designed to be straightforward and user-friendly and typically require approximately 15 minutes per data upload submission, based on actual usage patterns. Furthermore, 53 TPAs are able to submit data directly to the rebate platform on behalf of covered entities, which the commenter states would significantly reduce or eliminate any potential data compilation burden on covered entities. Over 10,000 covered entities have already completed registration on the 340B rebate platform.

With respect to other anticipated costs, including vendor fees and training, HRSA notes that participation in the 340B Program has always entailed some level of compliance and operational cost. Covered entities derive significant financial benefit from participation in the Program. For example, manufacturer commenters cited industry analyses estimating that covered entities derive substantial financial benefit from the difference between 340B acquisition costs and third-party reimbursement rates.

Covered entities are expected to maintain compliance as program requirements evolve. As part of its ongoing oversight, HRSA conducts audits and compliance reviews, and provides education and guidance to covered entities based on those efforts. Covered entities routinely update policies, procedures, IT systems and operational practices to align with program requirements and guidance and there may be operational costs associated with program participation and to ensure compliance. In addition, in 2025, covered entities purchased approximately $100 billion in covered outpatient drugs under the 340B Program, underscoring the scale of discounted drug purchasing available to covered entities and the resulting financial resources and savings available to support care for underserved populations.

Overall, HRSA concludes that while a rebate model may introduce incremental or transitional administrative and operational changes, HRSA believes the magnitude of the associated costs is likely to remain low. The core data elements required for rebate processing, namely, standardized pharmacy and medical claims data, are already generated, maintained, and routinely transmitted by covered entities and their contract pharmacy partners in the ordinary course of billing and reimbursement across Medicare, Medicaid, and commercial payers. As a result, the rebate model builds on existing data infrastructure and workflows rather than requiring the creation of entirely new systems or data streams. In addition, commenters note that established technologies, including automated claims processing, batch data submission, and TPAs, can be leveraged to facilitate rebate submission and reconciliation with minimal manual intervention once implemented. Also, increased claims-level transparency may reduce reliance on retrospective audits, dispute resolution processes, and other resource-intensive compliance activities, offsetting some administrative costs over time. Taken together, these considerations support HRSA's conclusion that the overall costs of implementing a rebate model are likely to be modest, and in some cases, may be offset by efficiencies gained through improved data visibility and streamlined program administration. HRSA believes the anticipated benefits of the Pilot outweigh the costs.

D. Payment Timing and Potential Cash-Flow Impacts for Covered Entities

Many commenters expressed concern that covered entities would be required to pay wholesale acquisition cost (WAC) upfront and wait for rebate payments, potentially creating liquidity constraints, reliance on credit, and financial instability, particularly for rural and safety-net providers. Other commenters stated that this would have limited impact because rebates would be paid prior to when drug purchase payments are due to wholesalers and that 340B rebate models cost the same or less than current drug inventory models. Commenters further state that the potential cash-flow impacts of a rebate-based model may be inaccurate or overstated. These commenters note that the numbers provided are only estimates and that healthcare providers already operate within reimbursement frameworks in which payment is received after the point of purchase, including under Medicare, Medicaid, and commercial payer systems, and asserted that rebate payment timelines could be structured to align with or occur prior to standard drug purchasing payment obligations. The commenters further note that wholesalers commonly provide covered entities with payment windows or credit arrangements for product purchases, allowing entities to receive and dispense medications prior to remitting payment for the corresponding wholesaler invoice. These commenters also indicate that unit-based rebate models could reduce delays associated with current models that require accumulation of a full package size before purchasing at the 340B discounted price and improve the predictability of reimbursement over time.

HRSA has considered the comments but based on available studies of a rebate model, HRSA believes that the Pilot is unlikely to result in unstable cash flow for covered entities, as certain commenters have predicted. IQVIA, a healthcare data analytics firm, recently empirically evaluated the opposing narratives about the impact of a shift from upfront discounts to rebates on providers' cash flow.[22] IQVIA modeled the effects on cash flow of existing drug inventory and replenishment models

[21] In 2021, several participating 340B manufacturers sought to limit the number and kinds of contract pharmacies to which they would ship orders by requiring certain claims level data in order for a covered entity to utilize a contract pharmacy. HRSA initially disallowed this practice, advising the manufacturers that the manufacturers needed to ''deliver covered drugs to any contract pharmacies with which a covered entity chooses to partner.'' In the D.C. Circuit's ruling in *Novartis Pharms. Corp.* v. *Johnson,* 102 F.4th 452 (D.C. Cir. 2024), the Court held that the manufacturers had discretion to impose certain conditions on delivery.

[22] *https://www.iqvia.com/locations/united-states/library/white-papers/how-will-a-rebate-model-impact-cash-flow-in-the-340b-drug-pricing-program.*

and compared those effects with a rebate model. Its analysis modeled liquidity impact and interest costs under a variety of assumptions, including different rebate timelines, different wholesaler payment timelines, different interest rates, and different 340B discount percentages. Their study concluded that: for entity-owned pharmacy purchases, interest costs for the rebate model (0.19%) were no larger than for the predominant drug inventory model used by those pharmacies, referred to as physical replenishment. For contract pharmacies, the rebate model had lower interest costs (0.03%) than both types of replenishment model, physical and credit-based replenishment. Even under unfavorable assumptions, rebate interest costs remained under 1.2%.

Similarly, a 2021 study by 3 Axis Advisors (another healthcare data analytics company) found a 340B rebate model improves cash flow relative to replenishment models in the case of covered entities that use contract pharmacies.[23]

HRSA has incorporated several design elements intended to mitigate potential cash-flow impacts on covered entities. First, the Pilot requires prompt rebate payments, within 10 calendar days of submission of a complete claim. This accelerated payment timeline is intended to precede the payment deadlines associated with standard wholesaler payment terms, thereby reducing or eliminating the need for covered entities to ''float'' the WAC price or finance drug purchases for extended periods. Thus, while many covered entities would need to place an order at the higher WAC price for the drugs included in the Pilot, payment to wholesalers for those orders, in most cases, would occur after the rebate from the manufacturer is received. Therefore, HRSA expects the cash-flow impacts on covered entities to be minimal. Second, the Pilot requires unit-level rebate processing, which allows covered entities to receive rebates based on individual dispenses or administrations rather than waiting for full package utilization, as occurs under the current replenishment model. This approach is expected to accelerate the timing and frequency of rebate payments, resulting in more predictable and continuous cash flow. Third, the Pilot accounts for starting inventory considerations to facilitate the transition from upfront discounts to rebates for a limited set of drugs. HRSA has incorporated operational flexibilities, such as a 15-day implementation grace period for unreplenished accumulations, to address commenter concerns regarding inventory timing, cash flow, and potential gaps between drug purchase and rebate eligibility during the transition to a rebate-based model.

