



Analysis of 340B modifier usage in Medicare Part B claims

- Analysis of Part B Claims from January 2025 through June 2026

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Summary:

CMS is increasingly relying on the required “TB” HCPCS 340B modifier for the Medicare Part B inflation rebate program, Maximum Fair Price (MFP) implementation, and other payment policies, yet key questions remain about the consistency of modifier usage across settings, provider types, and states. We examined the incidence of the CMS required “TB” 340B modifier on Medicare Part B drug claims for the time period January 2025 – June 2026. In doing so we found four key takeaways:

- 1.) 11.0% of Medicare Part B drug claims carried the required 340B TB modifier¹ in the first two quarters of 2026, a slight increase from 2025.** When segmented to only look at TB modifier incidence in the hospital outpatient department (HOPD) setting, 49.5% of claims carried the required TB modifier in 2025 and 54.1% in 2026.
- 2.) Modifier incidence varied substantially across 340B covered entity types.** Disproportionate Share Hospitals (DSH) had the highest incidence of TB modifier application across their Medicare Part B claims at 78.2%, while Ryan White clinics had the lowest at 0.2% in 2025.
- 3.) Accounting for the 340B orphan drug exclusion reflected mixed results** with some entity types impacted by the orphan drug exclusion having a higher incidence of TB modifier application when orphan drugs were removed from the analysis vs. some entity types having a lower incidence.
- 4.) State Medicaid carve-out policies also did not materially affect modifier application.** States requiring 340B carve-outs demonstrated modifier application rates that were generally consistent with national averages.

Introduction:

The ADVI Health SAVES team, in collaboration with Sabrina Aery of Aery Policy and Access Partners, analyzed 340B TB HCPCS modifier incidence in Medicare Part B data for physician administered drugs with the goal of informing future policy developments. As of January 1, 2025², CMS required all 340B covered entities, including hospital-based (HOPD) and non-hospital-based entities that submit claims for separately payable Part B drugs and biologicals to report the TB modifier on claim lines for drugs acquired through the 340B program³.

Accurate application of the 340B TB modifier on Medicare Part B claims has significant implications for pharmaceutical manufacturers because it directly affects efforts to prevent duplicate discounts across federal drug pricing programs in areas where statute dictates that manufacturers should not be billed for 340B acquired drugs.

¹[Revised Part B Inflation Rebate Guidance: Use of the 340B Modifier](#)

² <https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf>

³ Prior to 2025, 340B acquired drugs were also identified by either JG or TB HCPCS modifiers (depending on covered entity type). CMS has proposed to bring back the use of the JG modifier as part of the 2027 Outpatient Prospective Payment System proposed rule. Our analysis targeted the application of the TB modifier as the only 340B modifier required January 1, 2025, forward.

- The Medicare Part B inflation rebate program relies on the TB modifier to identify 340B acquired drugs to accurately exclude 340B units from the calculation of manufacturer inflation rebate payments, as required by the Inflation Reduction Act.¹
- Dual eligible cross-over claims for beneficiaries eligible for both Medicare and Medicaid may face duplicate discount risk if the TB modifier is not transmitted or recognized across payers.
- Beginning in 2028, manufacturers of selected drugs will begin effectuating Maximum Fair Prices (MFP) on drugs covered under Part B.⁴ Manufacturers will rely on the TB modifier to avoid unauthorized MFP/340B duplicate discounts.

Among the various provider types that bill Medicare Part B, there are several 340B eligible entity types. These include on-campus hospital outpatient departments (HOPDs) and, under HRSA guidance, 340B hospitals can also access 340B prices for certain off-campus HOPDs known as 340B child sites.⁵ These child sites often include previously independent physician offices that were acquired by a 340B hospital.

