

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PART B PAYMENTS FOR
340B-PURCHASED
DRUGS**



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EXECUTIVE SUMMARY: PART B PAYMENTS FOR 340B-PURCHASED DRUGS

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WHY WE DID THIS STUDY

Medicare Part B pays a set amount to health care providers who furnish drugs to its beneficiaries. Certain eligible health care providers—generally, those that serve a disproportionate share of needy patients—are allowed to purchase drugs using the 340B Drug Discount Program, thereby receiving sizable statutory discounts. Past Office of Inspector General (OIG) work found that Medicare payments to providers for 340B-purchased drugs substantially exceeded the providers' costs. Under the design of the 340B Program and Part B payment rules, the difference between what Medicare pays and what it costs to acquire the drugs is fully retained by the participating covered entities, allowing them to stretch scarce Federal dollars in service to their communities. However, some policymakers have questioned whether a portion of the savings mandated through the 340B Program should be passed on to Medicare and its beneficiaries.

HOW WE DID THIS STUDY

We determined how much Part B spent on 340B-purchased drugs in 2013 by identifying paid Medicare claims from covered entities. We compared 2013 Part B payment amounts to 340B ceiling prices at the individual drug level and the aggregate level. We also analyzed the financial impact on covered entities, the Medicare program, and Medicare beneficiaries of three different shared-savings arrangements that would enable Medicare and its beneficiaries to share in the cost savings resulting from 340B discounts.

WHAT WE FOUND

Medicare Part B and its beneficiaries paid \$3.5 billion for 340B-purchased drugs in 2013. In the aggregate, Part B payment amounts were 58 percent more than the statutorily based 340B ceiling prices that year, which allowed covered entities to retain approximately \$1.3 billion. The 340B statute does not restrict how covered entities may use these funds. The three shared-savings arrangements described in this report would have resulted in Medicare Part B savings of \$162 million to \$1.1 billion in 2013 while still providing covered entities with incentives to purchase those drugs through the 340B Program.

WHAT WE CONCLUDE

OIG has produced an extensive body of work examining the 340B Program from various angles. As stakeholders debate the nature of 340B discounts and whether statutory changes should be made to enable Medicare and/or Medicaid to share in these savings, this report presents an independent analysis to inform the ongoing discussion and to support congressional and Administration decisionmakers' efforts in striking a balance among the needs of these vital programs.

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OBJECTIVES

1. To estimate Medicare Part B expenditures for outpatient drugs purchased by covered entities in 2013.
2. To estimate the amount by which Medicare Part B payment amounts exceeded 340B ceiling prices in 2013.
3. To estimate the amount by which Medicare spending could have been reduced in 2013 if Part B had been able to share in the savings attributable to 340B discounts.

RATIONALE

The 340B Drug Discount program enables eligible health care providers—generally, those that serve a disproportionate share of needy patients—to purchase prescription drugs at statutorily discounted prices. The program does not address what eligible providers may charge, and many payers (including Medicare and, in some cases, Medicaid) reimburse at amounts that are much higher than the acquisition costs of the drugs.¹ Congress intended for the savings from these discounted prices to enable covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”² Current law or program guidance, however, does not specify exactly how covered entities are to use the savings.

The increase in the number and types of participating entities since the inception of the 340B Program in 1992 has led some stakeholders to question whether the program has exceeded its original congressional intent, and has led others to suggest that affected Federal insurance programs (i.e., Medicare and Medicaid) and their beneficiaries should share in the benefits of the discounted prices. In contrast, other stakeholders maintain that the program is in line with congressional intent, as it enables covered entities to use the savings achieved through 340B discounts to benefit vulnerable patient populations in ways that savings to Medicare or Medicaid would not.

Proposals for restructuring the 340B Program have been a topic of significant debate. Various issues related to 340B have been studied by the Medicare Payment Advisory Commission, the Government Accountability Office (GAO), and the Office of Inspector General (OIG). This study builds on OIG’s existing body of work by analyzing the

¹ Drugs purchased by 340B covered entities are hereinafter referred to as 340B-purchased drugs.

² H.R. Rep. No. 102-384(II), at 12 (1992)(Conf. Rep.).

financial intersection of the 340B program with Medicare Part B, including (1) costs to Part B for 340B-purchased drugs, (2) the amount by which Part B payment amounts exceed 340B prices, and (3) the shared savings that 340B covered entities, Part B, and Medicare beneficiaries would receive under three payment scenarios. As stakeholders debate the nature of 340B discounts and whether statutory changes should be made to enable Medicare and/or Medicaid to share in these savings, this report presents an independent analysis to inform the ongoing discussion and to support congressional and Administration decisionmakers' efforts in striking a balance among the needs of these vital programs.

