NET WORK LISER

Discussion Paper Series

IZA DP No. 19054

October 2026

How Will the 340B Rebate Model Pilot Affect Covered Entity Finances?

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IZA@LISER NETWORK
ISSN: 2365-9793

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Abstract

The Health Resources and Services Administration (HRSA) plans to implement a pilot switching 340B from an upfront discount model to a rebate model for drugs in the Medicare Drug Price Negotiation Program (MDPNP). This study uses calibration methods to predict the impact of the rebate model pilot (RMP) on covered entities' net revenues from the 340B program. I examine possible losses from averted duplicate discounts; denial of valid claims; manufacturers using data to exert influence; liquidity-related expenses; and administrative and staffing costs. I also project the effects of switching the entire 340B program to a rebate model. I project net revenue losses from the RMP of $1.5 billion. Expansion to all of 340B would increase the predicted losses to $22.8 billion, cutting net revenues from the program by 32%. The majority of losses will come from administrative and staffing costs, which do not benefit manufacturers, implying a net negative effect of switching to a rebate model. Covered entity losses from the RMP will be limited by the pilot only applying to a small percentage of 340B sales as well as restrictions HRSA's guidance places on manufacturers. If the rebate model expands to all of 340B or if the restrictions are inadequately enforced, the losses will grow substantially.

JEL classification

I11, I18, H51

Keywords

340B, covered entities, rebate model pilot, prescription drugs, pharmaceuticals

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I. Introduction

The 340B program, created by the Veterans Health Care Act (VHCA) of 1992 (Public Law 102-585), requires pharmaceutical manufacturers to sell drugs to "covered entities" at a discount, with the goal being to "stretch scarce federal resources" and enhance the ability of safety-net providers to provide unprofitable services. Initially, the law restricted eligibility as a covered entity to Disproportionate-Share Hospitals (DSHs) with a Medicare DSH percentage above a threshold, Federally Qualified Health Centers, and Ryan White HIV/AIDS clinics. 340B pricing only applies to drugs prescribed at covered entities' outpatient departments and filled at in-house pharmacies or external "contract pharmacies." The pharmacy collects the usual payment from patients and insurers and gives it to the covered entity in exchange for a dispensing fee. The entity then orders a replacement drug at the discounted price, keeping the difference between the two prices – less a dispensing fee when contract pharmacies are used – as its margin (Courtemanche and Garuccio, 2026).

Two major subsequent federal laws triggered substantial expansion of the 340B program. In both cases, drug companies were willing to agree to these expansions because these same laws benefited them in other ways, such as providing access to millions of new customers. First, the Medicare Modernization Act (MMA) of 2003, primarily known for adding prescription drug benefits to Medicare through the Part D program, also applied the DSH-percentage formula used for large urban hospitals to rural and smaller urban hospitals. This allowed many of them to clear the threshold required for 340B eligibility. Second, the Affordable Care Act (ACA) of 2010, which is best known for its large expansions of Medicaid and private non-group insurance, added critical access hospitals, rural referral centers, and sole community hospitals as new categories of covered entities.[1] It also expanded eligibility indirectly, since state Medicaid expansions under the ACA

[1] Additionally, the Deficit Reduction Act of 2005 added children's hospitals (Courtemanche, 2026b).

pushed many hospitals' DSH percentages over the 340B threshold (Courtemanche and Garuccio, 2026).

HRSA's revision of contract-pharmacy guidance also significantly expanded 340B. The agency's original 1996 guidance limited covered entities to a single contract pharmacy, but a 2010 shift removed that cap and allowed an unlimited number of pharmacies. This revised guidance was issued alongside the broader policy discussion surrounding the ACA and can be considered part of the bargaining process through which drug companies won access to a large new customer base while also avoiding a single-payer system (Courtemanche and Garuccio, 2026).

Ultimately, the size of the 340B program grew from around $8 billion in 2010 (in 2025 dollars) to $100 billion in 2025.[2] Nonetheless, U.S. pharmaceutical industry profits rose from $60 billion to $119 billion during this same time frame, outpacing the net revenues of hospitals, which grew from $84 billion to $94 billion.[3] If one views the 340B program as a transfer from drug manufacturers to covered entities, this means that the program's rapid expansion was essential to the hospital industry holding its net revenue steady in the face of other financing challenges.

The rapid growth of 340B has triggered pushback from drug companies. They contend that the program is plagued by "duplicate discounting," which can occur when drugs prescribed to Medicaid patients are eligible for both 340B discounts and Medicaid Drug Rebate Program (MDRP) rebates. According to the 340B statute, a manufacturer cannot be required to provide both the 340B

[2] The 2010 number comes from the Congressional Budget Office (2025) and is inflation-adjusted using the price deflator reported by the U.S. Bureau of Economic Analysis (2026). The 2025 number comes from Fein (2026b).

[3] Both 2010 numbers are inflation-adjusted based on the price deflator reported by the U.S. Bureau of Economic Analysis (2026). Information on drug company profits comes from the U.S. Census Bureau (2026). There is no comparable Census "corporate profits" series for hospitals since most are nonprofit. Instead, net revenues (aggregate revenue minus expenses) are computed by multiplying total national 'Hospital Care' spending (from CMS's National Health Expenditure Accounts; CMS Office of the Actuary, 2013) by the aggregate hospital percent margin from AHA/KFF analyses of Medicare cost report data (American Hospital Association, 2018; Levinson et al., 2024). In 2010, hospital care spending was $812.6 billion (CMS Office of the Actuary, 2013) and the margin was 7.2% (American Hospital Association, 2018), implying aggregate hospital net revenue of roughly $59 billion (which becomes $84 billion after adjusting for inflation). The latest available year of data is 2023 rather than 2025. Hospital care spending was roughly $1.47 trillion (calculated from CMS's reported 8.9% growth to $1.6 trillion in 2024; CMS Office of the Actuary, 2025); aggregate total margin was 6.4% (Levinson et al., 2024). That implies aggregate hospital profit of roughly $94 billion.

discount and a Medicaid rebate for the same drug fill (Public Law 102-585, 42 U.S.C. § 1396r-8). However, data fragmentation issues – particularly with Medicaid managed care – can make these cases difficult to identify in practice, leading to duplicate discounts being given in some cases. These challenges can also lead to diversion, which occurs when 340B pricing is given for ineligible patients – typically taking the form of a discount being sought by multiple covered entities for the same patient (Courtemanche and Garuccio, 2026).

Since 2024, manufacturers have sought to move 340B to a rebate system, arguing that the existing system of upfront payments and inadequate data linkage does not allow them to prevent duplicate discounting (Hut, 2024; HRSA, 2026b). Covered entities have expressed concerns that a rebate model would give drug companies too much decision-making authority, create delays that could lead to cash flow problems, and impose substantial administrative costs (Courtemanche, 2026a; HRSA, 2026b). Manufacturers were ultimately able to successfully lobby HRSA to implement an RMP for drugs included in the MDPNP, with the agency releasing guidance for the pilot in August 2026. Covered entities will no longer receive the upfront discount but instead purchase a drug at wholesale acquisition cost (WAC) and submit a claim to the manufacturer for a rebate (HRSA, 2026b).

