

The expanding presence of the 340B Drug Pricing Program and implications of CMS's proposed CY 2027 OPPS rule

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Executive summary

Since its inception in 1992, the 340B Drug Pricing Program has grown from a relatively small program into a central feature of the U.S. healthcare system that impacts drug pricing and hospital financials. Several recent developments suggest the program is approaching an inflection point and that reforms are likely in the near future.

Growth in the 340B program. The Health Resources and Services Administration (HRSA) reported that purchases by covered entities (CEs) under the 340B program across all markets surpassed \$100 billion in 2025, a more than twofold increase from four years before when the program was \$43.9 billion. Similarly, our analysis of the Medicare Part B fee-for-service (FFS) 100% Research Identifiable Files (RIF) found growth within the Medicare Part B market: From 2019 to 2025, 340B hospitals' share of Part B drug spend rose from 60% to 70%, and the proportion of hospitals leveraging 340B grew from 31% to 35%.

Interaction with other federal drug pricing programs. The 340B program interacts with other federal drug pricing programs, including Medicaid Best Price (BP) and Medicare Maximum Fair Prices (MFPs). As more drugs become subject to MFPs, the impact of these interactions will continue to shape manufacturers' launch and pricing strategies, and hospital reimbursement and financials. For both manufacturers and providers, the interconnectedness of these programs presents reporting and transparency challenges.

Proposed changes to some 340B Medicare payments. In the Outpatient Prospective Payment System (OPPS) proposed rule for 2027, the Centers for Medicare and Medicaid Services (CMS) lays out its plan to reduce payments for Medicare Part B 340B drugs reimbursed through the OPPS from average sales price (ASP) +6% to ASP -33.4%. The rule would include a corresponding 8.44% increase in nondrug OPPS payments to 340B and non-340B hospitals, to maintain budget neutrality. This change would result in a decline in revenue for Medicare Part B drugs for 340B hospitals only, while both 340B hospitals and non-340B hospitals would benefit from increases in payments for nondrug Part B services. Medicare Advantage (MA) plans may face benchmark and contracting mismatches, and Medicare patients could see lower Part B coinsurance on affected drugs. CMS previously reduced payment at 340B hospitals to ASP -22.5% in calendar year (CY) 2018, which the Supreme Court invalidated in *American Hospital Association v. Becerra* for lack of an acquisition-cost survey. The new proposal rests on such a survey, so the focus of any future legal challenges will likely focus on the survey's representativeness and its methods.

What comes next for healthcare affordability. Given its current size, interactions with other federal drug pricing programs, and impact on provider financials, 340B will continue to be an area that healthcare stakeholders and policymakers evaluate as a means to address healthcare affordability. The current proposed change to OPPS payments for 340B drugs could materially change stakeholder incentives and have material downstream financial effects on non-340B hospitals, MA plans, and beneficiaries. It remains to be seen whether the rule is finalized as proposed, but regardless, the 340B program will continue to be a meaningful component of the healthcare system.

Background on the 340B program

STATUTORY PURPOSE

The 340B Drug Pricing Program was established in 1992 through Section 340B of the Public Health Service Act.¹ The program requires pharmaceutical manufacturers that participate in Medicaid to provide covered outpatient drugs to specified eligible healthcare providers, known as CEs, at or below a statutory ceiling price.² By reducing the acquisition cost of covered outpatient drugs, the 340B program allows CEs to help maintain, expand, and subsidize services that might otherwise be financially difficult to sustain.³ The Affordable Care Act (ACA) expanded the 340B program by broadening CE eligibility and allowing greater use of contract pharmacies.⁴

CEs are limited to specific categories of hospitals and nonhospital providers identified in statute or that receive specific federal funding types. These categories include disproportionate share hospitals (DSHs), children's hospitals, rural referral centers, sole community hospitals, critical access hospitals, federally qualified health centers, hemophilia treatment centers, family planning clinics, Ryan White clinics, and certain other safety-net providers that meet statutory eligibility criteria.⁵ Participation in the program is conditioned on compliance with program requirements, including restrictions relating to diversion and duplicate discounts.^{6,7}

340B CEILING PRICE

The 340B ceiling price is established pursuant to a statutory formula that yields a discount specific to each manufacturer and drug combination. To begin, the ceiling price is the Average Manufacturer Price (AMP) less the basic Unit Rebate Amount (URA), as determined under the Medicaid Drug Rebate Program (MDRP) framework.^{8,9} Under MDRP, the minimum basic URA is 23.1% of AMP. Each drug's BP is also compared to its basic URA, with CEs having access to whichever methodology provides the greater discount, plus the MDRP inflation penalty.¹⁰ If the formula produces a zero or negative value, the ceiling price is floored at \$0.01.