While other types of entities that bill Medicare Part B can also participate in 340B (for example, “grantees” which include federally qualified health centers (FQHCs)), publicly available estimates indicate that 340B use in Medicare Part B remains concentrated in HOPD settings. For example, one study showed that 38% of total Part B outpatient drug administrations in 2024 occurred in the 340B HOPD settings (including at child sites).⁶ According to HRSA 2025 data, DSH hospitals accounted for 79% of the total 340B purchase price volume.⁷ HRSA does not publish which 340B eligible entities are also eligible to bill Medicare. From the CMS CY 2027 HOPPS Proposed Rule, CMS states that of the 4,494 entities eligible for HOPPS payment, 1,957 are 340B eligible or 44%.⁸

The following analysis provides a detailed overview of the incidence of 340B modifier use across Medicare Part B claims. We also segment the TB modifier incidence by 340B covered entity type. The analysis is then pressure tested by analyzing 340B modifier incidence when accounting for the 340B orphan drug exclusion and separately, when accounting for State Medicaid 340B carve-out policies.

Methodology:

We assessed the 100% Medicare Part B fee-for-service Prescription Drug claims from January 2025 through June 2026, the period of time to date when usage of the TB modifier was required across all Part B billing providers. The analysis identified all claims where a 340B TB modifier was present on the claim. Part B drug claims were selected if the HCPCS code was present in the Part B Average Sales Price (ASP) quarterly payment file. Drug lines were excluded from the analysis if they had any of the following: claims with total payment ≤\$0, claim lines with unspecified or not otherwise classified (NOC) HCPCS codes (e.g., J3480, J3590, or J9999), temporary C-codes, administrative A-codes, and skin substitutes or vaccines HCPCS/CPT. We then identified the incidence of TB

⁴ <https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf>

⁵ 59 Fed. Reg. 47884 (September 19, 1994)

⁶ [Site-of-Care Shift for Physician-Administered Drug Therapies: 2026 Update | Insights | BRG](#)

⁷ [2025 340B Covered Entity Purchases | HRSA](#)

⁸ [Calendar Year 2027 Hospital Outpatient Prospective Payment System \(OPPS\) and Ambulatory Surgical Center \(ASC\) Proposed Rule \(CMS-1850-P\) | CMS](#)

modifier application amongst HOPDs versus other locations and further segmented the analysis to examine the incidence of TB modifier usage by hospital and grantee type.

Under the 340B statute's orphan drug exclusion, orphan drugs sold to certain 340B hospitals (free-standing PPS-exempt cancer hospitals (CANs), critical access hospitals (CAHs), rural referral centers (RRCs), and sole community hospitals (SCHs)) are not categorized as covered outpatient drugs and thus are not subject to the 340B Program.⁹ For this reason, we then examined the incidence of TB modifier usage after excluding all orphan drug claims from the analysis.

State Medicaid policies vary in whether covered entities can claim 340B discounts on drugs dispensed or administered to Medicaid beneficiaries. A state-mandated carve-out policy is when a state Medicaid program informs 340B covered entities that they should not acquire drugs at 340B prices when billing Medicaid. 340B Carve-out States were identified by referencing publicly available sources which were manually validated by Aery Policy & Access Partners.¹⁰ We separately segment the analysis based on whether a state requires a 340B carve-out policy versus a 340B carve-in policy.

Findings:

Our analysis is presented in 4 sections:

- 1) Overall Medicare Part B drug claims for 2025 and 2026 to date, reflecting TB modifier incidence across all Medicare Part B drug claims as well as segmenting out the incidence in the HOPD claims.
- 2) Breakdown of the analysis by 340B Covered Entity Type for calendar year 2025 and separately for two quarters of 2026.
- 3) Accounting for the 340B Orphan Drug Exclusion by analyzing the incidence of the TB modifiers amongst non-orphan drugs for each period, 2025 and two quarters of 2026.
- 4) State Medicaid Carve-out analysis, accounting for States that require 340B covered entities to not acquire drugs for Medicaid recipients at 340B prices. This is also reflected by 2025 data vs. the first two quarters of 2026.

1.) Overall Medicare Part B Drug Claims:

We calculated the percent of Medicare Part B claims with a TB modifier as a percent of total paid claims in Medicare Part B. Overall, we found an incidence rate of 10.8% of Medicare Part B drug claims carrying the 340B TB modifier in 2025, accounting for 27.6% of total drug payments made on Medicare Part B claims. Through June 2026, that incidence rate increased slightly to 11% (27.9% of total Part B drug claims). These figures represent \$14B in total Medicare Part B fee-for-service drug payments in 2025 and \$7B in 2026 to date. (*Total Medicare Part B fee-for-service drug payments*

⁹ 42 U.S.C. 256b(e).