The MDPNP authorizes the federal government to negotiate the prices of selected high-cost prescription drugs with manufacturers. The negotiated prices are called “Maximum Fair Prices” (MFPs). The first ten drugs entered the program in 2026, with fifteen more scheduled for 2027, fifteen more for 2028, and twenty more slated to be added in each subsequent year (AHA News, 2025; Centers for Medicare & Medicaid Services [CMS], 2024, 2025). For 340B fills of drugs in the MDPNP, Medicare will only reimburse the MFP plus a small dispensing fee, lowering covered entity revenues. To help compensate, the statute requires that manufacturers sell covered entities

replacement drugs at whichever price is lower between the 340B ceiling price and the MFP (Courtemanche, 2026b; Santiago and Moldawer, 2025).

Instead of building a real-time system to automatically apply the lower price at the point of sale, CMS relies on manufacturers to issue a retrospective discount or refund to the dispensing entity within 14 days of a qualifying claim (Smalldon, 2025). That retrospective, claim-by-claim reconciliation process creates a logistical challenge that ultimately led HRSA to agree to pilot a rebate system. Since HRSA created the RMP to be a solution to the practical problem caused by the MDPNP rather than a general reworking of the 340B program, it only applies to drugs in the 2026 and 2027 MDPNP cohorts. However, the contentiousness of the debate raises the question of whether the RMP will remain connected to MFPs as the number of drugs in the MDPNP grows, expand to the entire 340B program as manufacturers prefer, or be short-lived as covered entities prefer.

This study begins by providing a more detailed discussion of manufacturer efforts to push back against the growth of the 340B program, culminating in the push for a rebate model. I include an extended discussion of duplicate discounting, arguing that its prevalence is considerably smaller than manufacturer statements suggest, which has implications for the benefits of the RMP. The disconnect appears to largely be attributable to the drug industry using a broader definition of the term that also includes overlap between 340B discounts and rebates contractually negotiated with pharmacy benefit managers (PBMs) who administer commercial drug plans and Medicare Part D.

I then conduct a calibration analysis to project the impacts of the RMP on covered entities' net revenues from 340B, holding all else constant. I also scale up these estimates to project the effect of implementing a rebate model for the entire 340B program. The analyses incorporate effects from both the rebate model itself and the fact that it will be implemented using the Beacon platform developed by Second Sight Solutions, whose parent company has substantial financial ties to the

pharmaceutical industry (Courtemanche, 2026a). Building off Courtemanche's (2026a) study of the sources of value to manufacturers from utilizing Second Sight's platforms and combining this with additional costs to covered entities identified by HRSA (2026b), I categorize these losses as coming from several sources: averted duplicate discounts; denial of valid claims; manufacturers using 340B claims data for the purposes of influence, lobbying, physician detailing, and pharmacy targeting; costs related to cash flow and liquidity; and administrative and staffing costs.

Using preferred parameter values, I project that these sources will combine to cause annual net revenue losses from the RMP of $1.5 billion, rising to $22.77 billion if the same model is expanded to all of 340B. Most of these losses will come from administrative and staffing costs associated with implementing the rebate model, as HRSA's (2026b) guidance imposes restrictions on manufacturers that aim to guard against some of the other concerns. However, the impact would be larger if this guidance is ignored or inadequately enforced. Large losses – whether from low compliance or rebate model expansion – would raise questions about impacts on covered entities' ability to provide unprofitable services and serve vulnerable populations.

II. Background

When the 340B program was created, administration was assigned to HRSA's Office of Pharmacy Affairs. Since the VHCA gave HRSA little specific rulemaking authority, the agency has administered most of the program's substance through sub-regulatory guidance rather than notice-and-comment regulation. Manufacturers have attempted to take advantage of this ambiguity by imposing restrictions designed to reverse the program's growth. This in turn triggered a flurry of lawsuits, with HRSA aiming to provide clarity where possible (Rogers, 2025). This section provides additional background about manufacturer efforts to shrink the 340B program and about the duplicate discounting that serves as the stated justification for these actions.

Beginning in 2020, Eli Lilly, AstraZeneca, Sanofi, Novartis, Novo Nordisk, and eventually over 20 other manufacturers began restricting 340B pricing on shipments to contract pharmacies. For instance, AstraZeneca would recognize only one contract pharmacy absent an in-house pharmacy, Sanofi and Novo Nordisk allowed more only if the covered entity supplied 340B claims data, United Therapeutics stopped recognizing contract pharmacies added after the third quarter of 2020, and Novartis limited recognition to pharmacies within 40 miles of the covered entity (Courtemanche and Garuccio, 2026).

HRSA responded with an advisory opinion in December 2020 declaring the restrictions unlawful, which led to a wave of manufacturer lawsuits (U.S. Department of Health and Human Services, Office of the General Counsel, 2020). In AstraZeneca Pharmaceuticals LP v. Becerra (2023), the Third Circuit held that the 340B statute does not require manufacturers to ship to an unlimited number of contract pharmacies. The D.C. Circuit reached a similar conclusion in May 2024, ruling for Novartis and United Therapeutics in a consolidated case (Novartis Pharmaceuticals Corp. v. Johnson, 2024). These rulings in favor of manufacturers, combined with HRSA's inability to force compliance, spurred state legislatures to act. By August 2025, 18 states had enacted laws protecting contract pharmacy networks against manufacturer restrictions (ASHP News, 2025). Manufacturers challenged the first of these laws, Arkansas's, but the Eighth Circuit upheld it in 2024, ruling that Congress' silence on contract-pharmacy distribution left room for state regulation (Pharmaceutical Research and Manufacturers of America v. McClain, 2024).

Manufacturers have also increasingly required covered entities and contract pharmacies to route their claims data through third-party compliance platforms before 340B pricing is honored. The dominant platform, the Enhanced Services Platform ("ESP"), was developed by Second Sight Solutions, LLC. Courtemanche (2026a) documents that this company's parent company, Berkeley

Research Group, has extensive ties to the pharmaceutical industry, raising conflict of interest questions.

Manufacturers' attempt to switch the 340B program from an upfront discount model to a rebate model represents the next step in their fight to reduce their forgone revenue from the program. This strategy dates back to August 2024, when Johnson & Johnson announced that a new platform by Second Sight, Beacon Channel Management, would administer 340B pricing for DSH hospitals purchasing Stelara and Xarelto as a rebate rather than a point-of-sale discount (Hut, 2024). HRSA directed the company to withdraw the plan, asserting that a manufacturer cannot unilaterally impose a rebate model without HHS approval (American Hospital Association, 2024). Johnson & Johnson unsuccessfully sued HHS and HRSA in the U.S. District Court for the District of Columbia, while a related challenge by Novartis, Eli Lilly, and Bristol Myers Squibb reached the same result on appeal (America's Essential Hospitals, 2025). Together, these rulings established that an HRSA-approved channel would be necessary for a rebate model to move forward. This is exactly what happened next with HRSA's rebate pilot.

The process leading to the RMP began with HRSA opening an application process for manufacturers in mid-2025. By November, the agency had approved rebate plans from the manufacturers of all ten first-cohort MFP drugs (Eyman Partners, 2025). The American Hospital Association sued the Department of Health and Human Services and obtained a preliminary injunction blocking the pilot just before its planned effective date. This was upheld by the First Circuit Court of Appeals (Pease Bell, 2026). HRSA subsequently issued a revised version of the pilot via Federal Register notice on August 3, 2026 (HRSA, 2026b), with hospital groups signaling possible further legal challenges (American Hospital Association, 2026).