BACKGROUND

The 340B Drug Discount Program

The Veterans Health Care Act of 1992 established the 340B Program in section 340B of the Public Health Service (PHS) Act. To have their drugs covered by Medicaid, manufacturers must agree to sell covered outpatient drugs at or below statutorily defined discount prices (340B ceiling prices) to covered entities.³ Covered entities include disproportionate share hospitals (DSHs)⁴, family planning clinics, federally qualified health centers, and hemophilia treatment centers, among others.⁵ In 2013, 11,250 entities were enrolled in the 340B Program.⁶

Overall financial margins for 340B DSHs tend to be lower than those for other hospitals, which may be attributable in part to the tendency for such hospitals to provide more uncompensated and charity care.⁷ HRSA estimates that covered entities saved \$3.8 billion in fiscal year (FY) 2013

³ Pursuant to 42 U.S.C. § 256b(a)(1).

⁴ A disproportionate share hospital is a hospital with a disproportionately large share of low-income patients. Centers for Medicare & Medicaid Services (CMS), *Medicare Disproportionate Share Hospital*, ICN 006741, August 2014.

⁵ 42 U.S.C. § 256b(a)(4). Section 7101 of the Patient Protection and Affordable Care Act (ACA) added five new eligible entity types: certain children's hospitals, certain freestanding cancer hospitals, critical access hospitals (CAHs), rural referral centers, and sole community hospitals.

⁶ HRSA, *Covered Entity Database*. Accessed at <https://openet.hrsa.gov/opa/CESearch.aspx> on April 3, 2014. Covered entities may have multiple sites for health care delivery. When taking into account every location, 25,039 covered entity sites were enrolled in the 340B Program in 2013.

⁷ GAO, *Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, June 2015, p. 11.

because of the discounts provided under the 340B Program.⁸ The 340B statute does not restrict how covered entities use these funds.

Calculation of 340B Ceiling Prices

HRSA calculates 340B ceiling prices each quarter. The 340B ceiling price formula is based on pricing data submitted by drug manufacturers for each of their national drug codes (NDCs). The 340B ceiling price is equal to the average manufacturer price (AMP) minus the Medicaid unit rebate amount (URA).⁹ See Appendix A for a detailed explanation of how AMPs, URAs, and 340B ceiling prices are calculated.

Covered entities that participate in the Prime Vendor Program often pay manufacturers less than 340B ceiling prices for drugs.¹⁰ The Prime Vendor Program is responsible for negotiating drug prices below the 340B ceiling price and contracting for the distribution of 340B-purchased drugs to covered entities. In 2013, the Prime Vendor Program had more than 7,000 drugs under contract, with an average discount of 10 percent below the 340B ceiling price.¹¹

Medicare Part B Payments for Prescription Drugs

Medicare covers a limited number of outpatient drugs under its Part B benefit, including injectable drugs used in the treatment of cancer, certain vaccines, and inhalation drugs used with durable medical equipment (DME).¹² Medicare beneficiaries can receive Part B drugs through hospital outpatient departments, physicians' offices, and DME suppliers. In 2013, Medicare paid for most Part B drugs at 106 percent of the

⁸ U.S. Department of Health and Human Services, *HRSA FY2015 Budget Justification*, p. 342.

⁹ 42 U.S.C. § 256b(a)(1-2). Occasionally, a drug's URA is equal to its AMP, resulting in a 340B ceiling price of \$0. In these instances, HRSA has advised manufacturers to charge covered entities \$0.01 per unit. See HRSA, *Clarification of Penny Pricing Policy*, November 21, 2011.

¹⁰ Participation in the Prime Vendor Program is voluntary and free.

¹¹ U.S. Department of Health and Human Services, *HRSA FY2015 Budget Justification*.

¹² 42 CFR § 414.900(b) and *Medicare Benefit Policy Manual*, ch. 15 § 50.

volume-weighted average sales prices (ASPs).^{13, 14} Medicare beneficiaries are responsible for 20 percent of Part B payments in coinsurance. See Appendix B for a detailed description of Part B payment methodologies for drugs in various settings.

Part B pays for most outpatient drugs on the basis of ASPs, regardless of the amount that the provider paid to purchase the drug from the manufacturer (i.e., regardless of whether the drug was purchased at the 340B discount price).¹⁵ As a result, Part B providers can retain the difference between the ASP-based payment amount and the drug's acquisition cost. Because acquisition costs for 340B-purchased drugs are usually substantially less than acquisition costs for drugs purchased through other channels (i.e., for non-340B drugs), providers are able to achieve a much larger "spread"—i.e., payment differential—on 340B-purchased drugs than for non-340B drugs. Medicare Part B does not share in any of the 340B discounts, and beneficiary coinsurance amounts are not reduced to reflect the discounted 340B prices. Instead, covered entities retain the entire difference between Part B payment amounts and the 340B prices.