¹⁰ Manatt Health: [State-Mandated 340B Carve-Out Policies in Medicaid 2026-07.pdf](#)

include Medicare reimbursement plus beneficiary co-payments and any applicable third-party payments).

When segmented to only look at TB modifier incidence in the hospital outpatient department (HOPD) setting, we found a 49.5% incidence in 2025 and 54.1% incidence in 2026. We also found directionally consistent results when measuring the share of total Part B units (vs. *claims*) where a TB modifier was used (*several drugs may be billed on the same claim*).

Overall Medicare Part B Drug Claims Detail

Providers Billing Part B	% Claims with TB Modifiers	% Total Units with TB Modifiers	Total Claims Part B Claims	Total Medicare Spend*	Total Drug Payment**
All					
2025	10.8%	14.1%	43,051,295	\$41,464M	\$51,162M
2026	11.0%	14.3%	18,737,830	\$20,439M	\$25,267M
HOPD					
2025	49.5%	63.0%	9,230,278	\$16,780M	\$20,153M
2026	54.1%	64.4%	3,711,182	\$8,239M	\$9,899M

*Total Medicare Spend equals the amount CMS paid to the provider on the Medicare fee-for-service Part B claim

**Total Drug Payment equals the Medicare fee-for-service reimbursement plus beneficiary co-pays and any third-party payments.

2.) Breakdown of Analysis by 340B Covered Entity Type:

We next segmented the overall claims set by 340B covered entity type as defined by HRSA. This is a more specific segmentation than by HOPD providers, which include both 340B and non-340B eligible providers. Among 340B eligible hospitals of all types, a TB modifier was attached to 52.5% of claims. For HRSA grantees of all types for the same period, a TB modifier was attached to 27.3% of claims, a notable difference from the blended hospital incidence rate. The 340B entity types with the largest incidence of TB modifier application are DSH hospitals, free-standing cancer hospitals, FQHCs, and look-alike FQHC's.

The data shown below reflects more detail by 340B covered entity type, broken out for calendar year 2025 and for the first two quarters of 2026. For example, in 2025 data for DSH hospitals, of the 4+ million claims paid under Medicare Part B, a TB modifier was attached to 78.2% of those claims, accounting for \$11 billion in Medicare payments and \$12.5 billion when adding the patient out of pocket portion and/or payment from any third parties. By comparison, in 2025 data for Ryan White Clinics, of the 211K claims paid under Medicare part B, a TB modifier was attached to 0.2% of the claims.

The data reflects a wide range of 340B modifier incidence in the Medicare Part B paid claims data. Neither HRSA nor CMS publishes numbers on how many 340B entities bill Medicare Part B, so we pulled in the recently published 340B purchase figures by HRSA to provide a comparison to the overall Total Medicare spend. It's important to note that the total HRSA 340B purchases represent all payer types, not just Medicare or Medicare Part B. This is also not apples to apples as the HRSA

340B purchase data represents the 340B ceiling price purchases whereas the Medicare Spend represents provider reimbursements at ASP + 6% (less sequestration).

2025 Extract from the Medicare Part B Fee-for-Service Claims Set by 340B Covered Entity Type

340B Covered Entity Type	% claims with TB Modifiers	Total Part B Claims	Total Medicare Spend*	Total Drug Payment**	HRSA 340B purchases+
DSH (Disproportionate Share Hospitals)	78.2%	4,449,403	\$10,654M	\$12,523M	\$79,235M
RRC (Rural Referral Centers)	44.2%	397,149	\$824M	\$969M	\$2,450M
CAH (Critical Access Hospitals)	19.6%	1,788,313	\$483M	\$1,036M	\$1,535M
SCH (Sole Community Hospitals)	38.5%	162,702	\$260M	\$308M	\$632M
CAN (Free Standing Cancer Hospitals)	50.5%	66,047	\$271M	\$308M	\$742M
Children's Hospitals	3.6%	324,222	\$303M	\$375M	\$2,530M
FQHC + Look alike	49.5%	906,650	\$1,857M	\$2,193M	\$6,441M
STD Clinics	2.2%	366,685	\$302M	\$377M	\$2,860M
Ryan White (all)	0.2%	210,720	\$87M	\$108M	\$3,093M
Other	3.4%	244,855	\$357M	\$447M	\$493M