Taken together, these design features are intended to ensure that covered entities can access 340B pricing in a timely manner while minimizing short-term liquidity pressures. HRSA emphasizes that timely rebate payment is a core requirement of manufacturer participation in the Pilot and is critical to maintaining operational stability for covered entities. HRSA intends to monitor manufacturer compliance with established payment deadlines and may take appropriate enforcement action where delays occur. Such actions may include corrective measures and, where warranted, removal of manufacturers from the Pilot that demonstrate repeated or systemic noncompliance with rebate payment requirements. If, for example, covered entities report that a manufacturer is consistently exceeding the 10 calendar day threshold for rebate payment, then HRSA could review a sample of allegedly affected transactions over a sufficient period of time (*e.g.,* 10 calendar days) and, if HRSA were to find that a significant portion of those transactions (*e.g.,* five or more percent) were delayed without justification, HRSA could initiate removal proceedings of that manufacturer from pilot participation for non-compliance.

E. Rebate Denials and Dispute Resolution

Commenters raise a range of concerns regarding rebate denials and dispute resolution under a potential 340B rebate model. Covered entities and other groups generally express concern that rebate determinations made after dispensing could introduce uncertainty regarding payment outcomes, including the risk of denied or delayed rebates. Several commenters indicate that even modest denial rates could result in unrecoverable financial losses and increase administrative burden associated with tracking, appealing, and reconciling denied claims. Commenters also express concern regarding the potential for inconsistent or non-standardized denial criteria across manufacturers, as well as the absence of clearly defined timelines, documentation requirements, or dispute resolution processes. In addition, some commenters noted that existing dispute mechanisms in related programs require significant manual effort and extended resolution periods, which could be exacerbated under a rebate model if claim volumes increase.

Other commenters disagree and argue that the rebate model could improve the accuracy and efficiency of rebate determinations by enabling claims-level validation prior to payment and reducing the need for post hoc reconciliation. These commenters indicate that improved data transparency could help prevent improper payments and reduce the volume of disputes over time, particularly if standardized data elements and submission processes are used. Some commenters also note that centralized or platform-based approaches could facilitate more timely identification and resolution of discrepancies, provided that clear rules, standardized data requirements, and defined dispute resolution processes are established. They also indicated that such centralized or platform-based approaches support more predictable outcomes for covered entities, facilitate more efficient manufacturer review processes, and minimize the need for appeals.

In response to commenter concerns regarding rebate denials and dispute resolution, HRSA includes design features within the Pilot to promote transparency, consistency, and accountability in rebate determinations. Specifically, the Pilot requires manufacturers to document and report denied claims, including the basis for each denial and the status of any associated dispute. HRSA intends to use this information to monitor denial patterns and assess whether rebate determinations are applied in a consistent and appropriate manner across participating manufacturers and will remove manufacturers from the Pilot where appropriate. If, for example, covered entities report that a manufacturer is consistently denying rebate payment without acceptable justification, then HRSA could review a sample of allegedly affected transactions over a sufficient period of time (*e.g.,* 10 calendar days) and, if HRSA were to find that a significant portion of those transactions (*e.g.,* 5 or more percent) were denied without acceptable justification, HRSA could initiate removal proceedings of that manufacturer from pilot participation for non-compliance.

In addition, the Pilot will provide a defined pathway for covered entities to challenge denied claims, including specified timeframes for review and response, to facilitate timely resolution of disputes. Tools will be made available for reporting rebate denials to be challenged to assist HRSA's review

[23] *https://www.3axisadvisors.com/projects/kalderos-rebate-model-1021.*

and facilitation of resolution. This information will be made public on our website within 30 calendar days of the Pilot's effective date. HRSA anticipates that these measures will reduce administrative burden associated with prolonged reconciliation efforts, improve visibility into rebate outcomes, and support more standardized processes for dispute resolution. To the extent that disputes cannot be resolved through these mechanisms, covered entities may pursue available remedies through the 340B Administrative Dispute Resolution (ADR) process in accordance with the regulations issued pursuant to 42 U.S.C. 256b(d)(3)(A).

Commenters recommend that HRSA establish mechanisms to receive ongoing feedback during implementation of any rebate model pilot program. Suggested approaches included formal stakeholder engagement processes, such as public listening sessions, advisory groups, or technical working groups representing a range of stakeholders, as well as periodic opportunities for written input. Commenters also emphasized the importance of collecting and analyzing quantitative data generated through the Pilot, including information on rebate submissions, denials, dispute resolution, and payment timelines, and suggested that certain data be made available to support transparency and evaluation. In addition, commenters recommend that HRSA issue interim and final evaluation reports and use implementation experience to refine program design. Some commenters further highlight the need for direct communication channels and technical assistance to address operational issues in real time. HRSA is considering these recommendations in developing processes to monitor Pilot implementation, gather stakeholder input, and evaluate program outcomes.

F. Data Collection and Reporting Requirements

Commenters provide differing perspectives regarding the data collection and reporting requirements associated with a 340B Rebate Model Pilot Program. Most covered entities generally state that a rebate model could require expanded data collection and reporting, including claims-level tracking, validation, and reconciliation across multiple systems. Some commenters indicate that these requirements could necessitate additional staff time and coordination across pharmacy, billing, compliance, and finance functions, particularly for entities with limited administrative resources or complex contract pharmacy arrangements. Commenters also raise concerns regarding the potential for variation in reporting requirements across manufacturers, which could increase complexity and require the use of multiple reporting systems or formats. Smaller covered entities indicate that they have limited IT capacity and express concern regarding the potential need for system modifications, increased reliance on TPAs, and additional data management resources. Some of these commenters also raised concerns regarding data privacy and security, particularly with respect to the transmission of claims-level information to manufacturers or third-party platforms.

On the other hand, manufacturers asserted that the incremental data collection and reporting burden would be limited, noting that covered entities already collect and maintain the relevant claims-level data as part of routine third-party billing, compliance, and audit processes. These commenters stated that existing TPAs and automated reporting systems could be leveraged to support data submission and reporting and that standardized data formats and centralized platforms could reduce duplicative reporting requirements over time.

In response to these comments, HRSA intends to limit data collection manufacturers may impose on covered entities under the Pilot to the minimum necessary to effectuate rebate payments and support 340B program integrity and nonduplication under the MDPNP. HRSA believes that limiting the required data collection to a narrowly defined set of standardized pharmacy and medical claims data elements substantially reduces the potential burden relative to broader reporting models considered during development of the Pilot. In response to stakeholder feedback, HRSA declined at this juncture to require additional data elements proposed by manufacturers, including purchasing data, encounter data, invoice-level information, and patient-level clinical information, because HRSA determined that collecting and reconciling such information could create additional operational complexity and systems burden for covered entities acclimating to a new rebate environment. Instead, the Pilot relies primarily on claims-level information that is already generated and maintained in the ordinary course of pharmacy and medical billing and that, in many cases, is already exchanged through existing payer, TPA, or contract pharmacy relationships.