In 2013, Medicare and its beneficiaries spent a total of \$22.2 billion for Part B drugs—\$7.7 billion in the hospital outpatient setting, \$12.8 billion in the physician-office setting, and \$1.7 billion in the DME setting.

¹³ 77 Fed. Reg. 68210, 68216 (Nov. 15, 2012) and section 1847A of the Act. Part B claims dated on or after April 1, 2013, incur a 2-percent reduction in payment in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (i.e., sequestration). This mandatory payment reduction is applied after the beneficiary's coinsurance has been determined, resulting in a payment rate for most Part B drugs of 104.3 percent of the volume-weighted ASP. See <http://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/downloads/2013-03-08-standalone.pdf>.

¹⁴ CAHs; certain hospitals in Maryland; hospitals located outside one of the 50 States, the District of Columbia, and Puerto Rico; and hospitals of the Indian Health Service are not paid on the basis of ASPs. They are excluded from the hospital outpatient prospective payment system (OPPS) and are paid at cost. 42 CFR § 419.20(b). Furthermore, several Part B drugs—including certain vaccines, blood products, and drugs infused through DME (which we refer to as DME infusion drugs)—are paid for on the basis of average wholesale prices (AWPs) and not on the basis of ASPs. Sections 1847A(a)(1) and 1842(o)(1) of the Act. See also *Medicare Claims Processing Manual*, ch. 17 § 20.1.3.

¹⁵ As previously mentioned, Medicare beneficiaries can receive Part B drugs through hospital outpatient departments, physicians' offices, and DME suppliers. Most 340B-purchased drugs are provided in hospitals. However, drugs provided by physicians and DME suppliers associated with these hospital covered entities may sometimes be purchased at 340B prices. Beneficiaries can also receive Part B drugs through nonhospital covered entities, such as comprehensive hemophilia treatment centers and grantees that receive funding through the Ryan White HIV/AIDS Program.

Medicaid Shared-Savings Payment Methodologies

All State Medicaid agencies offer outpatient prescription drug coverage and reimburse providers for covered outpatient drugs dispensed to Medicaid patients. For Federal financial participation to be available for covered outpatient drugs provided under Medicaid, manufacturers must enter rebate agreements with the Secretary of Health and Human Services and pay quarterly rebates for these drugs to State Medicaid agencies.¹⁶ Covered entities must choose whether to dispense 340B-purchased drugs to Medicaid patients. Covered entities that choose to dispense 340B-purchased drugs to Medicaid patients are said to “carve in” (or include) those patients and are described as “carve-in covered entities,” whereas covered entities that choose not to dispense 340B-purchased drugs to Medicaid patients are said to “carve out” those patients and are described as “carve-out covered entities.”¹⁷ If a covered entity chooses the “carve in” approach, State Medicaid agencies would not have access to rebates for 340B-purchased drugs provided to Medicaid patients because duplicate discounts are prohibited by law.¹⁸

The rates at which States reimburse 340B-purchased drug claims determine whether the full 340B discount is retained by the covered entity, passed through to Medicaid, or shared among both parties. OIG has found that approximately half of States have written policies that direct covered entities to bill Medicaid at cost for 340B-purchased drugs.¹⁹ In these cases, the State Medicaid agencies receive the full 340B discount and the covered entities do not benefit from the price spreads. However, some of these States provide a higher per-prescription dispensing fee for 340B-purchased drugs as an incentive for covered entities to dispense 340B-purchased drugs to Medicaid patients.

METHODOLOGY

Data Analysis

Estimating Part B Expenditures for 340B-Purchased Drugs. We identified 472 drug Healthcare Common Procedure Coding System (HCPCS) codes

¹⁶ Sections 1927(a)(1) and (b)(1) of the Act.

¹⁷ See, e.g., *340B & Medicaid*. Accessed at https://docs.340bpvp.com/documents/public/resourcecenter/340B_Medicaid.pdf on August 21, 2015.

¹⁸ 42 U.S.C. § 256b(a)(5)(A). A duplicate discount situation would arise if a State Medicaid agency sought Medicaid rebates for drugs sold at 340B discounted prices. Most State Medicaid agencies use HRSA’s Medicaid Exclusion File—which lists carve-in covered entities—to identify and exclude from rebate invoices the claims for 340B-purchased drugs submitted by these covered entities.

¹⁹ OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011.

(1) that were billed in the hospital outpatient, physician-office, and/or DME settings in 2013 and (2) for which we could determine 340B ceiling prices.²⁰ These 472 HCPCS codes accounted for 86 percent (\$19 billion) of Part B drug expenditures in 2013. We obtained Part B claims associated with covered entities for the 472 HCPCS codes in 2013.²¹ We then removed claims submitted by carve-out covered entities for dual-eligible beneficiaries (beneficiaries enrolled in both Medicare and Medicaid) because by electing to carve out, the entities should not have used 340B-purchased drugs for these patients. We determined how much Medicare paid for 340B-purchased drugs by summing payments listed on the remaining claims.