The effective 340B discount may vary considerably by drug. A number of factors influence the ceiling price, including the product's classification, applicable Medicaid rebate rules, baseline pricing metrics, inflation-based rebate components, and any separate statutory treatment applicable to the product.¹¹ In particular, when a drug's price has increased more rapidly than inflation, the inflation-related rebate component of the URA may increase the discount reflected in the 340B ceiling price. As a result, some drugs may be subject to relatively modest discounts, whereas others may be available to CEs at substantially reduced prices.

HOW THE DISCOUNT IS REALIZED

CEs generally realize the benefit of the 340B program by acquiring eligible covered outpatient drugs at a discounted price and then billing payers at reimbursement rates that are higher than their acquisition cost. Reimbursement may come from Medicare, Medicaid, commercial insurers, or other third-party payers, as well as patients, depending on the payer and site of care.

The difference between the CE's acquisition cost and the reimbursement it receives represents program revenue that can be used to support the CE's broader operations and patient-care mission. CEs may use this financial margin to help fund a wide variety of services and functions, including uncompensated care, expanded access to pharmacy and clinical services, care coordination, service lines that treat vulnerable populations, and programs that might otherwise be underfunded.

The ACA's expansion of CE eligibility and its changes to Medicaid rebate calculations increased the practical importance of the program. As participation expanded and the financial value of the discounts increased for many drugs, 340B program revenue has become a more prominent component of the fiscal structure for CEs.

The 340B program is structured as an agreement between the pharmaceutical industry and CEs, and is focused almost entirely on acquisition. It does not require CEs to pass discounted prices directly through to patients.¹² Instead, the program operates at the provider-acquisition level. The financial benefit is thus realized by the CE rather than automatically transferred to individual patients, unless the CE independently elects to share those savings through its own pricing or assistance policies.

PREVIOUS 340B MEDICARE PAYMENT REDUCTION AND COURT CHALLENGE

In Medicare Part B, historically both 340B and non-340B providers were reimbursed ASP +6%. Beginning in CY 2018, CMS reduced OPPS payment for many 340B-acquired drugs from the statutory default rate of ASP +6% to ASP -22.5%. CMS stated the reduction was intended to better approximate 340B hospitals' acquisition costs¹³. Because OPPS changes are subject to budget neutrality, CMS paired the lower 340B drug payment with a corresponding increase to OPPS payments for nondrug items and services.¹⁴

However, a number of entities sued over the change, and the issue ultimately landed in front of the Supreme Court. In *American Hospital Association v. Becerra*, the Supreme Court reversed a lower court ruling and held that CMS could not vary OPPS drug reimbursement rates for 340B hospitals without relying on a statutorily required hospital acquisition-cost survey.¹⁵ The Court's decision invalidated the differential 340B payment approach, and CMS subsequently finalized a remedy for CYs 2018 through 2022 that included lump-sum payments to affected 340B hospitals while recouping the prior budget-neutrality increase through reduced future payments for nondrug OPPS items and services.^{16,17}

THE CY 2027 OPPS PROPOSAL

Similar to the prior Medicare payment change, CMS's CY 2027 OPPS proposed rule would reduce Medicare payment for most separately payable 340B-acquired drugs from ASP +6% to ASP -33.4%.¹⁸ The proposed rule states that rural sole community hospitals, children's hospitals, and prospective payment system (PPS)-exempt hospitals would be exempt from this new reimbursement adjustment, as well as critical access hospitals and rural emergency hospitals, as these hospitals are not paid under OPPS. These exemptions are consistent with the 2018 through 2022 policy.