Manufacturers have consistently framed these actions as protecting against duplicate discounting and diversion. In its July 2020 letter to HRSA justifying its contract-pharmacy policy,

AstraZeneca cited "significant increases in covered entity violations of the statutory prohibitions against product diversion and duplicate discounting" (AstraZeneca Pharmaceuticals LP v. Becerra, Complaint, 2021). Eli Lilly offered a similar rationale for its claims-data requirement, stating that the data collection was "intended to stop the rampant fraud, waste, and abuse in the 340B program that is harming employers, state and federal governments, and patients," and that manufacturers "can lawfully collect this claims data to detect fraud, abuse, and unlawful duplicate discounts" (Eli Lilly and Company, 2026). PhRMA has advanced the same justification for the rebate model, arguing in an April 2026 comment letter to HRSA that the pilot not initially being implemented left manufacturers with no way to prevent duplicate 340B and Medicaid discounts, that a rebate model "could directly benefit patients by encouraging 340B patient identification at the pharmacy or point of administration," and that payers, manufacturers, and the public "are no longer obligated to shoulder the ever-increasing costs of rampant 340B program violations" (Pharmaceutical Research and Manufacturers of America, 2026).

However, a closer look reveals that the evidence does not support claims of widespread statutory duplicate discounting, and that manufacturers' interest in claims data and a rebate model likely reflects additional sources of value. Based on results from HRSA audits of covered entities combined with information on the share of Medicaid patients, Courtemanche (2026a) estimates that $1.9 billion of 340B purchases nationally (a relatively modest 2.3% of the annual total of $81.4 billion) end up receiving duplicate discounts from 340B/Medicaid overlap while diversion occurs for an additional $1.22 billion (1.5%). The actual additional revenue pharmaceutical companies would make if these errors were corrected is less than these amounts, which represent the aggregate purchase price of all units bought with the 340B discount rather than the size of the erroneous discounts. In contrast, Courtemanche (2026a) estimates that other sources of value that full utilization of Second Sight's platforms would create for manufacturers – including from avoiding

payment on valid 340B claims, building derivative data products for lobbying purposes, using the data to target and influence individual health care providers, and licensing the data – totals a much more substantial $9.33 billion per year.

The gap between industry statements regarding duplicate discounting and the available evidence can be largely explained by differences in how duplicate discounting is defined. The 340B statute only defines duplicate discounting as the combination of a 340B discount with an MDRP rebate (Public Law 102-585, 42 U.S.C. § 256b(a)(5)(A)(i)). 340B discounts can occur alongside other discounts or rebates given by drug manufacturers, but there is no statutory basis for denying 340B claims in such cases. For instance, in both commercial insurance and Medicare Part D, pharmacy benefit managers commonly negotiate confidential rebates with drug manufacturers in exchange for favorable formulary placement, which could include preferred tier status, absence of prior authorization, or preferred positioning over a competitor. These rebates are typically paid after the point of sale, often quarterly, and are not visible to the pharmacy or patient (Coster, 2025).

When a drug subject to such a rebate also receives a 340B discount, manufacturers consider this duplicate discounting, even though it is not characterized as such by the law. A white paper by IQVIA – a company whose customer base is mostly drug and biotech companies (Umbrex, 2026) – makes this clear by stating that "products dispensed to a 340B patient, should not be subject to a payor (commercial or state) rebate," and describing such rebates as resulting in "significant financial losses for manufacturers" (Singh, 2023, pp. 3–4). Using the expansive definition of duplicate discounting favored by the pharmaceutical industry, IQVIA estimates it to be $34 to $37.5 billion per year (Singh, 2023), representing almost 30% of the study's estimated size of 340B.[4] As a percent of the program, this is about 13 times larger than Courtemanche's (2026a) estimate. This stark difference is not surprising; whereas the statutory definition limits duplicate discounting to

[4] IQVIA computes a larger program size than HRSA because it uses WAC pricing rather than 340B pricing.

Medicaid, which covers only 18% of the U.S. population, the expansive definition also includes commercial insurance (66%) and Medicare (19%) (Bunch and Ketema, 2025).

III. Methods and Results

This section aims to quantify the losses to covered entities from the RMP, holding all else constant. Drawing on the discussion in Courtemanche (2026a), there are two specific aspects of this pilot that could lead to losses. The first is the rebate structure itself, which switches the default from payment to non-payment, could lead to liquidity challenges from delays, and could impose substantial administrative costs. The second is the fact that the rebate model will be implemented via Second Sight's Beacon platform, raising questions about how the data will be used due to the pharmaceutical industry's connection to Second Sight's parent company Berkeley Research Group.

I follow Courtemanche's (2026a) categorization of sources of the value to pharmaceutical companies of full implementation of Second Sight's platforms, which effectively means a rebate model through Beacon. This means separately quantifying the effects of recovered duplicate discounts, the ability to deny or delay valid claims, lobbying leverage, improved physician detailing, and data sublicensing. Courtemanche estimates these sources of value to manufacturers combine to yield $9.33 billion per year.

However, my analysis differs from that of Courtemanche (2026a) in three important ways. First, the pilot will only apply to the first two cohorts of MFP drugs, scaling down the potential impacts. Second, I focus on the losses to covered entities, which are not simply the reverse of the value to manufacturers. For instance, administrative costs and liquidity challenges from payment delays represent losses to covered entities but not gains to manufacturers, whereas improved physician detailing and data sublicensing are sources of value to manufacturers but not (at least directly) losses to covered entities. Additionally, while all averted duplicate discounting benefits

manufacturers, it only causes losses for covered entities if the insurer rebate is preserved and the 340B discount is eliminated.

Third, HRSA's August 2026 guidance aims to address some of covered entities' concerns that were incorporated into Courtemanche's (2026a) modeling (HRSA, 2026b). Indeed, we will repeatedly see in the analysis below that whether losses are small or large hinges on the extent to which HRSA's guidelines and prohibitions are followed. The lack of a clear mechanism to identify and sanction violations creates ambiguity about how closely manufacturers will adhere to these rules. The only potential punishment specified in HRSA's guidance is extreme – removal from the rebate pilot – and HRSA gives itself wide discretion as to whether and when to impose it (Hananoki and Franco, 2026; HRSA, 2026b). This raises the question of whether HRSA will actually do so, or whether the agency will instead rely on warnings that do little to incentivize compliance.

The first step in the analysis is to establish a baseline. According to HRSA (2026a), covered entities combined to make $100 billion in discounted 340B purchases in 2025. IQVIA (2026) finds that the WAC value of these purchases was $179.5 billion. Courtemanche (2026b) computes covered entity revenues of $171.9 billion, which is less than $179.5 billion because one payer – Medicaid fee-for-service (FFS) – reimburses at a lower rate than the WAC. Implied net revenues are therefore $71.9 billion. These numbers need to be scaled down to reflect the fact that the drugs in the initial two MDPNP cohorts comprise only 5.5% of the dollar amount of 340B-discounted purchases (HRSA, 2026b). Multiplying the above numbers by 0.055 yields baseline discounted 340B purchases of $5.5 billion, covered entity revenues of $9.45 billion, and covered entity net revenues of $3.95 billion.

Preventing Statutory Duplicate Discounting and Diversion

Courtemanche (2026a) estimates the total annual amount of 340B purchases for which duplicate Medicaid rebate/340B discounts are given to be $1.91 billion per year. His numbers are

based on an $81.4 billion total size of the 340B program, which is from the year before the $100 billion size used in the analyses in this paper. Scaling up the amount to reflect the new program size yields $2.35 billion. Scaling down to focus on the 5.5% of 340B volume that comes from the first two cohorts of MDPNP drugs yields $129 million.

