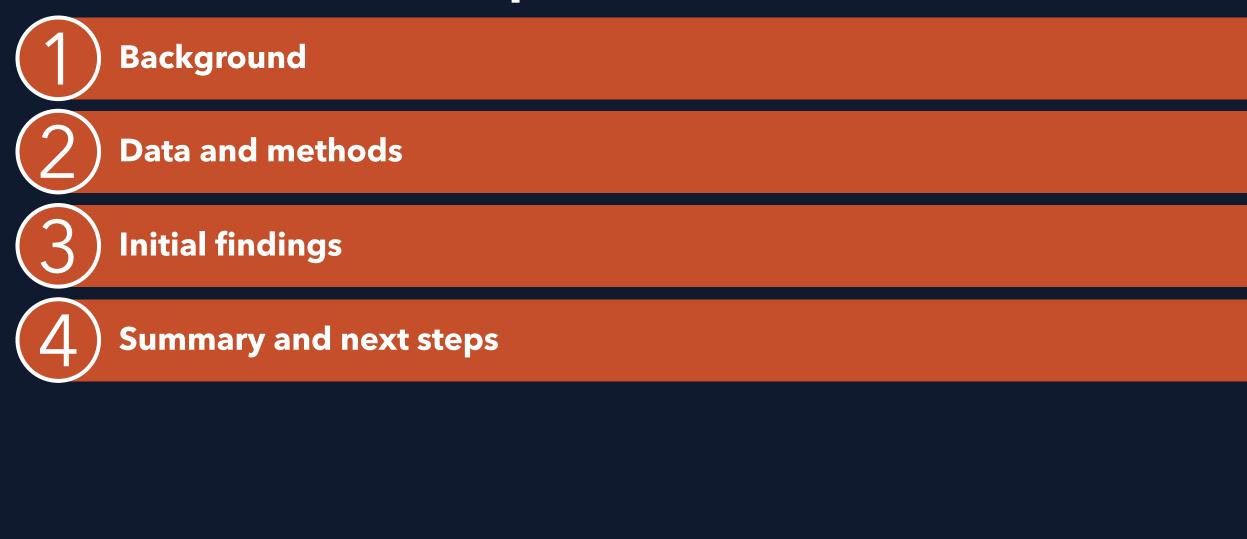


Advising the Congress on Medicare issues

Initial findings from analysis of Medicare Part B payment rates and 340B ceiling prices

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Presentation roadmap





340B Drug Pricing Program

- Allows safety-net providers ("covered entities") to purchase outpatient drugs at discounted prices from drug manufacturers
 E.g., DSH hospitals, CAHs, RRCs, SCHs, cancer hospitals
- Manufacturers sell drugs at or below the 340B ceiling prices to covered entities for Medicaid to cover their drugs
- According to HRSA, "The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" (HRSA 2024)

Note: DSH (disproportionate share hospital), CAH (critical access hospital), RRC (rural referral center), SCH (sole community hospital), HRSA (Health Resources Services Administration).
 Source: Health Resources Services Administration. 2024. 340B Drug Pricing Program. https://www.hrsa.gov/opa.



Part B payment for 340B-purchased drugs

- Medicare pays same payment rate for Part B drugs to all hospitals even though 340B hospitals can purchase drugs at discounted prices
- Difference between Part B payment and ceiling price is substantial
 - HHS OIG found Part B payment exceeded ceiling price by 58% in 2013
 - MedPAC, using ASP as a proxy, estimated that Part B payment exceeded ceiling price by at least 35% on average in 2013
- MedPAC recommendation (2016): Reduce FFS payment for hospitals 340B drugs and direct the savings to the Medicare funded uncompensated care pool

Note: HHS OIG (Department of Health and Human Services Office of Inspector General), ASP (average sales price), FFS (fee-for-service).

Source: Office of Inspector General, Department of Health and Human Services. 2015. <u>Part B payments for 340B-purchased drugs</u>. Medicare Payment Advisory Commission. 2015. *Report to Congress: Overview of the 340B drug pricing program*. <u>Report to Congress: Overview of the 340B drug pricing program</u>. <u>Medicare Payment</u> Advisory Commission. 2016. *Report to Congress: Medicare Payment Policy*. <u>Report to Congress: Medicare Payment Policy</u>.



Changes in Medicare payment for Part B drugs furnished by 340B hospitals, 2018-2022

- Part B drug payment generally based on manufacturers' ASP
 Before 2018: ASP + 6%
- Between 2018 and 2022, CMS lowered the Part B payment for most 340B drugs paid for under the OPPS
 2018-2022: ASP - 22.5% for most drugs furnished by 340B hospitals
- In 2022, Supreme Court ruled that CMS's process to change the 340B payment rate did not adhere to the Medicare statute
 - CMS reprocessed 2022 340B drug claims at rate of ASP + 6%
 - Since 2022: ASP + 6%

Updating our estimate of the difference between the Part B drug payment rate and 340B ceiling prices

- We estimated 340B ceiling prices (based on AMP and BP data) and compared them to Part B payment rates (i.e., ASP + 6%)
 Ceiling price = AMP unit rebate amount (basic rebate + inflation rebate)
- Data source: 2022 NDC-level pricing data that manufacturers reported to CMS; CAA gave MedPAC access to these confidential data
- Confidential pricing data are subject to disclosure limitations specified in the statute; we aggregated the results to ensure confidentiality

Note: AMP (average manufacturer price), BP (best price), NDC (national drug code), CAA (Consolidated Appropriation Act, 2021).