Taking the Supreme Court ruling into account, CMS is now relying on a hospital acquisition-cost survey to support the new, more significant reduction in reimbursement. The proposal is intended to align Medicare payment more closely with hospitals' actual acquisition costs while also lowering beneficiary Part B cost sharing for affected drugs.¹⁹ OPPS overall growth is tied to a target rate, so the reduced 340B drug payments will be offset through higher OPPS payments for nondrug items and services. Under the proposed rule, OPPS payments for nondrug items and services are expected to increase by 8.44%.²⁰

At the time of writing, the proposed rule has not yet been finalized. The final rule, expected in late November 2026, could modify or even remove the proposal. Given CMS is now relying on a survey, legal questions may arise as to whether the new survey is sufficiently representative, transparent, and methodologically sound to support the new national rate across affected 340B hospitals and drugs.

340B OUTPATIENT DRUG SPENDING IN MEDICARE

To better understand the implications of the CY 2027 OPPS proposed rule, we used CMS's 100% RIF to analyze Part B 340B drug claims (physician-administered drugs administered in the outpatient setting) across all patients in the Medicare FFS market. We analyzed 2019 through 2025 Medicare FFS drug spend for patients receiving Part B drugs at hospitals participating in the 340B program (340B hospitals) relative to non-340B hospitals, using data from HRSA to identify 340B hospitals.^{21,22} For all years in our study period, we repriced claims to ASP +6% to normalize for CMS's ASP -22.5% reimbursement for Part B drugs administered at 340B hospitals from 2019 through 2022.

MEDICARE PART B FFS MARKET

Figure 1 shows the percentage of patients, Part B drug claims, and spend for Part B drugs that are attributable to 340B hospitals for each year of the study period.

FIGURE 1: PERCENTAGE OF PATIENTS, CLAIMS, AND SPEND ATTRIBUTABLE TO 340B HOSPITALS, AND PERCENTAGE OF HOSPITALS PARTICIPATING IN 340B

YEAR	PATIENTS	CLAIMS	SPEND	HOSPITALS ²³
2019	48%	52%	60%	31%
2020	51%	54%	63%	33%
2021	52%	55%	65%	34%
2022	52%	56%	66%	35%
2023	54%	57%	68%	37%
2024	55%	58%	69%	38%
2025	53%	57%	70%	35%

Some observations stand out from Figure 1:

- **340B hospitals account for more claims and spend than their share of patients.** Within each year, the proportion of claims from 340B hospitals is larger than the proportion of patients, and the proportion of spend is larger than the proportion of patients and claims. This implies that, relative to patients who receive Part B drugs at non-340B hospitals, patients who receive Part B drugs at 340B hospitals have more claims per patient, higher spend per patient, and higher spend per claim.²⁴
- **Higher drug spend per claim reflects drug mix, not price.** Because we repriced all claims to ASP +6%, we assume a given drug costs the same in either hospital type (340B or non-340B). The spend difference comes from the mix of Part B drugs or units per drug claim. One explanation could be that 340B hospitals treat patients who need higher-cost therapies. However, a recent Milliman commissioned analysis found that the higher mix persists even after using regression and propensity score matching to align 340B and non-340B populations.^{25,26}
- **The proportion of Medicare Part B FFS drugs that are 340B has become a larger share of total Part B drugs over time.** One potential reason for this is that the number of 340B-eligible hospitals has increased as a share of all hospitals. As a result, more of the Part B drugs Medicare patients receive are provided at 340B hospitals. Within our analysis, we observed that the count of 340B-eligible hospitals increased from approximately 1,450 in 2019 to 1,770 in 2025.

This growth within Medicare Part B FFS matches the widely reported growth of the 340B program nationally. HRSA, which administers the program, publishes an annual report on total 340B CE purchases (referred to here as 340B spend). In 2025, 340B CE purchases surpassed \$100 billion.²⁷ In 2021, 340B CE purchases were \$43.9 billion,²⁸ meaning purchases grew 2.3 times over the subsequent four-year period.

TOP 10 DRUGS BY 340B SPEND

We also analyzed Part B drug-specific claims and spend within the Medicare Part B FFS data. Figure 2 shows the top 10 Part B drugs by spend at 340B outpatient hospitals in 2025. For each Part B drug, we also show the therapeutic area and the proportion of the Part B drug's total Part B outpatient spend that is from 340B hospitals.