HRSA anticipates relying on a defined set of standardized pharmacy and medical claims data elements that are commonly available and already maintained by covered entities or their vendors in the ordinary course of billing and dispensing operations. For example, CMS requires submission of prescription drug event data (PDE) for purposes of calculating payments to Part D plans. HRSA expects that data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained through existing third-party vendor relationships and therefore does not expect a significant impact on covered entities disproportionate to the significant benefits covered entities derive from the 340B Program.

In addition, the reporting requirements are limited to the selected drugs for initial price applicability years 2026 and 2027 as included on the CMS Medicare Drug Price Negotiation Selected Drug List during their price applicability periods, which represents a small portion of overall 340B utilization relative to the total number of covered outpatient drugs available under the Program. HRSA anticipates that this limited scope will allow covered entities and vendors to leverage existing infrastructure and implement operational changes incrementally rather than across the full universe of 340B transactions. HRSA also encourages the use of standardized reporting formats and interoperable systems to reduce variability and improve efficiency.

HRSA further believes that the burden associated with limited claims-level reporting is justified by the importance of ensuring program integrity, duplicate discount prevention, and coordination across federal pricing programs, including the MDPNP and Medicaid rebate programs. The Pilot is intended to generate implementation data and operational experience regarding these issues in a controlled and limited environment. HRSA anticipates that the Pilot will help to improve transparency, support prospective validation of transactions, and reduce reliance on retrospective audits and dispute resolution processes that many stakeholders described as resource-intensive under the current framework.

HRSA further notes that the Pilot introduces new reporting requirements for manufacturers that are not present under the upfront discount model. As a condition of participation, manufacturers will be required to report rebate data to HRSA, including information necessary to support program oversight and monitoring. HRSA anticipates that these requirements will enhance transparency

and enable HHS to evaluate the operational impacts of the rebate model.

G. Data Privacy Considerations and HIPAA Compliance

In light of the differing perspectives regarding the data collection and reporting requirements discussed in Section F, HRSA recognizes the importance of addressing questions regarding the applicability of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to the data transfers contemplated under the Pilot. Although specific public comments raising concerns about HIPAA compliance and the ability of 340B covered entities that are HIPAA covered health care providers to disclose protected health information (PHI) under the Pilot were not submitted in response to the RFI, HRSA is aware that questions regarding the intersection of HIPAA and claims-level data submissions have arisen in other contexts within the 340B Program. HRSA addresses these questions here to provide clarity to covered entities, manufacturers, and other stakeholders regarding the applicability of HIPAA to the disclosure of PHI under the Pilot.

As an initial matter, HRSA notes that the data elements required under the Pilot, as set forth in Section VIII.D of this Notice, are limited to standardized pharmacy and medical claims fields such as date of service, NDC–11, quantity dispensed, prescriber ID, service provider ID, 340B ID, RX BIN, RX PCN, and health plan identification information. These data elements do not include direct patient identifiers such as patient names, addresses, dates of birth, Social Security numbers, medical record numbers, or other information that would directly identify individual patients.

To the extent that the data submitted under the Pilot is not individually identifiable health information, it is not PHI as defined under the HIPAA Privacy Rule, 45 CFR 160.103, and accordingly is not subject to the restrictions on use and disclosure set forth in the HIPAA Privacy Rule (45 CFR part 160 and subparts A and E of part 164). The Pilot requires that manufacturer plans ensure the IT platform used for data submission has mechanisms in place to protect the privacy of the data submitted. Under the HIPAA Privacy Rule, individually identifiable health information that has been de-identified in accordance with 45 CFR 164.514 is no longer PHI, and the Privacy Rule's restrictions on use and disclosure do not apply to such de-identified information. The HIPAA de-identification standard may be satisfied through either the expert determination method, under which a person with appropriate knowledge and experience applies statistical and scientific principles and methods to determine that the risk of identifying an individual is very small, 45 CFR 164.514(b)(1), or the safe harbor method, under which specified identifiers are removed and the covered entity has no actual knowledge that the remaining information could be used alone or in combination with other information reasonably available to an intended recipient to identify an individual, 45 CFR 164.514(b)(2). Any de-identification of PHI to meet HIPAA obligations must comply with the HIPAA Privacy Rule requirements. Covered entities that submit data that has been properly de-identified consistent with 45 CFR 164.514 to manufacturers through the platforms would not be disclosing PHI to manufacturers and therefore would not need to rely on a HIPAA permission to allow the disclosure.

HRSA also recognizes that some stakeholders have raised questions in other contexts regarding the point at which de-identification occurs in the data transmission process, and specifically whether data may be considered PHI at the moment of transfer from a covered entity to a manufacturer's platform even if it is subsequently de-identified. HRSA's general view is that this concern may reflect a misunderstanding of how rebate processing platforms operate. As described in publicly available documentation for existing 340B claims data platforms, de-identification occurs through automated processes prior to data ingestion by the platform, such that neither the manufacturer nor its vendor receives or retains PHI.[24] Where such automated de-identification is validated through an expert determination under 45 CFR 164.514(b)(1), the resulting data does not constitute PHI regardless of whether the underlying source data, prior to automated processing, included identifiable elements.[25] HRSA emphasizes that the Pilot's design is intended to ensure that manufacturers do not receive or have access to PHI at any point in the data submission process.

Even assuming, for purposes of analysis, that the data submitted by covered entities under the Pilot were to constitute PHI, HRSA notes that the HIPAA Privacy Rule generally permits covered entities to disclose PHI without individual authorization for purposes of payment. Under 45 CFR 164.506(c), a covered entity may use or disclose PHI for its own payment activities, which include activities undertaken to obtain reimbursement for the provision of health care, including the determination of eligibility or coverage and the adjudication of health benefit claims. See 45 CFR 164.501 (definition of ''payment''). A covered entity's submission of claims-level data to a manufacturer, including vis-à-vis a rebate processing platform, in order to effectuate a rebate that reduces the covered entity's net acquisition cost for a covered outpatient drug relates to, and may affect by rebate, the payment activity of the covered entity.[26] HRSA further notes that the HIPAA Privacy Rule's minimum necessary standard, 45 CFR 164.502(b) and 164.514(d), requires that disclosures of PHI be limited to the minimum necessary to accomplish the intended purpose. The Pilot's data requirements, which are restricted to a defined and limited set of standardized claims fields, are designed to satisfy this standard.

HRSA also notes that certain of the covered entities that have raised data privacy concerns in other contexts routinely transmit materially identical claims-level data, including through the same or similar vendor platforms, for purposes of contract pharmacy replenishment, third-party payer billing, and compliance with Medicare, Medicaid, and commercial insurance requirements. The data elements required under the Pilot are comparable to, and in many cases, a subset of the information that covered entities already collect, maintain, and transmit in the ordinary course of these operations.