These amounts reflect covered entity expenditures on 340B purchases for which duplicate discounts were given rather than the extra amount made by covered entities due to the errors. Estimating the latter requires an understanding of covered entity margins on fills billed to Medicaid, which vary by type of Medicaid. 52% of Medicaid enrollees nationally are either completely on fee-for-service (FFS) or live in states that carve out drug benefits and reimburse on the same fee-for-service basis. A federal regulation limits the Medicaid FFS reimbursement rate for 340B-eligible drugs to actual acquisition cost (the 340B ceiling price) plus a small dispensing fee that varies by state but generally comes to around 6% (Courtemanche, 2026b). Therefore, assuming enrollee shares mirror expenditure shares, the added covered entity revenues from the duplicate discounting of MDPNP drugs billed to Medicaid FFS come to 6% of 52% of $129 million, which is $4.02 million. The other 48% of enrollees are on Medicaid managed care, which typically reimburses more similarly to commercial insurance – at around WAC (Courtemanche, 2026b; Dolan and Tian, 2020; Medicaid and CHIP Payment and Access Commission, 2026). I therefore assume a 340B margin of 79.5%, given by the percentage difference between the $179.5 billion in WAC value and $100 billion in 340B-discounted purchases. Estimated covered entity revenue from the duplicate discounting of MDPNP drugs among this group is therefore 79.5% of 48% of $129 million, which comes to $49.2 million. This brings the total revenue from 340B/Medicaid rebate duplicate discounting to $53.2 million.

The other statutory violation is diversion, which occurs when multiple covered entities claim the same fill. Courtemanche (2026a) estimates that diversion occurs on $1.22 billion of 340B-

discounted expenditures. Again, this is based on an $81.4 billion total size of the 340B program. Scaling up to reflect a $100 billion program size yields $1.5 billion. Assuming 5.5% of this amount is from MDPNP drugs yields $82 million. Diversion could occur on fills billed to any payer, not just Medicaid. Therefore, I assume a margin equal to the average margin across all 340B purchases, which is 71.9% based on the numbers above. 71.9% of $82 million yields $58.96 million of extra covered entity revenue from diversion.

The next step is to estimate what percentage of statutory duplicate discounting is likely to be prevented by the RMP. This depends on two factors. The first is the percentage of duplicate discounting the combination of a rebate system with Beacon's data collection capabilities is able to prevent. Courtemanche (2026a) assumes a 50% recovery rate, but this was based on Second Sight's ESP platform, which collects the same data as Beacon but is designed for upfront discounts rather than rebates. In theory, a rebate model ought to improve manufacturers' ability to stop duplicate discounting, as avoiding making payments is much easier than seeking reimbursement for payments already made. A rebate model puts the burden of proof on covered entities, whereas the current upfront discount mechanism places it on manufacturers, presumably preventing any criteria wider than the statutory 340B/Medicaid definition of duplicate discounting from being utilized.

However, recognizing the risk of giving manufacturers too much decision-making leeway, HRSA's (2026b) guidance prohibits them from denying refunds solely because of suspicion of duplicate discounting. Instead, they are instructed to pursue resolution by either raising their concerns with HRSA or using the statutory 340B audit process and administrative dispute resolution – effectively requiring a "neutral referee" (Hananoki and Franco, 2026). If this guidance is followed, then the benefit of Beacon would be limited to the ability to identify possible duplicate discounting, rather than to both identify and prevent it. In other words, the benefit would be functionally the same as that of ESP, which collects the same data elements as Beacon. Therefore, Courtemanche's

(2026a) 50% recovery rate applies, and I use this percentage for my central estimate. I also conduct sensitivity analyses using 25% and 75%. An argument could be made for the higher percentage due to the lack of a clear enforcement mechanism.

The second factor is whose discount is eliminated when duplicate discounting is identified and prevented. In the case of statutory duplicate discounting in which 340B discounts and Medicaid rebates are both given, covered entity finances would only be affected if the 340B discount is the one dropped. This point does not apply to diversion since that involves discounts being given to multiple covered entities, which means that a covered entity will lose revenue regardless of which discount is avoided.

For 340B/Medicaid rebate duplicate discounting, the law says that covered entities are prohibited from billing Medicaid in a way that would trigger both a 340B discount and an MDRP rebate on the same unit, but it does not say which takes precedence (Public Law 102-585, 42 U.S.C. § 1396r-8). This leaves covered entities to decide whether to "carve in" a particular drug fill for the 340B discount or "carve out" the fill for the Medicaid rebate. One might think that covered entities would always carve in since they receive the 340B discount but not the Medicaid rebate, but it is not that simple. In the case of prescriptions filled at an in-house pharmacy, the small 340B Medicaid margin can result in the spread from carve-out (standard Medicaid reimbursement rate minus standard acquisition cost) being higher than the spread from carve-in, which is just the dispensing fee (12 Va. Admin. Code § 30-80-40; 42 C.F.R. § 447.518(a)(2); Virginia Department of Medical Assistance Services, 2023). When the prescription is filled at a contract pharmacy, many covered entities default to carving out, as the 340B dispensing fee paid by Medicaid is too small to be worth the additional administrative challenges (Loucks et al., 2018; Simons, 2022). The weak incentive to retain the 340B Medicaid discount raises the possibility that some covered entities may voluntarily switch to a carve-out model for simplicity as scrutiny of duplicate discounting increases. Given the

arguments in both directions, my baseline scenario assumes that 50% of resolutions involve eliminating the 340B discount. Sensitivity analyses will use 25% and 75%.

Table 1: Sensitivity of Predicted Annual Covered Entity Net Revenue Loss from Eliminating Statutory Violations to Different Parameter Calibrations

% Eliminated	% Resolved by Eliminating 340B Discount	Net Revenue Loss from RMP	Net Revenue Loss from Switching Entire 340B Program to Rebate Model
50%	**50%**	**$42.78M**	**$777.82M**
25%	25%	$18.07M	$328.45M
25%	50%	$21.39M	$388.91M
25%	75%	$24.72M	$449.36M
50%	25%	$36.13M	$656.91M
50%	75%	$49.43M	$898.73M
75%	25%	$54.20M	$985.36M
75%	50%	$64.17M	$1,166.73M
75%	75%	$74.15M	$1,348.09M

Note: The bold and highlighted row represents the central scenario.

Table 1 shows predicted annual covered entity net revenue losses from averted statutory duplicate discounting and diversion violations, given by the sum of the effects on 340B/Medicaid rebate duplication and diversion. The former is given by $53.2 million * percent of duplicate discounting eliminated * percent resolved by eliminating the 340B discount. The latter is given by multiplying $58.96 million by just the percent of duplicate discounting eliminated since both discounts are to covered entities. The first two columns contain the parameter values. The third shows the predicted covered entity losses from the RMP. Finally, the fourth column projects the impact of switching the entire 340B program to a rebate model with the same stipulations as the RMP. This is obtained by simply multiplying the RMP estimates by 100 / 5.5. The preferred calibration – which uses the central value of 50% for both parameters – is shown in the first row, which is highlighted and in bold. This central scenario predicts annual losses from the RMP of $42.78 million. The sensitivity analyses, shown in the following rows, establish a range from $18.07 million to $74.15 million. These effects would become considerably larger if a rebate model were to

be adopted for the entire 340B program: $777.82 million in the baseline scenario, with a range from sensitivity analyses of $328.45 million to $1.348 billion.