+[2025 340B Covered Entity Purchases | HRSA](#)

+HRSA Purchase data is at the 340B ceiling price whereas Medicare reimbursement data is at ASP + 6%, less sequestration

*Total Medicare Spend equals the amount CMS paid to the provider on the Part B claim

**Total Drug Payment equals the Medicare reimbursement plus beneficiary co-pays and any third-party payments.

2026 Extract from the Medicare Part B Fee-for-Service Claims Set by 340B Covered Entity Type

340B Covered Entity Type	% claims with TB Modifiers	Total Part B Claims	Total Medicare Spend*	Total Drug Payment**
DSH	81.9%	1,859,370	\$5,287M	\$6,221M
RRC	49.8%	158,300	\$404M	\$475M
CAH	24.3%	690,037	\$221M	\$487M
SCH	42.7%	60,866	\$129M	\$154M
CAN	53.5%	31,671	\$142M	\$162M
Children's Hosp.	4.4%	136,075	\$129M	\$160M
FQHC +	50.6%	371,551	\$919M	\$1,086M
STD	5.5%	160,997	\$117M	\$146M
Ryan White (all)	0.6%	85,785	\$42M	\$52M
Other	2.8%	93,922	\$142M	\$177M

*Total Medicare Spend equals the amount CMS paid to the provider on the Part B claim

**Total Drug Payment equals the Medicare reimbursement plus beneficiary co-pays and any third-party payments.

3.) 340B Orphan Drug Exclusion Analysis:

One reason why the incidence of TB modifier usage may be lower at rural referral centers (RRCs), sole community hospitals (SCHs), critical access hospitals (CAHs), and free-standing cancer centers (CANs) than at DSH hospitals is because of the 340B Orphan Drug Exclusion discussed above. To assess this, we identified and excluded claims associated with drugs meeting the definition of an orphan drug. The charts below show the percentage of claims for non-orphan drugs with TB modifiers by impacted covered entity type. When compared with the overall incidence of the TB modifiers amongst all Part B drug claims from those entity types, we found that in some the modifier incidence was higher when the orphan drugs were removed, while amongst others such as RRC or SCH it was lower.

2025 Extract from the Medicare Part B Fee-for-Service Claims Set, non-Orphan Claims.

340B Covered Entity Type	% Non-Orphan Claims with TB Modifiers	Total Non-Orphan Claims
RRC	17.1%	1,566,900
CAH	43.8%	281,525
SCH	34.2%	126,394
CAN	57.8%	40,215

2026 Extract from the Medicare Part B Claims Set, non-Orphan Claims

340B Covered Entity Type	% Non-Orphan Claims with TB Modifiers	Total Non-Orphan Claims
RRC	21.9%	600,270
CAH	52.4%	112,300
SCH	39.5%	45,944
CAN	63.6%	20,600

4.) State Carve-In/Carve-Out Analysis:

States are permitted by CMS to set their own policies on how 340B covered entities handle drugs administered or dispensed to Medicaid enrollees, with some states specifying that 340B covered entities may not claim 340B discounts on drugs for Medicaid enrollees such that the state may always claim a Medicaid rebate (this is known as a mandated 340B “carve-out” policy as noted above).

Because claims for dually eligible Medicare and Medicaid beneficiaries in mandated carve-out states potentially may not carry a TB modifier, we might expect that the incidence of modifier usage across all Part B claims in carve-out states would be lower than the overall U.S. average. There are seven states with state-mandated 340B carve-out policies in place: Delaware, Indiana,

Massachusetts, Montana, New Hampshire, South Dakota, and Wyoming.¹¹ We note that if there was any type of 340B carve-out in the State, we identified them as a 340B carve-out State. For instance, amongst these States, some may dictate a 340B carve-out for fee-for-service enrollees or for Managed Medicaid enrollees or for both.