Finally, HRSA notes that the Pilot incorporates multiple data safeguard requirements that further mitigate any residual privacy risk to individuals. As

[24] 340B ESP Frequently Asked Questions, available at *https://help.340besp.com/en/articles/14482537-frequently-asked-questions-faqs#h_2b2d0863da.*

[25] If a HIPAA covered health care provider is relying on the platform to de-identify PHI, the platform would be acting as a HIPAA business associate of the provider and would be required to have a valid business associate agreement in place. For additional information about HIPAA business associates and their requirements, see: *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html.*

[26] We note that OCR has acknowledged the permitted disclosure of PHI for rebate purposes to a pharmaceutical manufacturer In a similar scenario, stating ''the Privacy Rule permits a health plan to disclose protected health information, such as prescription numbers, to a pharmaceutical manufacturer for purposes of adjudicating claims submitted under a drug rebate contract.'' *See: https://www.hhs.gov/hipaa/for-professionals/faq/455/does-hipaa-permit-health-plans-to-disclose-information-to-pharmaceutical-manufacturers/index.html.*

detailed in Section VIII.A, manufacturer plans must ensure that the IT platform has assurances in place to ensure data security, that data collection is limited to the specific elements necessary for providing 340B rebates, and that the platform has mechanisms in place to protect patient identifying information consistent with HIPAA and other applicable privacy and data security laws not inconsistent with federal law or 340B program requirements. The Pilot further requires that IT platforms have the capacity to filter and use only the data required to effectuate the rebate. These requirements, taken together, are designed to ensure that data submitted under the Pilot is collected, transmitted, and maintained in a manner that protects patient privacy while enabling the claims-level transparency necessary to support program integrity. HRSA does not anticipate that compliance with the Pilot's data submission requirements will require covered entities to violate HIPAA or any other applicable federal data privacy law. HRSA will further monitor implementation to confirm that participating manufacturers and their designated platforms maintain appropriate privacy and data security protections and whether any such violations would need to be reported to appropriate officials.

H. Required Reporting by Manufacturers

Manufacturers, technology and data intermediaries, and certain transparency-oriented stakeholders generally support the submission of data regarding the Pilot by manufacturers to HRSA. They indicate that the data can be used to assess compliance with a rebate model and its effectiveness. Commenters suggest that aggregate data, making certain to protect confidential and proprietary information, should be shared with the public and would be useful for all stakeholders. Several commenters express concern about the use of the 340B Prime Vendor to collect this information due to a perceived conflict of interest.

HRSA will require participating manufacturers to submit purchase data reports to the agency. HRSA will continue to assess reporting burden and implementation experience and may refine requirements as appropriate to balance program integrity objectives with administrative feasibility. HRSA agrees that the collection of Pilot data is important to evaluate adherence to the rebate framework and to evaluate the impact and effects of the Pilot. HRSA also agrees that providing aggregate data, which will not contain confidential or proprietary information, to the public is important to provide further transparency into the 340B Program.

HRSA appreciates the commenters' concerns regarding perceived conflicts of interest in connection with the agency's use of the 340B Prime Vendor for certain Pilot-related activities. The 340B Prime Vendor, a contractor engaged by HRSA to provide operational support to covered entities participating in the 340B Program, including negotiating additional discounts with manufacturers and offering tools and resources to help entities manage Program compliance, does not make any eligibility determinations, enforcement decisions, or policy judgments regarding the 340B Program. HRSA does not agree that use of the 340B Prime Vendor to assist with Pilot data collection, for example, would pose a conflict of interest—actual or perceived. HRSA retains full authority over all aspects of the 340B Program and the long-standing role of the 340B Prime Vendor, which is recognized in the 340B statute (42 U.S.C. 256b(a)(8), is operational and administrative in nature and akin to contractor support functions.

I. Impact on Patient Care

Covered entities, provider organizations, and some patient advocacy groups generally state that a shift from upfront discounts to a rebate-based model could affect the timing and availability of financial resources used to support patient care. They express concerns that patients will lose access to discounted drugs and needed services because covered entities will necessarily have to divert resources away from patient care and toward complying with a rebate pilot that carries a significant price tag. These commenters state that the rebate Pilot will undermine access to care for patients, particularly for small, rural, or under-resourced covered entities. They assert that certain covered entities will not be able to pay the list price for IRA drugs because they lack cash reserves or borrowing power to cover the initial costs of these medications and will be forced to turn away patients in need because they cannot afford to maintain their usual inventory of drugs. If the Pilot is implemented, these commenters indicate that potential delays in receiving rebates combined with potential rebate denial rates could reduce funds available to support patient services.

Several commenters also provide examples of the scale of services supported by 340B savings, noting that such savings are used to fund sliding fee discount programs, medication assistance for uninsured and underinsured populations, and clinical services, with some entities reporting that tens of thousands of patients annually rely on these programs. Other commenters indicate that 340B savings support a broad range of services, including behavioral health, chronic disease management, and outreach programs, and expressed concern that reductions or delays in these resources could result in reduced service capacity, limitations on access to medications, or delays in care, particularly for smaller or resource-constrained providers. Patient and caregiver submissions emphasize the importance of ensuring that 340B savings translate into direct patient benefits, including reduced out-of-pocket costs. As a further adverse impact on patient access to care, commenters also highlight the potential withdrawal of certain retail pharmacies from processing 340B claims for IRA drugs dispensed at contract pharmacies. According to these commenters, if pharmacy chains opt not to provide 340B pricing, even on a temporary basis, for drugs included in the Pilot, this could result in patients having to go elsewhere and potentially travel far distances to obtain necessary medications—a problem that is particularly acute for rural communities.

In contrast, manufacturer commenters state that a rebate model could maintain or enhance patient access by improving program integrity and ensuring that discounts accrue to the patients that the 340B Program was intended to benefit. Some commenters cite industry analyses suggesting that duplicate discounts may affect up to approximately 25% of 340B drug transactions, representing tens of billions of dollars annually, and asserted that reducing such inefficiencies could improve the overall availability of resources within the healthcare system. These commenters also indicate that improved claims-level transparency and coordination across programs, including with the MDPNP, could support more accurate pricing and reduce the need for post hoc reconciliation, which may contribute to more predictable financial flows over time. While pharmacy stakeholders raise concerns about the seamless implementation of the Pilot with respect to contract pharmacy claims, they also highlight that testing rebates in the 340B Program could be done with certain safeguards in place such as 10-day rebate payment timelines, minimal

necessary data, and clear federal oversight.

Congress created the 340B Program so covered entities could ''stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'' H.R. Rep. No. 102–384(II), at 12 (1992). The Pilot does not deviate from that statutory purpose. Nor does implementation of a rebate-based model modify the statutory 340B ceiling price, covered entity eligibility requirements, or the legal framework governing patient eligibility under the 340B Program. Rather, the Pilot changes the mechanism and timing by which the 340B price is effectuated, shifting from an upfront discount to a post-dispense rebate that is expressly authorized by the 340B statute.