With that said, even the losses from a fully implemented rebate model appear relatively modest compared to the overall size of the 340B program. An annual loss of $777.82 million translates to just 1.1% of the estimated $71.9 billion in annual covered entity net revenues from 340B, with the high end of the range being 1.9%. While manufacturer savings will exceed covered entity losses because they also include Medicaid rebates averted, even these are relatively modest. The formula becomes ($53.2 million + $58.96 million) * percent of duplicate discounting eliminated * 100/5.5. This yields $1.020 billion (1.4%) at the central parameter value of 50% and $1.529 billion (2.1%) at the high end of the range. These modest percentages support Courtemanche's (2026a) contention that the motivation behind the pharmaceutical industry's strong push for a rebate model likely goes beyond preventing statutory duplicate discounting.

Preventing Non-Statutory "Duplicate Discounting"

One of these other sources of motivation likely comes from the ability to stop other forms of what drug manufacturers consider to be duplicate discounting that are not classified as such by statute. Recall that, using the expansive definition of duplicate discounting, IQVIA estimates that duplicate discounting accounts for almost 30% of the 340B program (Singh, 2023). The previous subsection asserted that statutory 340B/Medicaid duplicate discounting occurs on $2.35 billion of 340B purchases and diversion occurs on $1.50 billion, for a total of $3.85 billion, or 3.85% of the $100 billion size of the program. Combining these estimates suggests that non-statutory forms of duplicate discounting account for 26.15% of this $100 billion, or $26.15 billion.

These other forms of duplicate discounting involve overlap between 340B discounts and rebates given to the commercial PBMs that represent Medicare Part D and privately insured patients. Since Part D and commercial insurance have historically paid around WAC (Courtemanche, 2026b),

the appropriate estimate of the 340B margin for these fills is 79.5%. 79.5% of $26.15 billion comes to $20.8 billion. Scaling down to account for MDPNP drugs comprising 5.5% of 340B expenditures yields $1.14 billion. Again, the portion of this amount that covered entities lose due to the RMP depends on the percentage of such forms of "duplicate discounting" eliminated and the percentage of these cases in which the 340B discount is withheld rather than the insurer rebate.

The claims data collected by Beacon should drastically increase detection of cases in which both 340B discounts and PBM rebates are given, but the degree to which manufacturers will be able to eliminate such duplication is less clear. Recall HRSA's (2026b) guidance about suspicion of duplicate discounting *not* being sufficient to deny covered entity rebate claims and disputes having to go through government channels. If this guidance is followed, it is unlikely that drug companies will be able to recoup 340B rebates in cases of 340B/PBM rebate overlap because this is not considered duplicate discounting by law. Of course, as discussed at the beginning of this section, the guidance being followed and enforced should not be taken for granted. Whether drug companies can recoup PBM rebates is a private contractual matter, with some form of meet-in-the-middle negotiation seeming likely. Accordingly, I assume a 50% recoupment rate, with 25% and 75% being used as sensitivity analyses.

For the same reasons, conditional on a non-statutory duplicate discount being prevented, the PBM rebate should be much more likely to be the one eliminated than the 340B discount. However, it is important to note that drug companies benefit from rebates given to commercial PBMs through negotiating leverage but do not similarly benefit from giving 340B discounts to covered entities, creating an incentive to deny the 340B discount if possible. This makes enforcement of HRSA's guidance especially important. Given the potential for noncompliance and inconsistent enforcement, I assume that the 340B discount is the one dropped 10% of the time, meaning that the PBM rebate is the one dropped 90% of the time. Sensitivity analyses will use 0% and 20%.

Using these parameter calibrations, Table 2 reports predicted annual covered entity net revenue losses from averted non-statutory duplicate discounting. The formula is $1.14 billion * percent eliminated * percent resolved by the 340B discount being dropped. In the central scenario, the loss is $57 million, rising to $1.036 billion if the rebate model expands to the entire 340B program. The range for the loss from the RMP is $0 to $171 million, while the range for the fully expanded rebate model is $0 to $3.1 billion.

Table 2: Sensitivity of Predicted Annual Covered Entity Net Revenue Loss from Resolving Non-Statutory "Duplicate Discounting" to Different Parameter Combinations

% Eliminated	% Resolved by Eliminating 340B Discount	Net Revenue Loss from RMP	Net Revenue Loss from Switching Entire 340B Program to Rebate Model
50%	**10%**	**$57.00M**	**$1,036.36M**
25%	0%	$0.00M	$0.00M
50%	0%	$0.00M	$0.00M
75%	0%	$0.00M	$0.00M
25%	10%	$28.50M	$518.18M
25%	20%	$57.00M	$1,036.36M
75%	10%	$85.50M	$1,554.55M
50%	20%	$114.00M	$2,072.73M
75%	20%	$171.00M	$3,109.09M

Note: The bold and highlighted row represents the central scenario.

Denial of Valid Claims

Another source of value for manufacturers of the Beacon-plus-rebate-model combination discussed by Courtemanche (2026a) is the ability to deny valid 340B claims (or delay them to the point where they are abandoned) through the imposition of bureaucratic hurdles. Courtemanche draws a parallel between a rebate model with manufacturers in charge of decision-making and the claim approval process in the health insurance industry, which is notorious for administrative complexity and claim denials. Based on this comparison, he estimates the rebate model will lead to an 8.6% improper-denial rate. Importantly, this does *not* include denials due to 340B plus

Medicare/commercial insurance duplicate discounting, even though 340B rebate claims would be legally valid in such cases. Therefore, there is no overlap with the previous subsection.

For the RMP, a lower percentage is warranted, as HRSA's (2026b) guidance closes off some of manufacturers' avenues for denying and delaying claims. It requires manufacturers to decide on claims within ten days, and denials must be accompanied by documentation. It also sets a 5% ceiling for claim denial rates unless "acceptable justification" is given, with removal from the program threatened as possible punishment. With duplicate discounting and diversion excluded from the acceptable reasons for claim denial, the true percentage of invalid claims ought to be very small, meaning that most denials (excluding those from easily rectifiable clerical errors) would be of valid claims. At the same time, the lack of consequences for denial rates below 5% gives manufacturers a strong incentive to deny close to that percentage. I therefore assume a denial rate of valid claims of 4%, with 3% and 5% being used in sensitivity analyses.

To compute a dollar amount, start with the $3.95 billion total baseline covered entity net revenue from the first two cohorts of MDPNP drugs derived above. Assuming a constant 4% denial rate across payers and that the denial decision is uncorrelated with price leads to an estimated loss of net revenue of $158 million. 3% would translate to $119 million, while 5% implies $198 million. The projected effect of switching the entire 340B program to a rebate model can be obtained by multiplying by 100 / 5.5, yielding $2.873 billion for the central estimate with a range from $2.163 billion to $3.6 billion.

Influence and Lobbying

The next source of value to manufacturers discussed by Courtemanche (2026a) is the ability to use data covered entities are required to submit via Second Sight's platforms against them by constructing derivative data products (e.g., on the pervasiveness of duplicate discounting based on the expansive definition) for the purpose of influencing public perception and lobbying

policymakers. He estimates the expected value of using 340B claims data this way at $352 million annually. This is based on a hypothetical 20% probability of a legislative win of the magnitude achieved in the loosening of the exemption of orphan drugs (drugs approved to treat only a single rare disease) from the MDPNP (Bentz et al., 2025).