FIGURE 2: DRUG-SPECIFIC DATA IN THE 2025 MEDICARE PART B FFS MARKET

DRUG NAME	THERAPEUTIC AREA	340B SPEND IN 2025 (BILLIONS)	PORTION OF TOTAL SPEND THAT IS 340B	PERCENTAGE OF 340B SPEND
Keytruda (Pembrolizumab)	Oncology	\$3.2	71%	16%
Darzalex (Daratumumab)	Oncology	\$1.6	71%	8%
Opdivo (Nivolumab)	Oncology	\$1.0	71%	5%
Prolia (Denosumab)	Bone Density Regulators	\$0.9	69%	4%
Imfinzi (Durvalumab)	Oncology	\$0.6	71%	3%
Reblozyl (Luspatercept-Aamt)	Hematology	\$0.4	72%	2%
Amyvuttra (Vutrisiran Sodium)	Transthyretin Amyloidosis Agents	\$0.4	88%	2%
Enhertu (Fam-Trastuzumab Deruxtecan-Nxki)	Oncology	\$0.4	71%	2%
Padcev (Enfortumab Vedotin-Ejfv)	Oncology	\$0.4	68%	2%
Ultomiris (Ravulizumab-Cwvz)	Complement Inhibitors	\$0.3	77%	2%

Key observations from Figure 2:

- **Ten drugs account for almost half of 340B spend.** The drugs in Figure 2 make up 14% of 2025 Medicare Part B FFS 340B claims but 45% of spend (\$9.2 billion of \$20.5 billion). Keytruda alone accounts for 16% of 340B spend (\$3.2 billion).
- **Most of the spend is oncology.** Oncology drugs account for 77% of top 10 spend, \$7.1 billion of the \$9.2 billion represented by the top 10 drugs. Though not displayed, oncology drugs account for 59% (\$12 billion) of all 2025 Medicare Part B FFS 340B spend.
- **This 340B spend captures most of the total market for the drugs.** Most drugs have close to 70% of their spend at 340B hospitals (with Amyvuttra being the notable exception), and this aligns with the 70% market average in Figure 1.

HRSA REPORTING – ALL MARKETS

HRSA provides reporting of total 340B spend across the U.S., including both medical and pharmacy drugs, and across all payer types (e.g., Medicare, Medicaid, commercial). Of the outpatient drugs in HRSA's 2025 reporting of total U.S. 340B spend, four drugs are also captured within Figure 2 (Keytruda, Darzalex, Opdivo, and Imfinzi).²⁹

Keytruda is the top drug in both lists. Keytruda represents 9% of total U.S. 340B spend across all markets (\$8.9 billion out of \$100 billion) and 16% of Medicare Part B FFS 340B outpatient drug spend (\$3.2 billion out of \$20.5 billion).³⁰

Spend is more concentrated in Medicare Part B. Our top 10 Part B drugs account for 45% of Medicare FFS spend, compared with about 29% for HRSA's top 10 across all drugs and markets. There are two distinctions between our analysis and HRSA's that may explain the differences in concentration of top spend drugs.

- **Benefit and setting:** Our analysis focused on hospital outpatient drugs only, which tend to be higher-cost and have fewer treatment alternatives. HRSA's reporting includes self-administered drugs typically covered under the pharmacy benefit, which have a wider range of costs.
- **Population and condition prevalence:** Medicare beneficiaries use more oncology treatments than the under-65 population, so oncology drugs carry more weight in a Medicare-only analysis.

“TB” MODIFIER

In the 2024 OPPS final rule,³¹ CMS codified that beginning in January 2025, all 340B hospitals paid under the OPPS fee schedule would be required to report “TB” on the claim line modifier column for all 340B-acquired drugs. This was a change from the years leading up to 2025, when modifier codes of JG or TB were accepted for different reasons. In codifying the TB modifier requirement, CMS stated that this singular modifier code “will allow for greater simplicity” and “reduce burden on providers.”³²

We analyzed 2025 Medicare Part B FFS data to see how well the TB modifier was populated. Across all the hospital outpatient claims, the TB modifier was on 45% of claims, which accounted for 69% of total spend. These amounts are less than the percentage of claims and spend we attributed to 340B-eligible hospitals in 2025, as shown in Figure 1.