Analysis approach

- Time frame: 2022
- Included OPPS hospitals that bill Part B for drugs acquired under 340B program*
 - Did not include retail pharmacy drugs, including those furnished by 340B contract pharmacies
- Included 189 Part B drug billing codes for single-source drugs, biologicals, and biosimilars

• Account for 97% of OPPS spending for 340B-acquired products

Note: OPPS (outpatient prospective payment system).

*We excluded hospitals paid under alternate payment systems (e.g., critical access hospitals, cancer hospitals, Indian Health Service hospitals, Maryland hospitals, and pediatric hospitals).



Analytic methods

- Estimated 340B ceiling prices at the individual NDC level using Medicaid data
- For billing codes with multiple NDCs, aggregated NDC-level ceiling prices to the billing code level by calculating the volume-weighted ceiling price
- To permit comparison, converted 340B ceiling prices to same units as Part B payment rates (e.g., 1 mg)



Aggregate Medicare payments substantially exceeded 340B ceiling-price costs in 2022

For the 189 single-source products:

- Medicare and beneficiaries paid OPPS hospitals \$11.9 billion for 340B-purchased products
- Estimated cost at 340B ceiling prices: \$8.1 billion
 - 340B ceiling-price costs equated to approximately ASP 29% in aggregate
- Aggregate payments by FFS Medicare and beneficiaries exceeded 340B ceiling-price costs by 48% (\$3.9 billion)
 - Payments exceeded 340B ceiling prices by 42% for cancer products and 57% for noncancer products in aggregate*

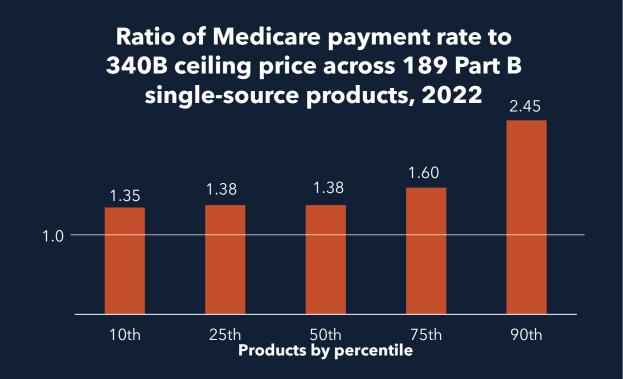
Note:

Source:

OPPS (outpatient prospective payment system), FFS (fee-for-service). Payments are net of the sequester for the portions of 2022 when the sequester was in effect. *For purposes of this analysis, cancer products are defined as drugs, biologics, and biosimilars in the antineoplastics therapeutic class. MedPAC analysis of Medicare claims data, ASP pricing data, and Medicaid rebate program data.



Medicare payment rate substantially exceeded 340B ceiling prices for many single-source Part B products



 Note: "Medicare payment rate" reflects published pre-sequester payment. Ceiling prices are MedPAC estimates based on analysis of data from the Medicaid rebate program. For each product, the ratio of payment rate to ceiling price reflects the median ratio across the 4 quarters of 2022.
 Source: MedPAC analysis of Medicare claims data, ASP pricing data, and Medicaid rebate program data. Across the 189 single-source products:

- For the median product, the Medicare payment rate exceeded the 340B ceiling price by 38%
- For half of products, the Medicare payment rate exceeded the 340B ceiling price by 38% to 60% (25th to 75th percentile)
- 10% of products had a Medicare payment rate at least 145% above the 340B ceiling price (90th percentile)

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Caveats of analysis

- Analysis reflects 340B ceiling prices; if manufacturers offer 340B subceiling discounts for some products, the difference between Medicare payments and 340B prices could be larger than we estimated
- Excludes drugs with generic competition
- Excludes 340B products furnished by providers not paid under OPPS (e.g., critical access hospitals, hemophilia clinics)

Note: OPPS (outpatient prospective payment system). Part B drug billing codes that include generic drugs comprise less than 3 percent of OPPS spending on separately payable 340B-acquired drugs.

Summary and next steps

- In aggregate, we estimate payments by FFS Medicare and beneficiaries exceeded 340B ceiling prices by about 48% (\$3.9 billion) for 189 single-source drugs, biologics, and biosimilars
- Update the analysis as data become available
- Feedback on additional research ideas
- Questions?





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