To apply this analysis to the RMP specifically, first note that creating and promoting derivative data products appears to fall into a gray area regarding HRSA's (2026b) guidance. On one hand, HRSA states that covered entity data can only be used for the purposes stated in the pilot, which implies that creating derivative data products to influence and lobby is not allowed (Hananoki and Franco, 2026). On the other hand, creating derivative data products is not expressly prohibited in the manner that other uses (such as denying claims on suspicion of duplicate discounting) are, so no enforcement mechanism or punishment is specified. Such use therefore does not appear to be a priority for HRSA, suggesting that little effort will be made to prevent it. I therefore assume a 75% usage rate relative to no HRSA guidance, and I consider 50% and 100% in sensitivity analyses.

Another factor is whether gains to manufacturers equal losses to covered entities. Presumably, most lobbying efforts enabled by data collected in Beacon would be directed towards shrinking the 340B program. However, some might not be; for instance, manufacturers could use information on their forgone revenue from the 340B program to lobby for other unrelated policy changes that help offset these losses. Therefore, I assume that covered entity losses equal 75% of manufacturer gains. 50% and 100% are used as sensitivity checks.

A third factor is whether the data's influence and lobbying value scales with the percentage of drugs in the rebate pilot. More drugs mean more data, which should increase its usefulness to at least some extent. However, the value added by additional data is generally nonlinear, with marginal benefit falling once sufficient data exist to support one's argument. To illustrate, data on the 22 drugs in the 2026 and 2027 MDPNP will be sufficient to make a broad generalization about the

pervasiveness of duplicate discounting via extrapolation.[5] Adding another 22 drugs would add value by making the estimate more convincing and allowing more drug-specific analyses, but this value is lower than that of the first 22 drugs.

I model these diminishing returns as follows. Since $352 million is Courtemanche's estimated lobbying value if the entire $100 billion 340B program used a rebate model through Beacon, whatever functional form is used needs to generate a value of $352 million for the dependent variable when the independent variable is $100 billion. We can meet this constraint while also imposing diminishing returns by solving for a in the equation $\$352 \text{ million} = (\$100 \text{ billion})^a$, which yields 0.777. Therefore, covered entity losses are given by multiplying the two parameters above by $x^{0.777}$, where x is the 340B volume for which the rebate model applies. This is $5.5 billion for the pilot and $100 billion for the entire program.

Table 3: Sensitivity of Predicted Annual Covered Entity Net Revenue Loss from Manufacturers using Data for Influence and Lobbying to Different Parameter Calibrations

Loss to Gain Ratio	HRSA Ratio	Net Revenue Loss from RMP	Net Revenue Loss from Switching Entire 340B Program to Rebate Model
75%	**75%**	**$20.82M**	**$198.21M**
50%	50%	$9.25M	$88.09M
50%	75%	$13.88M	$132.14M
75%	50%	$13.88M	$132.14M
50%	100%	$18.50M	$176.19M
100%	50%	$18.50M	$176.19M
75%	100%	$27.75M	$264.28M
100%	75%	$27.75M	$264.28M
100%	100%	$37.01M	$352.37M

Note: The bold and highlighted row represents the central scenario.

Table 3 reports the results for the baseline scenario and sensitivity checks. In the central (preferred) scenario, estimated covered entity losses from the RMP are $20.82 million per year. The range across the sensitivity analyses is $9.25 million to $37.01 million. The fourth column projects

[5] These two cohorts initially contained 25 drugs, but three have since exited the program due to the emergence of generic competition (Courtemanche, 2026b).

the effect of switching the entire 340B program to a rebate model. The central estimate is $198.21 million, with a range from $88.09 million to $352.37 million.

Physician and Pharmacy Targeting

Courtemanche's (2026a) next source of value to manufacturers – estimated at $1.98 billion – lies in using the 340B claims data to improve physician detailing and pharmacy targeting. Physician detailing refers to pharmaceutical sales representatives visiting physicians to promote a drug by pitching its benefits and distributing samples. The prescriber data typically used for detailing does not include information such as how much of a physician's volume flows through 340B or the price-sensitivity of their 340B-eligible patient population. This information could be used, for instance, to identify prescribers with high volumes of lower-margin 340B-discounted prescriptions and nudge them towards higher-margin drugs. Similarly, pharmacy targeting would be improved if manufacturers use 340B claims data to identify contract pharmacy volume, thereby informing decisions about contracting, restrictions, or commercial outreach (Courtemanche, 2026a).

The same three factors discussed for influence/lobbying are again relevant here. First, this use of data falls into the same gray area regarding HRSA's guidance, making the same parameter value of 75% – with sensitivity analyses of 50% and 100% – appropriate. Second, the effect of improved detailing/targeting on covered entity finances is less direct than it was for the other sources of value discussed above. However, it is unlikely to be zero. For instance, successfully nudging prescribers towards drugs with higher 340B manufacturer margins likely means smaller covered entity margins in many cases. Additionally, pharmacy targeting could conceivably influence carve-in versus carve-out decisions. I therefore use a central value of 50% (rather than 75%), with 25% and 75% serving as sensitivity analyses. Third, similar logic about diminishing returns applies, but less so than for influence/lobbying since detailing/targeting is more drug-specific. Conveniently, solving for a in the equation $\$1.98 \text{ billion} = (\$100 \text{ billion})^a$ yields 0.8452, which exhibits a slower rate of

diminishing returns than the 0.777 used in the preceding subsection. Covered entity losses are therefore projected by multiplying the two parameters by $x^{0.8452}$, with x again being $5.5 billion for the pilot and $100 billion for the entire program.

Table 4 shows the resulting numbers. Using the preferred calibration of the parameters, annual covered entity losses from the RMP are $64.06 million, with the low and high ends of the range from the sensitivity analyses being $21.35 million and $128.12 million. Implementing a rebate model for the entire 340B program is predicted to cost covered entities $743.41 million per year, with the range being $247.80 million to $1.486 billion.

Table 4: Sensitivity of Predicted Annual Covered Entity Net Revenue Loss from Improved Physician Detailing and Pharmacy Targeting to Different Parameter Calibrations

Loss to Gain Ratio	HRSA Ratio	Net Revenue Loss from RMP	Net Revenue Loss from Switching Entire 340B Program to Rebate Model
50%	**75%**	**$64.06M**	**$743.41M**
25%	50%	$21.35M	$247.80M
25%	75%	$32.03M	$371.71M
25%	100%	$42.71M	$495.61M
50%	50%	$42.71M	$495.61M
75%	50%	$64.06M	$743.41M
50%	100%	$85.41M	$991.22M
75%	75%	$96.09M	$1,115.12M
75%	100%	$128.12M	$1,486.83M

Note: The bold and highlighted row represents the central scenario.

Data Sublicensing

Courtemanche's (2026a) final source of value to manufacturers is the ability to sublicense a comprehensive 340B claims dataset to researchers and other businesses. He estimates this value at a relatively modest $11.8 million annually. This value simply accrues to drug companies' bottom line and has no clear impact on covered entities. Therefore, I omit it from my analysis.

Liquidity Cost

Since Courtemanche (2026a) focuses on sources of value to manufacturers, his report omits costs to covered entities that are not also benefits to drug companies. One such type of cost imposed

by the RMP that is acknowledged by HRSA's (2026b) notice relates to cash flow and liquidity. Because covered entities must now purchase pilot drugs upfront at WAC rather than receiving the 340B discount at the point of purchase, and only recoup the difference later via rebate, entities face an increase in the capital they must carry between purchase and reimbursement (Dykema, 2026). HRSA (2026b) acknowledged receiving numerous such concerns during the comment period, including from representatives of one large health system, who reported roughly $10 million in additional annual working-capital requirements. In response, HRSA's final guidance included a requirement for manufacturers to issue rebates for valid claims within ten days of submission. An industry analysis determined the cost of keeping enough liquidity to cover that gap will average roughly 0.19% relative to WAC for prescriptions filled at in-house pharmacies and 0.03% for those filled at contract pharmacies (Hananoki and Franco, 2026).