HRSA further notes that the Pilot is structured to mitigate any potential operational or financial disruption to covered entities. Manufacturers participating in the Pilot would be required to issue rebates within the defined 10-day timeframe, from the date of data submission and the agency expects that, in most cases, covered entities will submit data shortly after dispense so that covered entities would receive rebate payments before payment obligations to wholesalers become due. As a result, HRSA does not anticipate that the Pilot will materially impair covered entities' cash flow or their ability to furnish services to patients.

In addition, HRSA anticipates the Pilot will provide program integrity benefits that ultimately support patient care and stewardship of federal resources. By introducing claims-level verification and improved transparency, a rebate model will reduce the risk of duplicate discounts and diversion that undermine the integrity and sustainability of the 340B Program.

J. Other Comments

Commenters also raise a range of additional issues that did not fall within the specific topics outlined above. Several covered entities and provider organizations recommend that any rebate model pilot be limited in scope, including restricting participation to a subset of covered entities, such as voluntary participants, specific provider types, or entities with sufficient administrative and financial capacity to implement the model. These commenters state that a more targeted approach would allow HRSA to evaluate operational feasibility while minimizing potential disruption to smaller or resource-constrained entities. Other commenters suggest limiting the Pilot to certain drug categories, dispensing settings, or payer types to better isolate potential program impacts.

Additional comments address issues such as the need for clear implementation guidance, stakeholder education and training, alignment with existing federal and state requirements, and coordination across federal programs including the MDPNP. Some commenters also emphasized the importance of standardization across manufacturers, including consistent data requirements, timelines, and processes, to reduce complexity and administrative burden.

HRSA has designed the Pilot to be limited in scope. HRSA will continue to consider stakeholder input regarding participation parameters and implementation approaches and may refine design elements. HRSA intends to ensure that stakeholders receive education and technical assistance as the Pilot is underway and more information on the mechanism by which stakeholders submit feedback and receive technical support is forthcoming.

VI. Alternatives Considered

As noted in the comment summaries above, covered entity commenters proposed several alternatives to a rebate model that they contend would address program integrity concerns within the existing upfront discount framework. These alternatives generally included: (1) enhanced use of claims modifiers; (2) establishment of a centralized clearinghouse or similar data-sharing mechanism; (3) more intensive audits and oversight activities; and (4) narrower pilot structures, including limiting participation to voluntary participants, restricting the Pilot to certain covered entity types, limiting the Pilot to fewer drugs or dispensing settings, or excluding physician-administered drugs, contract pharmacy arrangements, or other categories of transactions. HRSA carefully considered each of these proposals and, for the reasons explained below, does not believe that any of these alternatives, individually or in combination, would adequately achieve the program integrity and evaluation objectives that the Pilot is designed to advance. Several covered entity commenters urged HRSA to rely on enhanced use of claims modifiers as the primary mechanism for preventing duplicate discounts, rather than transitioning to a rebate model. Under this approach, covered entities and pharmacies would apply standardized identifiers to claims at the point of adjudication to flag 340B transactions, enabling payers and manufacturers to distinguish 340B utilization from non-340B utilization without altering the upfront discount purchasing model. HRSA acknowledges that claims modifiers are a component of the current framework for identifying 340B transactions. However, HRSA does not believe that reliance on claims modifiers alone would adequately address the program integrity deficiencies that the Pilot is designed to mitigate and prevent.

The existing MEF, which HRSA created in 1993 to prevent duplicate discounts under the Medicaid Drug Rebate Program, relies on claims modifiers as its central mechanism. Yet multiple governmental oversight bodies have found this approach may be insufficient. In 2016, the HHS Office of Inspector General (OIG) reported that the MEF is inadequate to capture duplicate discounts with respect to Medicaid managed care enrollees, and that this inadequacy results in both duplicate discounts going unreported as well as the exclusion of some non-340B claims from rebate invoices, thereby resulting in foregone Medicaid rebates to states.[27] The OIG further noted in that same report that contract pharmacy arrangements create additional complications in preventing duplicate discounts. The GAO has identified similar deficiencies.[28] And the House Committee on Energy and Commerce, in its 2018 review of the 340B Program, documented the exponential growth of the program and the corresponding challenges in maintaining program integrity under existing mechanisms.[29] These findings demonstrate that claims modifiers, as currently implemented, may not be the best method to ensure compliance with the statutory duplicate discount prohibition, particularly in the context of Medicaid managed care and the increasingly complex distribution channels through which 340B drugs are dispensed.

Moreover, claims modifiers can be applied inconsistently, may be incomplete or unavailable at the time of adjudication, and depend on voluntary compliance by covered entities and dispensing pharmacies without an enforcement mechanism that ties the receipt of the 340B discount to verified claims data. Under the current model, manufacturers have argued that they lack timely access to claims-level data to identify all units subject to 340B pricing. The implementation of maximum fair prices under the MDPNP further increases concerns of

[27] OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates, supra note 7.

[29] Committee on Energy and Commerce, *Review of 340BDrug Pricing Program,*'' supra note 2.

overlapping price concessions across programs, potentially compounding the limitations of a claims modifier approach.

Other covered entity commenters proposed the establishment of a centralized or third-party clearinghouse model as an alternative to a rebate-based approach. Under this proposal, an intermediary would serve as a central data hub to coordinate 340B transaction information among covered entities, manufacturers, and payers, with the goal of facilitating real-time or near-real-time identification of 340B utilization and preventing duplicate discounts without requiring covered entities to transition away from upfront discounts.

HRSA has considered this proposal and concludes that a clearinghouse model is, in substance, an enhanced claims modifier system operating under a different name. Like claims modifiers, a clearinghouse would depend on covered entities to accurately and completely report 340B transaction data to the intermediary, and on the intermediary to relay that information to manufacturers and payers in a timely and standardized manner. As manufacturer commenters have observed, unlike a clearinghouse, a rebate model by its very nature incentivizes covered entity compliance as a prerequisite to receiving 340B discounts. Under a rebate model, the covered entity must affirmatively submit validated claims data to receive the discount, which may help to align the incentive structure with program integrity objectives. A clearinghouse, by contrast, would preserve the current dynamic in which the discount is provided upfront and compliance verification occurs only after the fact. In addition, proposals to establish clearinghouses or similar intermediaries are not explicitly authorized under the 340B statute.

Commenters also proposed significantly narrowing the Pilot itself, including limiting participation to voluntary participants, restricting participation to entities with sufficient operational capacity, limiting the Pilot to fewer drugs or dispensing settings, or excluding physician-administered drugs or contract pharmacy arrangements. HRSA carefully considered these alternatives, including limiting the Pilot to certain entity types.