Implications of the proposed 2027 OPPS rule

REIMBURSEMENT EXAMPLES

The proposed reimbursement reduction from ASP +6% to ASP -33.4% would place pressure on program revenue for nonexempt 340B hospitals by directly narrowing the margin between hospital acquisition cost and Medicare payment. Figures 3 and 4 illustrate the impact of the proposed rule to hospital revenue using two examples for a hypothetical drug with an ASP of \$1,000. In Figure 3, the 340B ceiling price is assumed to be ASP -23.1% (the minimum possible discount); in Figure 4, the 340B ceiling price is assumed to be lower, at 40% below ASP. The resulting impact to hospital revenue depends on the depth of the 340B discount: If the 340B ceiling price is greater than CMS's proposed reimbursement level, a previously positive drug margin becomes negative; if the ceiling price is materially below ASP -33.4%, the hospital will likely still retain a positive drug margin, but at a substantially reduced level.

FIGURE 3: IMPACT OF CY 2027 OPPS PROPOSED RULE TO HOSPITAL PROFITABILITY – ASP = \$1,000, 340B CEILING PRICE = \$769 (ASP -23.1%)

340B CEILING PRICE SET AT ASP -23.1%			
	NON-340B	340B (CURRENT ASP +6% REIMBURSEMENT)	340B (PROPOSED ASP -33.4% REIMBURSEMENT)
Hospital Acquisition Cost	\$1,000	\$769	\$769
Medicare Reimbursement	\$1,060	\$1,060	\$666
Hospital Gross Gain/Loss	\$60	\$291	(\$103)

FIGURE 4: IMPACT OF CY 2027 OPPS PROPOSED RULE TO HOSPITAL PROFITABILITY – ASP = \$1,000, 340B CEILING PRICE = \$600 (ASP -40%)

340B CEILING PRICE BELOW PROPOSED REIMBURSEMENT			
	NON-340B	340B (CURRENT)	340B (PROPOSED)
Hospital Acquisition Cost	\$1,000	\$600	\$600
Medicare Reimbursement	\$1,060	\$1,060	\$666
Hospital Gross Gain/Loss	\$60	\$460	\$66

Note: AMP is assumed equal to ASP. Hospital acquisition cost is ASP for non-340B hospitals and the 340B ceiling price for 340B hospitals. Hospital gross gain/loss is the drug margin before considering any other costs. All values are for illustrative purposes only.

BUDGET NEUTRALITY

The proposed rule is intended to be budget neutral across all of Medicare. However, only 340B hospitals will see the decrease in drug reimbursement, while *all* hospitals will share in the increase in nondrug OPPS payments, meaning the nondrug increases at any given 340B hospital will likely not be sufficient to offset the decrease in drug reimbursement. As such, the majority of 340B hospitals will likely see a revenue decline, offset by increased revenue at non-340B hospitals. This is illustrated using a numeric example in Figure 5. The values are intentionally simplified to illustrate the effect. In the example, 340B and non-340B hospitals use the same mix of services. The 340B hospital drug reimbursement is reduced from ASP +6% to ASP -33.4%, and the nondrug reimbursement is increased such that the grand total of OPPS reimbursement across all hospitals remains the same. While the increase in nondrug reimbursement helps offset the decrease in drug reimbursement for the 340B hospitals, there is still likely a net decrease, while the non-340B hospitals only experience the nondrug increase in reimbursement.

FIGURE 5: BUDGET NEUTRALITY OF CY 2027 OPPS PROPOSED RULE

Legend:

Orange: Decrease in reimbursement

Green: Increase in reimbursement

	CURRENT (ASP +6% REIMBURSEMENT)	PROPOSED (ASP -33.4% REIMBURSEMENT)	CHANGE
340B HOSPITALS			
Outpatient drug	\$106	\$66	(\$40)
Outpatient nondrug	\$235	\$255	\$20
Total	\$341	\$321	(\$20)
NON-340B HOSPITALS			
Outpatient drug	\$106	\$106	\$0
Outpatient nondrug	\$235	\$255	\$20
Total	\$341	\$361	\$20
Grand Total	\$682	\$682	\$0