Translating these percentages into dollar amounts requires information on the share of 340B volume run through in-house versus contract pharmacies. The most recent publicly available estimate is 83% for the former and 17% for the latter in 2021 (Congressional Budget Office, 2025). However, the number of contract pharmacy relationships has doubled since then (Fein, 2026a), suggesting that a better estimate of the current percentage for contract pharmacies would be 34%. This implies an average percentage liquidity cost – given by 0.19% * 0.66 + 0.03% * 0.34 – of 0.1356%. Recall that the WAC value of the $100 billion of 340B purchases in 2025 was $179.5 billion, which translates to $9.873 billion after multiplying by the 5.5% share of the 2026 and 2027 cohorts of MDPNP drugs. Therefore, the liquidity cost comes to 0.1356% of $9.873 billion, which is $13.4 million. As a sensitivity analysis, using the 17% contract pharmacy figure from 2021 would yield an average percentage liquidity cost of 0.1628%, which translates to $16.1 million. Alternatively, a same-sized change in contract pharmacy percentage in the other direction – to 51% – would imply an average percentage liquidity cost of 0.1084%, leading to $10.7 million. Since the

liquidity cost should scale relatively linearly as the share of 340B drugs using a rebate model increases, I estimate the effect of full implementation of the rebate model using Beacon by multiplying these numbers by 100 / 5.5. This yields a central estimate of $243.6 million and a range of $194.5 million to $292.7 million.

Administrative and Staffing Costs

HRSA (2026b) also acknowledges that covered entities will incur administrative and staffing costs from the RMP. These costs will include new claims-submission workflows, data reconciliation, and dispute handling. HRSA estimates this cost to be a total of $523.34 million per year across 15,249 covered entities, for an average of $34,320 per entity. However, covered entity representatives who submitted comments claim that these annual costs will be higher, ranging from $30,000 to over $200,000 for staffing alone (Hananoki and Franco, 2026). The midpoint of this range implies total costs across all 15,249 covered entities of $1.75 billion per year. There will also be one-time administrative and information technology (IT) costs associated with implementation, though HRSA's notice requires manufacturers to bear all costs for the IT platform (Dykema, 2026). For this reason, and because startup costs will pale in comparison to annual costs in the long run, I ignore startup costs in my analysis. To calibrate annual administrative and staffing costs, I use HRSA's $523.34 million estimate as the low end of the range, covered entities' $1.75 billion as the high end, and the average of these – $1.14 billion – as the central (preferred) value.

Extrapolating to the costs of implementation of the rebate model using Beacon for the entire 340B program is not straightforward because there are likely to be at least some economies of scale, which means that a linear projection would likely overstate the losses. I therefore use an inverse process to that used to model diminishing returns above, since the predicted effect of the RMP is known rather than the predicted effect of a rebate model for the entire program. This means solving for a in the equation $\$1.14 \text{ billion} = (\$5.5 \text{ billion})^a$, which yields 0.9298. Therefore, the cost from

full implementation at central parameter values comes to $(\$100 \text{ billion})^{0.9298}$, which is $16.9 billion. The low end of the range is given by solving for a in $\$523.34 \text{ million} = (\$5.5 \text{ billion})^a$, which gives 0.8951, and then computing $(\$100 \text{ billion})^{0.8951}$, which is $7.02 billion. Similarly, determining the high end requires solving $\$1.75 \text{ billion} = (\$5.5 \text{ billion})^a$, which is 0.9489, and then calculating $(\$100 \text{ billion})^{0.9489}$, which gives $27.4 billion.

Total Annual Losses

We are now ready to add together the different projected sources of covered entity losses from the RMP as well as full implementation of a rebate model using Beacon for the entire 340B program. Table 5 reports the estimates for the RMP, displaying the central estimate of each source of losses along with the highest and lowest estimates from sensitivity analyses. Using central parameter values, *I predict total annual covered entity lost net revenue from the RMP to be $1.5 billion.* The low end of the range is $702 million and the high end is $2.37 billion. Table 6 reports analogous estimates for full implementation. I project that the expansion of the rebate model to the entire 340B program would lead to annual net revenue losses of $22.77 billion, with a range from $10.04 billion to $37.59 billion. In all columns in both tables, the substantial majority of the losses – between 70% and 76% – come from administrative and staffing costs.

Table 5: Total Predicted Annual Covered Entity Net Revenue Losses from the RMP

Source of Revenue Loss	Low	High	Central
Preventing Statutory Violations	$18.07M	$74.15M	$42.78M
Preventing Non-Statutory "Duplicate Discounting"	$0.00M	$171.00M	$57.00M
Denial of Valid Claims	$119.00M	$198.00M	$158.00M
Influence and Lobbying	$9.25M	$37.01M	$20.82M
Physician and Pharmacy Targeting	$21.35M	$128.12M	$64.06M
Liquidity Cost	$10.70M	$16.10M	$13.40M
Administration and Staffing	$523.34M	$1.75B	$1.14B
Total	**$701.71M**	**$2.37B**	**$1.50B**

Note: The bold and highlighted cell represents the central estimate of the total.

Table 6: Total Predicted Annual Covered Entity Net Revenue Losses from Implementing the Rebate Model using Beacon for the Entire 340B Program

Source of Revenue Loss	Low	High	Central
Preventing Statutory Violations	$328.45M	$1.35B	$777.82M
Preventing Non-Statutory "Duplicate Discounting"	$0.00M	$3.11B	$1.04B
Denial of Valid Claims	$2.16B	$3.60B	$2.87B
Influence and Lobbying	$88.09M	$352.37M	$198.21M
Physician and Pharmacy Targeting	$247.80M	$1.49B	$743.41M
Liquidity Cost	$194.50M	$292.73M	$243.60M
Administration and Staffing	$7.02B	$27.40B	$16.90B
Total	**$10.04B**	**$37.59B**	**$22.77B**

Note: The bold and highlighted cell represents the central estimate of the total.

IV. Conclusion

For drugs in the MDPNP, 340B covered entities are eligible for the lower of the MFP and 340B ceiling price. The lack of a system to identify and charge the lower price in real time creates implementation challenges. This, combined with longstanding manufacturer concerns about duplicate discounting, led HRSA to develop a pilot to implement a 340B rebate model for MDPNP drugs. Covered entities have objected to the RMP due to concerns about drug companies being given the power to approve or deny claims, cash flow challenges from delayed payments, administrative costs, and the conflict of interest created by the RMP's claims submission platform being run by a company with connections to the pharmaceutical industry. After legal challenges, HRSA released an official notice for a revised version of the pilot that aims to address some of these concerns in August 2026. This study asks two questions. First, how will the RMP affect covered entities' net revenues from the 340B program? Second, what would be the impact of implementing the same rebate model for all of 340B, rather than just the 22 drugs in the first two MDPNP cohorts?