Regulatory regimes that impose fixed compliance costs (*e.g.,* legal, operational, and administrative) may disproportionately burden small entities that often lack the economies of scale of larger entities. Large hospitals, for example, have dedicated legal, compliance, accounting, and information technology departments capable of absorbing shifting regulatory mandates without disrupting patient care. As discussed throughout and below, we do not believe small hospitals and non-hospital healthcare entities will struggle to accommodate such changes. The Regulatory Flexibility Act of 1980 (RFA) directs agencies to avoid ''one-size-fits-all'' approaches and instead consider alternatives that mitigate impacts on small entities, especially when ''the problems that gave rise to government action may not have been caused by those smaller entities.'' [30] The procedural requirements of the RFA (*e.g.,* 5 U.S.C. 604) are not statutorily mandated for this notice since this notice does not constitute a rulemaking action per 5 U.S.C. 553. Nevertheless, HRSA has carefully considered the principles of the RFA in line with HHS's 2003 guidance.[31] This guidance directs HRSA to mitigate impacts on small entities through, for example, ''lessening the record-keeping and reporting requirements, delaying effective dates, establishing minimal requirements, or, if possible, waiving certain requirements'' for any ''proposed and final notices that function as rules.'' [32] Furthermore, Executive Order 12866 directs agencies to consider streamlining regulatory requirements for small entities when developing significant regulatory actions and the Office of Management and Budget's Office of Information and Regulatory Affairs (OMB OIRA) has determined that this notice is ''significant'' per Section 3(f)(1) of E.O. 12866.[33] Likewise, the Paperwork Reduction Act of 1995 directs agencies to minimize the paperwork burden imposed on small entities.[34]

HRSA categorizes covered entities by types that correspond to the statutory definition of ''covered entity'' provided at Section 340B(a)(4) of the PHSA.[35] There are 22 such types that are largely divisible into two categories: 340B hospitals and non-hospital entities. The former category, nonprofit or governmental hospitals participating in 340B, accounted for about 87% of program purchases in 2024.[36] These 340B hospitals constitute roughly half of all U.S. hospitals [37] and they provide inpatient and outpatient care. About 90% of hospitals' 340B purchases ($64.1 billion; roughly 79% of total 340B purchases) come from disproportionate share hospitals (DSH). DSHs are nonprofit or governmental hospitals that serve a large volume of low-income, Medicaid, and uninsured patients. The latter category, non-hospital entities, are generally clinics and health centers that receive federal grant funding. These non-hospital entities are more variegated in purpose and structure. Federally qualified health centers (FQHC, also known as Community Health Centers) provide comprehensive outpatient primary care while other non-hospital entities provide specialized care restricted to a narrow public health mission (*e.g.,* 340B Black Lung Clinics treat active and retired coal miners suffering from Coal Mine Dust Lung Disease). FQHCs and Look-Alikes (*i.e.,* clinics that meet all FQHC rules but do not receive federal funding; FQHC–LAs) constitute about half non-hospital entities' 340B purchases ($5.2 billion; roughly 6% of total 340B purchases).

As mentioned earlier in the discussion of potential impacts of a 340B Rebate Model Pilot Program, a 2025 report estimated that 340B covered entities' financing (interest) costs associated with transitioning to a 340B rebate model would be negligible (less than one half a percent of the drugs' list price), but it also found that these costs may be disproportionately larger for smaller entities that would need to obtain small business loans at higher

[30] Regulatory Flexibility Act, 5 U.S.C. 603(a) (2024).

[31] U.S. Dep't of Health & Hum. Servs., Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services (May 2003), *https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf.*

[32] U.S. Dep't of Health & Hum. Servs., Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services (May 2003), *https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf.* While participation in this 340B Rebate Model Pilot Program is voluntary for 340B manufacturers, when HRSA approves a given manufacturer's plan for pilot participation, it will become mandatory for 340B covered entities acquiring 340B drugs from that manufacturer.

[33] Exec. Order No. 12,866, 58 FR 51735 (Oct. 4, 1993).

[34] Paperwork Reduction Act, 44 U.S.C. 3501–3520.

[35] 42 U.S.C. 256b(a)(4) (2018).

[36] This includes Disproportionate Share Hospitals, Children's Hospitals, Rural Referral Centers, Critical Access Hospitals, Free-Standing Cancer Hospitals, and Sole Community Hospitals. *2024 340B Covered Entity Purchases,* Health Res. & Servs. Admin. (Dec. 2025), *https://www.hrsa.gov/opa/updates/2024-340b-covered-entity-purchases.*

[37] The American Hospital Association (AHA) estimates a total of over 6,000 hospitals and HRSA data shows about 3,000 participate in 340B. Am. Hosp. Ass'n, Fast Facts on U.S. Hospitals, 2026 (2026), *https://www.aha.org/statistics/fast-facts-us-hospitals. 340B OPAIS,* Health Res. & Servs. Admin., *https://340bopais.hrsa.gov/* (last visited July 5, 2026).

interest rates.[38] But after careful consideration, HRSA has determined that these differences between the average hospital and the average FQHC do not justify carving up the Pilot. Phasing in, or otherwise scoping, the Pilot would fail to account for these differences and would undermine the integrity of the Pilot, which will provide important information to HRSA. Indeed, clean delineations along the lines of covered entity type may not be a particularly robust measure of disproportionality of impact (rendering such a distinction potentially arbitrary). HRSA specifically determined that limiting participation to non-hospital entities, voluntary covered entities, or only operationally sophisticated entities could introduce substantial selection bias and reduce the reliability and generalizability of Pilot findings. Covered entities vary significantly in size, structure, patient population, dispensing models, and reliance on contract pharmacy arrangements. A narrowly tailored or self-selected participant pool would not adequately reflect these differences and would constrain the agency's ability to assess how a rebate model functions across the broader 340B environment. Similarly, further limiting the number of drugs included in the Pilot would reduce the agency's ability to evaluate rebate administration and duplicate discount prevention in the context of the MDPNP and other overlapping pricing programs.

The nonduplication and duplicate discount issues that the Pilot is designed to address are inherently drug-specific and apply to all covered entities. The program integrity risk, along with the nonduplication risk, that the Pilot is designed to mitigate thus attaches to particular drugs, namely, those drugs for which overlapping federal pricing obligations create a heightened risk of duplicative price concessions, rather than to particular categories of covered entities. Scoping the Pilot by the drugs that generate the specific compliance challenge is therefore a rational and direct means of targeting the identified problem.

HRSA additionally notes that scoping the Pilot by entity type alone would not adequately address the identified 340B program integrity concern. The risk of duplicate discounts arises whenever a selected drug is dispensed by any 340B covered entity, regardless of whether that entity is a hospital, FQHC, or other provider type. Limiting the Pilot to a subset of entity types while excluding others would leave the duplicate discount problem unaddressed for a significant portion of selected drug transactions, undermining the Pilot's ability to generate meaningful implementation data and to fulfill its program integrity objectives. By contrast, a drug-type scope ensures that the Pilot captures all transactions for which the specific compliance risk exists, across the full range of covered entity settings in which those drugs are dispensed, precisely the comprehensive and representative evaluation that the Pilot requires.