STAKEHOLDER IMPACTS

340B hospitals: Under the proposed rule, 340B hospitals would see a direct reduction in Medicare drug reimbursement for separately payable 340B-acquired drugs, compressing or eliminating the spread between 340B acquisition cost and Medicare payment. The revenue impact will not be uniform across 340B hospitals due to differences in drug mix used at the hospital and mix of nondrug OPPS services. Hospitals with relatively lower 340B drug exposure will recover a larger share of lost drug margin through higher nondrug reimbursement, while 340B hospitals with a high share of drug utilization, particularly for drugs with the lowest ceiling prices, will likely experience a meaningful net operating margin decline. In practical terms, the proposed rule shifts profitability away from 340B drug spread and toward nondrug outpatient service volume, making hospital-level impacts highly sensitive to drug mix, outpatient service mix, site-of-care strategy, and payer-contract structures; though most 340B hospitals are expected to see a net decrease as illustrated in the budget neutrality example in Figure 5.

Non-340B providers: Non-340B OPPS providers would generally continue to receive ASP +6% for separately payable drugs while also benefiting from the budget-neutral increase to nondrug OPPS payments. This creates a relative payment advantage versus affected 340B hospitals for drug reimbursement. Providers with comparatively higher nondrug OPPS service volume will benefit the most from the nondrug payment increase.

Pharmaceutical manufacturers: The proposed rule does not directly change manufacturers' statutory 340B ceiling price obligations, but it could indirectly affect manufacturer economics if hospitals respond to lower Medicare reimbursement by changing drug utilization, site-of-care strategy, purchasing behavior, or service-line economics. Manufacturer responses to broader 340B growth have increasingly focused on claims-level visibility, duplicate-discount prevention, contract-pharmacy restrictions, and rebate-based models rather than continued reliance on the traditional upfront-discount structure.³³ HRSA's revised 340B Rebate Model Pilot, which would permit qualifying manufacturers to effectuate the 340B ceiling price through rebates for a limited set of drugs, reflects an attempt to shift toward transaction-level validation; industry commentary similarly describes manufacturer strategies centered on rebate validation, claims data, and restrictions designed to manage perceived duplicate-discount and diversion risk.^{34,35}

MA plans: MA plans are not required to pay providers at the same rate as FFS, though many contracts are set equal to or as a percentage of standard Medicare rates. In turn for providing coverage, MA plans are paid a capitated, benchmark-based payment by CMS,³⁶ and OPPS changes can influence those benchmarks. MA plans may be affected by the rule if the change in benchmark does not match their plan-specific change in reimbursement, which could be driven by differences in mix of 340B providers, mix of outpatient drug versus nondrug services, or provider contract terms. MA plans will need to evaluate whether and how OPPS cost shifts are reflected in provider contracts, delegated risk arrangements, bid assumptions, and member cost-sharing designs. Plans may also need to monitor whether providers attempt to recapture lost 340B drug margins by negotiating higher reimbursement for other outpatient services.

Patients: For Medicare FFS beneficiaries receiving drugs from a 340B hospital, the most direct patient impact is lower Part B cost sharing for those drugs because beneficiary coinsurance is generally tied to Medicare's allowed amount. Conversely, patients receiving nondrug services may see increased cost sharing. That said, a large number of patients may experience no or little total annual impact if they receive Medicaid benefits, have a Medigap or other supplemental plan that buys down their cost sharing, or have an MA plan with fixed copayments or enough spending to reach their maximum out-of-pocket limit. Patient access effects are less certain and would depend on whether affected hospitals change infusion capacity, drug administration sites, service-line availability, or referral patterns in response to lower 340B drug margins.

Additional considerations

The 340B program has been a growing segment which has required drug manufacturers to cede an increased number of discounts, and discounts to more entities (as the number of covered entities has significantly increased) over time. 340B interplays with a number of other market forces. Stakeholders should consider the following dynamics:

- **Best price:** The 340B ceiling price is calculated directly from the MDRP URA, so any contracting changes affecting BP or other elements of URA will also affect 340B. Thus, even if a given product has very low volume in the Medicaid market, changes to BP are still very important, as 340B discounts will impact commercial and Medicare business as well.
- **Medicare Drug Price Negotiation Program (MDPNP):** Under MDPNP, drugs are selected by CMS to be subject to MFPs in Medicare Part D and Part B. The MFP flows into BP, which as noted above, has direct implications for 340B pricing. Manufacturers with a drug facing MFP in the future should consider the Medicaid and 340B changes to gross-to-net, not just the impact in Medicare.
- **Provider behaviors:** The CY 2027 proposed OPPS rule would cause a significant change in provider reimbursement, as discussed previously. As an analog, for drugs facing MFPs under MDPNP, provider reimbursement will also decrease, with provider margin moving from 6% of ASP to 6% of MFP. Multiple sources, including oncology advocacy organizations, have suggested this reduction in margin on MFP products could cause providers to stop dispensing selected drugs, cut staffing, or even shut down.^{37,38,39} Given MFP only affects a small subset of drugs, whereas the proposed OPPS rule applies to all drugs dispensed at 340B hospitals, the behavioral consequences could be even more severe. From a drug manufacturer's perspective, this could reduce the volume of 340B discounts provided, but it could also have a significant negative impact on patient access.

In conclusion, 340B is no longer only a purchasing-discount program; it is increasingly connected to Medicare payment policy, drug price negotiation, rebates, specialty distribution, and provider economics. The proposed ASP - 33.4% reimbursement rate could materially change incentives for hospital outpatient drug administration and also has downstream financial effects on non-340B hospitals, MA plans, and beneficiaries. It remains to be seen whether the rule is finalized as proposed, but regardless, the 340B program will continue to be a meaningful component of healthcare economics and drug pricing in the years to come.

Data and Methodology

DATA SOURCES AND STUDY POPULATION

The primary data source for this study is the CMS 100% Medicare RIFs spanning January 1, 2019, through December 31, 2025. The RIFs contain claim-level and enrollment information for all FFS patients nationwide. We used the Outpatient Part B claims to identify patients who received physician-administered drugs (PADs) in an outpatient hospital setting.

340B Hospital Identification

Hospital 340B participation status was determined using the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs Information System (OPAIS) database,⁴⁰ linked to Medicare facility identifiers available in the RIF claims and the Provider of Services (POS) reference files.

A hospital is classified as having 340B status in a given study year only if it maintained full-year 340B participation during that calendar year. This criterion accounts for more than 90% of the 340B participating hospitals. In cases where an entity sub-division has a recorded termination date for its 340B registration while the parent entity retains active 340B status, the facility is treated as a 340B-participating facility for the purposes of this analysis. This approach reflects the operational reality that drug purchasing decisions are typically governed at the organizational level.

Hospital Outpatient Physician-Administered Drugs

We identified outpatient PAD using Average Sales Price (ASP) Healthcare Common Procedure Coding System (HCPCS) codes from the April 2026 Medicare Part B Drug Payment Limit file.⁴¹ HCPCS codes included in earlier or later Medicare Part B Drug Payment Limit files but excluded from the April 2026 file are not included. The analysis focuses exclusively on outpatient hospital claims for drugs reimbursed under Medicare Part B and excludes nondrug services, such as drug administration services, to the extent they are separately identifiable from the PAD HCPCS code definition.

We excluded claim lines with \$0 allowed amounts, including bundled claims. Excluding bundled claim lines materially reduces claim line counts and unique utilizer counts; however, the impact on total allowed amounts is minimal, as these claims carry no independent reimbursement.

Patient Definition

A patient is classified as a 340B patient if they had a PAD claim at a 340B-participating hospital during the study year. Conversely, a patient is classified as a non-340B patient if they had a PAD claim at a non-340B hospital during the study year. Patients with Part B drug utilization at both 340B- and non-340B-participating hospitals account for less than 4% of the total PAD utilizers.

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23. The count of hospitals was calculated using CMS Certification Numbers (CCNs).
24. For this analysis, we counted a patient as a 340B patient if they received a Part B drug at a 340B hospital and as a non-340B patient if they received one at a non-340B hospital, so a patient who received drugs at both hospital types is counted in both groups. However, in each year of the study period, approximately 96% of patients received all their Part B drugs at only one hospital type.
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30. Note that HRSA reports the 340B data as purchases at 340B prices, while this analysis uses ASP +6% repriced spend, which are slightly different bases for reporting.
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