I begin with a section that provides background information about manufacturers' efforts to push back against the growth of the 340B program. I examine the premise behind these efforts: that duplicate discounting by covered entities is widespread. I argue that a major source of the gap between industry statements and the available evidence is that drug companies define duplicate discounting much more broadly than the 340B statute. Courtemanche (2026a) suggests that

manufacturers' interest in the rebate model likely extends beyond preventing statutory duplicate discounting, as requiring covered entities to submit claims data through an industry-connected platform creates other sources of value that are much more substantial than the benefit from stopping duplicate discounting by the statutory definition.

I then turn to the quantitative analyses, allowing effects to come both from the rebate model itself and manufacturers' ability to use the data collected to implement it in ways that can shrink the 340B program. More specifically, covered entity losses can come from averted duplicate discounts; denial of valid claims; manufacturers using 340B claims data for the purposes of influence, lobbying, physician detailing, and pharmacy targeting; costs related to cash flow and liquidity; and administrative and staffing costs. Based on preferred parameter values, I estimate annual net revenue losses of $1.5 billion from the RMP and $22.77 billion from expanding the rebate model to the full program. The majority of these losses will come from administrative and staffing costs, but losses from other sources have the potential to be much higher if HRSA's guidance for manufacturers is ignored, not enforced, or not included in a scaled-up rebate model. One specific concern is that compliance may be high during the initial pilot period as manufacturers aim to convince HRSA that the rebate model is working, but then worsen once the model has expanded beyond the point where it would be impossible to reverse.

Losses of $22.77 billion would eliminate 32% of net revenues from 340B and, strikingly, 24% of the combined net revenues of all hospitals in the U.S.[6] Losses of this magnitude have the potential to significantly affect access to care. In their review of the scholarly literature on 340B, Courtemanche and Garuccio (2026) document substantial evidence that covered entities use at least some of their 340B revenue to maintain or expand provision of services to vulnerable populations. According to the Chartis Center for Rural Health (2026), 417 rural hospitals are vulnerable to

[6] 24% is based on the calculation in footnote 3 that annual hospital net revenues total $94 billion.

closure, 448 have dropped chemotherapy in the past decade, and 331 have dropped obstetrics. Therefore, a loss of 340B net revenue of the magnitude found in this study would likely lead to closures of unprofitable departments and, in some cases, entire hospitals.

Adding to the concern are two other developments that have the potential to substantially harm covered entity finances. The first is the MDPNP itself, which lowers covered entity costs when MFPs are below the 340B ceiling price but reduces revenues by lowering Medicare reimbursement rates to MFP plus a dispensing fee, which in turn will likely trigger a downward adjustment in commercial rates. Courtemanche (2026b) computes that the revenue reduction – which occurs across a broader base of drugs and payers – will far outweigh the cost reduction, harming covered entity finances on net.

Second, CMS has proposed a 2027 Outpatient Prospective Payment System (OPPS) rule that would reduce 340B Part B hospital reimbursement from 6% above average sales price to 33.4% below. CMS estimates a $4.55 billion reduction in Medicare drug payments from this change, which means an equivalent reduction in covered entity revenue. This would be accompanied by a budget-neutral increase in non-drug OPPS payments that would be spread across all OPPS hospitals, whereas only covered entities would bear the losses (CMS, 2026).

These other developments highlight the importance of viewing the challenges facing covered entities holistically rather than separately. Unfortunately, it is not feasible with available data to develop a single comprehensive model that incorporates the interactive effects of these different forces. The impacts predicted by my analysis were computed in "all else equal" fashion based on a 2025 baseline. Changes to payment rules would inevitably influence effect sizes. With that said, this influence is somewhat limited by three factors. First, since Part B drugs were not included in the 2026 and 2027 MDPNP cohorts, the proposed OPPS payment changes are not relevant for the projections about the RMP – though they are for the projections about switching the entire 340B

program to a rebate model. Second, conversely, MDPNP payment changes are relevant for the RMP but not for extrapolation to the rest of the 340B program, as drugs not in the MDPNP are unaffected. Third, there is considerable policy uncertainty surrounding whether the OPPS changes will be implemented, whether the MDPNP will expand as planned, and whether the rebate model will scale up with the MDPNP if it does. Therefore, it is unclear whether incorporating all these potential changes into a single model would be desirable even if it were feasible.

Modeling details aside, the fact that the 340B program faces pressures from several directions underscores the importance of taking a holistic view of these challenges when evaluating the merits of any single revenue-reducing policy change. To illustrate, when viewed in isolation, one might argue that covered entity losses from the RMP are relatively modest. However, this argument becomes weaker once observers recognize that covered entities face multiple forces putting substantial downward pressure on 340B net revenue. When viewed in this manner, even seemingly modest losses from the RMP could be consequential for safety-net providers struggling to remain financially viable. Similarly, once the pressures covered entities already face from the MDPNP and potential expansion of the rebate model is understood, implementing the OPPS rate cuts may appear less desirable. Alternatively, policymakers could consider offsetting covered entities' losses with an additional policy lever such as increased disproportionate share funds. While identifying the ideal bundle of policies is beyond the scope of this paper, taking a holistic view would give policymakers a better chance of achieving their objectives while minimizing unintended consequences.

Another relevant aspect of this study's results for optimal policy is that the majority of projected losses from the rebate model come from administrative and staffing costs. In contrast to other sources of losses such as averted duplicate discounting, drug manufacturers do not benefit when covered entities incur higher administrative and staffing costs. This means that manufacturer gains from the RMP are smaller than covered entity losses, implying a negative net effect of the

rebate model. In a full social welfare calculation, employment created by the added administrative work would be counted as an offsetting force, but employment effects are not an objective of the RMP and would not be expected to outweigh the efficiency loss.

The analyses in this paper also have implications for the broader policy debate over 340B. First, because the program faces several simultaneous revenue pressures, evaluating each policy change in isolation is likely to understate its consequences for covered entities and the populations they serve. Second, the distinction between statutory and non-statutory duplicate discounting matters for interpreting prevalence estimates. HRSA's (2026b) guidance cites statistics from pharmaceutical-industry-funded studies using the expansive definition of duplicate discounting, which my analysis suggests overstates the prevalence of statutory duplicate discounting by an order of magnitude. It seems unlikely that HRSA's citation of these numbers was meant to give tacit approval of the expansive definition, as the agency has always clearly defined duplicate discounting in the statutory sense. Instead, HRSA likely quoted these numbers simply because they are the most publicized estimates. Independent, transparent estimates based on the statutory definition would help inform this debate. For instance, HRSA reports results from its audits in terms of the percentage of covered entities with at least one violation; releasing information on the extent of the violations where at least one occurs would be more informative.

Finally, if it becomes clear that the rebate model will become permanent – either for just MDPNP drugs or for the entire 340B program – attention should go towards minimizing its costs. This takes two forms. First, the estimates in this study depend critically on the extent to which HRSA's restrictions on manufacturers are followed and enforced. Policymakers should therefore prioritize monitoring and enforcement of these restrictions and ensure that comparable safeguards accompany any expansion of the rebate model. Second, because administrative and staffing costs account for most of the projected losses, policymakers could consider offsetting them through

government or manufacturer funding or modifying implementation details to reduce them. The 340B program is at a critical juncture, and the cumulative effects of these policy changes on safety-net providers warrant careful consideration.

Acknowledgments

I acknowledge support for this research from a grant from the Kentucky Hospital Association and a consulting agreement with Hall, Render, Killian, Heath, & Lyman, P.C. Claude AI was used to assist with background research and the formatting of references, figures, and tables. The author is fully responsible for the content of this paper, which did not require approval of the funders.

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