Retrospective enforcement mechanisms are inherently reactive and identify potential duplicate discounts only after they occur. By contrast, HRSA believes that a rebate-based model may improve prospective identification and validation of transactions by linking price concessions to standardized claims-level data submitted as part of the rebate process. Retrospective reviews, audits, and dispute resolution processes are inherently reactive, identifying potential duplicate discounts only after they have occurred. The exponential growth of the 340B Program, which now encompasses more than 15,000 covered entities, over 49,000 associated sites, and $100 billion in annual purchases, has further strained the capacity of audit-based approaches.

In contrast, a rebate model shifts the compliance framework from a reactive enforcement posture to a prospective approach in which verification and claims-level validation occur before the discount is provided. This structural difference addresses a core limitation shared by all three of the alternatives proposed by covered entity commenters: under a clearinghouse, claims modifier, or audit-based approach, the 340B discount is provided upfront and compliance is assessed only retrospectively. Under a rebate model, the covered entity must submit validated claims data as a precondition to receiving the discount, creating an inherent incentive for accurate reporting and reducing the opportunity for duplicate discounts to go undetected.

For these reasons, HRSA concludes that none of the proposed alternatives would adequately serve the program integrity and evaluation objectives that the Pilot is designed to advance, and that a limited rebate pilot provides the most appropriate mechanism to evaluate operational feasibility, duplicate discount prevention, transparency, and coordination across federal pricing programs in the current programmatic environment.

VII. Pilot Evaluation and Transparency

HRSA will evaluate the Pilot using a combination of quantitative and qualitative methods. Quantitative measures will include data submitted by participating manufacturers and covered entities regarding rebate requests, rebate payments, payment timeliness, claim denials, dispute resolution outcomes, reporting burden, and other operational metrics. HRSA will also review information relating to administrative burden, duplicate discount prevention, data quality, and program integrity and may use data gleaned from the Pilot during reviews of routine 340B Program audits of both covered entities and manufacturers. Qualitative information will be collected through stakeholder engagement activities, including written feedback, listening sessions, technical assistance interactions, and other implementation-related communications.

HRSA intends to conduct ongoing monitoring throughout the Pilot and shall publish interim periodic summaries of implementation findings and lessons learned on our public-facing website. Upon conclusion of the first year of Pilot operations, HRSA will publish an evaluation by April 30, 2028. To the extent practicable and consistent with applicable law, HRSA will ensure that any public and aggregated information regarding Pilot performance will not contain confidential, proprietary, or individually identifiable information.

VIII. Supplemental Information

In light of all the comments received on the RFI, prior rebate model discussions with manufacturers, and feedback received from stakeholders on a rebate model, HRSA has developed a 340B Rebate Model Pilot Program that is consistent with the 340B statute, and that balances the burden on program stakeholders with the benefits to transparency and program integrity that a rebate model would provide. In developing the rebate pilot, HRSA considered the full range of stakeholder feedback and incorporated key updates to the prior 340B rebate model in direct response to that feedback.

HRSA is introducing this rebate approach in a methodical and thoughtful manner and limiting it to a select group of drugs (as described below). This approach will ensure a fair and transparent 340B rebate model process for all stakeholders involved. The drugs in the 340B Rebate Model Pilot Program are limited to the NDC–11s of the selected drugs for initial price applicability years 2026 and 2027

[38] IQVIA, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?* (2025), *https://www.iqvia.com/locations/united-states/library/fact-sheets/how-will-a-rebate-model-impact-cash-flow-in-the-340b-drug-pricing-program.*

included on the CMS Medicare Drug Price Negotiation Selected Drug List,[39] regardless of payer or indication and shall be limited to the price applicability period for the selected drug. Accordingly, the call to submit plans for HRSA/OPA review is limited to the manufacturers that have active selected drugs in the MDPNP for initial price applicability years 2026 and 2027.[40] HRSA/OPA is inviting qualifying drug manufacturers that meet this criteria to apply for participation in the 340B Rebate Model Pilot Program for a minimum 1-year period.

Manufacturer plans for participation in the 340B Rebate Model Pilot Program should be submitted to *340BPricing@hrsa.gov* no later than August 24, 2026. Approvals, if any, will be made by September 24 2026, for a January 1, 2027, effective date for drugs that are a selected drug for initial price applicability period 2026 and 2027. Manufacturers may not implement plans without first receiving HHS approval in accordance with section 340B(a)(1) of the PHSA.

Manufacturer plans for the 340B Rebate Model Pilot Program must include the criteria outlined below. Manufacturer plans that exceed or go beyond these criteria must include detailed justification and will be subject to additional levels of review by HRSA/OPA prior to approval HRSA/OPA will review submitted plans and notify manufacturers if their plan is approved and the manufacturer may participate in the 340B Rebate Model Pilot Program. Submitted plans should succinctly describe how they meet all the criteria below. HHS reserves the right to revoke a manufacturer's approval to participate in the 340B Rebate Model Pilot Program at any time if a manufacturer is not in compliance with the criteria outlined below and with any other requirements set forth in the approved manufacturer plan.

A. General 340B Rebate Model Pilot Plan Requirements

1. Plan must identify the IT platform to be used for covered entity data submission and include assurances that all costs for IT platform used for data submission, be borne by the manufacturer.

2. Plan must allow for 90 calendar days' notice to covered entities and other impacted stakeholders before implementing an approved rebate pilot plan, with instructions for registering for any IT platforms. Changes to approved plans must be submitted to OPA for review and approval prior to implementation, including the mechanism by which covered entities are to acquire drugs included in the rebate model pilot. OPA will determine if the changes can take effect immediately or if they require a notification period to covered entities. Manufacturers will be expected to provide HRSA with a copy of their final approved plan for public posting on HRSA's website to ensure consistency with what HRSA approved.

3. Plan must allow for covered entities to order the selected drugs under existing distribution mechanisms (*e.g.,* 340B wholesaler accounts with WAC prices loaded) to ensure purchases flow through existing infrastructure.

4. Plan must provide technical assistance/customer service component and ensure that opportunities to engage directly with the manufacturer in good faith regarding questions or concerns are made available to covered entities through both the IT platform and provide a point of contact at the manufacturer.

5. Plan must ensure that the IT platform has assurances in place to ensure that the data is secure and protected and collection of the data is limited to the elements listed below that are necessary for providing 340B rebates pursuant to section 340B(a)(1) of the PHSA.

6. Plan must ensure that the manufacturer and the IT platform have mechanisms in place to protect the privacy and security of PHI or other PII, which is required to be safeguarded in a manner consistent with any applicable federal privacy and data security laws, including HIPAA.