As shown in the chart below, when looking at the seven states with mandated carve-out policies, we found the application rate of the TB modifier across all HOPD Part B claims to be in line with the overall national HOPD application rate of 49.5% for 2025 and 54.1% for 2026, with the exception of Wyoming. Thus, a State's carve-out status did not seem to impact the application incidence of the 340B TB modifier to the claims. States vary in the level of detail they apply to their 340B policies related to dual eligible cross-over claims. Because Medicare is the primary payer, the cross-over of the TB modifier would make sense and should be expected, even with Medicaid as the secondary payer. Where we see a lower incidence could indicate provider confusion.

340B Carve-Out State Analysis:

340B Medicaid Carve-Out State	TB Modifier Incidence % in HOPD claims	Total HOPD Claims	Total HOPD Medicare Drug Payment*
Delaware			
2025	48.7%	16,217	\$49M
2026 YTD	44.5%	6,602	\$22M
Indiana			
2025	49.8%	125,081	\$299M
2026 YTD	58.5%	59,412	\$144M
Massachusetts			
2025	53.5%	188,058	\$441M
2026 YTD	56.2%	82,044	\$223M
Montana			
2025	31.8%	35,915	\$82M
2026 YTD	38.2%	15,685	\$38.2M
New Hampshire			
2025	44.8%	45,430	\$75M
2026 YTD	49.9%	22,738	\$46M
South Dakota			
2025	47.3%	45,181	\$105M
2026 YTD	53.0%	18,020	\$48M
Wyoming			
2025	2.7%	1,242	\$3M
2026 YTD	3.3%	616	\$1M
Carve-Out State Totals			
2025	46.1%	916,367	\$2,108M
2026 YTD	51.1%	406,572	\$1,0468M

All percentages and numerical amounts were rounded upwards.

2026 data period 1/1/2026 – 6/30/2026

*Total Medicare Spend equals the amount CMS paid to the provider on the Part B claim

¹¹ Aery Policy & Access Partners internal 50 State extract + Manatt Health: [State-Mandated 340B Carve-Out Policies in Medicaid 2026-07.pdf](#)

Conclusion:

CMS increasingly relies on the TB modifier to support implementation of multiple Medicare payment policies, including Part B inflation rebates. It is critical that modifiers are attached and passed through across all channels. However, our analysis suggests that modifier application remains inconsistent across provider settings, covered entity types and the incidence amongst some hospital types is not impacted by the orphan drug exclusion. State 340B carve-out policies also do not have a significant impact on the incidence, with some exceptions which may indicate confusion amongst 340B providers.

While it is difficult to assess the true level of what 100% compliance would look like based on publicly available data, enough evidence is present to reflect that TB modifier usage alone, even when required, is likely not sufficient to accurately capture all claims for drugs acquired at the 340B price.

Notably, HRSA reached a similar conclusion in its 2026 rebate model pilot notice¹², acknowledging that claim identifiers may be inconsistently applied, incomplete, or unavailable at the time of adjudication. The Administration's proposal as part of the Calendar Year 2027 Outpatient Prospective Payment System (OPPS) Proposed Rule to require a non-340B modifier across nearly all OPPS Part B claims for drugs that were not acquired under the 340B Program¹³ is a key step that could help improve compliance with modifier usage if finalized. And HRSA's implementation of a rebate-based approach for a set of drugs in 340B suggests an acknowledgement that additional mechanisms may be necessary to support compliance across federal drug pricing programs.

With Federal Policy still evolving across CMS and HRSA, continuing to analyze and publish on 340B modifier incidence rates over time is needed. This paper follows our previously published White Paper analyzing the incidence of 340B modifier application in the Medicare Part D claims set.¹⁴

¹² Notice Regarding 340B Rebate Pilot Program, 91 Fed. Reg. 48883, 41889 (Aug. 3, 2026) [2026-15633.pdf](#)

¹³ See 91 Fed. Reg. 41734, 41893 (July 7, 2026). CMS proposes to require all providers paid under the OPPS to use a non-340B modifier for all separately payable drugs purchased outside of the 340B program.

¹⁴ https://advi.com/wp-content/uploads/2026/04/ADVI-White-Paper-340B-Modifier-Usage-in-Medicare-Claims_Final_2026.04.14.pdf