7. Plan must describe whether an exception that would not apply broadly to all covered entities, and if any, will be communicated to both HRSA and affected covered entities (*e.g.,* covered entities without access to a third-party administrator or rural hospitals or health centers).

B. Reporting Requirements

1. Plan must ensure that covered entities are allowed to submit and report data (as detailed below), at a minimum, up to 45 calendar days from date of dispense, with allowances for extenuating circumstances and other exceptions, including adjustments when a 340B status change occurs on a claim.

2. Plan must ensure that the IT platform will have the capacity to receive data from all applicable covered entities and to filter and use only the data required to effectuate the rebate (*e.g.,* if drugs other than a selected drug for initial price applicability year 2026 or 2027 during its price applicability period under the MDPNP are submitted, the platform will be able to identify and discard unneeded data).

3. Plan must ensure that the IT platform will have the capability to provide real-time reconciliation reports for covered entities to be informed of the rebate status of submitted claims.

4. Plan must ensure that a quarterly 340B price file for each of the manufacturer's 11-digit NDCs is made available to covered entities, so that covered entities may use the price file in conjunction with pharmacy billing systems to appropriately account for actual acquisition cost (*i.e.,* post rebate price) for Medicaid billing and also to assist with sliding fee scales or cost sharing with patients.

5. Plan must require the manufacturer to provide HRSA/OPA with periodic reports consistent with the information outlined in this Notice, in a format and manner specified by HRSA/OPA (instructions forthcoming). Such data should detail data on purchases provided through rebates, information related to claim denials, and other information that may evaluate the effectiveness of the rebate model.

C. Rebates

1. Plan must include the rebate calculation equal to the wholesale acquisition cost (WAC) less the 340B ceiling price on the day of dispense.

2. Plan must specify that rebates are paid at the unit level.

3. Plan must include details to accommodate up to 2 unreplenished accumulated packages during the implementation phase. Covered entities shall have a 15-calendar day grace period, in which they may submit rebate requests for up to 2 unreplenished accumulated packages prior to the Pilot's effective date. For example, a covered entity may request a rebate for up to 2 packages of a product dispensed from its neutral inventory on December 16, even though the effective date for the product's participation in the pilot is January 1. The request for such rebates should still be made within 45 days of dispense.

4. Plan must ensure that all rebates are paid to the covered entity (or denied, with documentation to support)

[39] *Medicare Drug Price Negotiation Selected Drug List,* available at *https://www.cms.gov/files/zip/selected-drug-list-negotiated-prices-also-known-maximum-fair-prices-statutezip.zip.*

[40] *https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdfhttps://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf Fact Sheet for Negotiated Prices for Applicability Years 2026 and 2027,* available at *https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf* and *https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf,* respectively.

within 10 calendar days of completed data submission. If the submission is returned for incomplete data, the 10-day clock for rebate payment will restart when all necessary data is submitted.

5. Plan must ensure that 340B rebates are not denied based on eligibility or compliance concerns with diversion or Medicaid duplicate discounts, pursuant to section 340B(a)(5)(A) and (B) of the Public Health Service Act and should provide for rationale and specific documentation for reasons claims are denied (*e.g.,* nonduplication of discounts for a selected drug for which the MFP is required under the MDPNP or 340B rebate provided to another covered entity on the same claim). Rebates may not be denied for perceived lack of WAC purchases. If a manufacturer has concerns regarding Medicaid duplicate discounts, diversion, eligibility, or insufficient WAC purchases to support rebate requests, the manufacturer must raise those concerns directly with HRSA/OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution, for addressing such issues. Covered entities are also afforded opportunities to raise concerns with HRSA/OPA if there are issues with rebate denials through reporting tools sent to *340Bpricing@hrsa.gov.*

6. Plan must ensure that its implementation of the Pilot is limited to using the 340B rebates model only on sales of active selected drugs for the initial price applicability years 2026 or 2027, as included on the CMS Medicare Drug Price Negotiation Selected Drug List (''List''),[41] regardless of payer, or indication, and only during the selected drug's effective dates of negotiated prices. The NDC–11s of the selected drug are included in the Pilot only to the extent they are on the List, and the selected drug is in its price applicability period in the MDPNP.

D. Data

1. All data requested as part of the Plan should be limited to only the following claim fields:

Pharmacy claims data fields	Medical claims data fields
Date of Service	Date of Service.
Date Prescribed	Claim Line Number.
Rx number	Claim Number.
Fill number	Unit of Measure.
NDC–11	NDC–11.
Quantity Dispensed	Quantity.
Prescriber ID	Rendering Physician ID.
Service Provider ID	Service Provider ID.
340B ID	340B ID.
RX BIN	Health Plan Name.
RX PCN	Health Plan ID.
	Health Plan ID Qualifier (if available).

[41] *https://www.cms.gov/files/zip/medicare-drug-price-negotiation-selected-drug-list.zip.*

- Data definitions for each field must be submitted with the plan for HRSA's approval to ensure consistency and make it available for covered entities. Purchasing data and encounter data requests should not be requested as part of the pilot at this time.
- For BIN, PCN, and Health Plan fields for uninsured or cash paying patients, please allow the submission in the fields to be marked ''CASH''.
- Covered entities must be permitted to resubmit data if a rebate request is deemed incomplete or missing data.
- Instructions for providing data regarding wasted or undispensed units must be provided as part of the manufacturer's plan and communicated to covered entities.

Covered entity data that is handled by technology platforms and received by manufacturers as a part of this Pilot should not be used for any purpose other than those explicitly identified in this Pilot. This limitation extends to any collecting, aggregating, sharing, or licensing of Pilot data by manufacturers or technology platforms.

Thomas J. Engels,

Administrator.

[FR Doc. 2026–15633 Filed 7–31–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; National Health Service Corps Scholar/Students to Service Travel Worksheet, OMB No. 0906–0087—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than September 2, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: National Health Service Corps Scholar/Students to Service Travel Worksheet, OMB No. 0906–0087—Revision

Abstract: Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program and the Students to Service (S2S) Loan Repayment Program use the online Travel Request Worksheet to request and receive travel funds from the federal government to, in accordance with the Public Health Service Act, section 331(c)(1), visit eligible NHSC sites to which they may be assigned.

The travel approval process is initiated when an NHSC scholar or S2S participant notifies the NHSC of an impending interview at one or more NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation reimbursement process, in accordance with the Public Health Service Act, section 331(c)(3), after an NHSC scholar or S2S participant has successfully been matched to an approved practice site. Upon receipt of a completed Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the NHSC scholar or S2S participant and the NHSC logistics contractor regarding travel arrangements and authorization of the funding for the site visit or relocation.

A 60-day notice published in the **Federal Register** on May 20, 2026, vol. 91, No. 97; pp. 29498–99. There were no public comments.