Comparing 340B Ceiling Prices to Part B Payment Amounts. For each HCPCS code representing a drug purchased by a covered entity, we compared the quarterly 340B ceiling price to its Part B payment amount. We then estimated an overall aggregate difference between 340B ceiling prices and Medicare payment amounts among all HCPCS codes.

We also calculated the per-beneficiary difference between 2013 drug acquisition costs and Medicare payment amounts among covered and noncovered entities for five selected high-expenditure cancer drugs.

Calculating Potential Spending Reductions. To estimate the distribution of savings under various possible scenarios, we developed three ASP-based payment options that would allow Medicare to share in varying proportions of the 340B discount while still providing covered entities with incentives to “carve in” Medicare patients. These payment scenarios would pay for 340B-purchased drugs as follows: (1) by volume-weighted ASP (i.e., 100 percent of ASP), (2) by volume-weighted ASP reduced by a percentage that would enable Medicare and covered entities to equally share in 340B discounts, and (3) by the 340B ceiling price plus 6 percent of volume-weighted ASP. We estimated how much Medicare and beneficiary spending would have been reduced in 2013 under each of these shared-savings payment scenarios.

See Appendix C for a detailed description of our sources and analysis.

Limitations

To calculate valid estimates despite certain data limitations (for example, lack of a 340B identifier on Part B claims), we made assumptions and

²⁰ Providers submit claims for Part B drugs using HCPCS codes. Each HCPCS code defines the drug’s name and the amount of the drug represented by one unit of the HCPCS code but does not specify manufacturer or package size information.

²¹ Because there is no identifier on Part B claims indicating that a drug was purchased through the 340B Program, we could not confirm that claims submitted by covered entities were in fact for drugs purchased at or below the 340B discount price.

analytic decisions that may have resulted in over- or underestimates of provider acquisition costs, Part B expenditures for 340B-purchased drugs, and Medicare spending reductions under shared-savings methodologies. This report examines only the changes in expenditures that would result under three different payment scenarios. It does not examine the impact these changes would have on covered entities' ability to provide services to their communities. See Appendix C for a detailed description of these limitations.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Medicare Part B and its beneficiaries spent \$3.5 billion for 340B-purchased drugs in 2013

Medicare spent \$3.5 billion on discounted drugs purchased by covered entities in 2013, representing nearly one-fifth of the \$19 billion that Part B spent that year on the HCPCS codes included in our review.^{22, 23} As Table 1 shows, 340B expenditures were concentrated among hospital outpatient settings rather than associated physicians' offices and DME suppliers. In total, payments for 340B-purchased drugs accounted for almost half (\$3.2 billion) of Part B hospital outpatient drug expenditures.

Table 1: 340B and Non-340B Part B Drug Expenditures by Setting

Setting	340B Expenditures	Non-340B Expenditures	Total	340B Expenditures' Share of Total
Hospital Outpatient	\$3,160,272,265	\$3,414,983,101	\$6,575,255,366	48%
DME	\$54,969,170	\$1,586,415,434	\$1,641,384,603	3%
Physician Office	\$264,576,235	\$10,561,603,279	\$10,826,179,514	2%
Total	\$3,479,817,670	\$15,563,001,813	\$19,042,819,483	18%

Source: OIG analysis of HRSA's covered entities database and 2013 hospital outpatient, DME, and physician-office claims from the National Claims History (NCH) file.

Notes: All figures include both Medicare and beneficiary portions of expenditures for the HCPCS codes included in our review. Hospital outpatient figures include only spending under OPSS.

In the aggregate, Medicare Part B payment amounts exceeded 340B ceiling prices by 58 percent in 2013

The 340B ceiling prices represent the maximum amount that a manufacturer should charge covered entities for a drug. Assuming covered entities paid the 340B ceiling prices for the drugs under review, we estimate that in 2013, covered entities spent \$2.2 billion to acquire Part B drugs and were reimbursed \$3.5 billion for these purchases by Medicare. In other words, Part B paid covered entities a total of \$1.3 billion (58 percent) more than the cost of the drugs.

²² Payments for 340B-purchased drugs (i.e., payments to covered entities) will hereinafter be referred to as 340B expenditures.

²³ Part B 340B and non-340B expenditure figures exclude hospitals that are paid at cost rather than under OPSS (e.g., CAHs, hospitals of the Indian Health Service). The 340B expenditures associated with these types of entities totaled \$329 million.

Overall, 398 of the 420 HCPCS codes with 340B expenditures had payment amounts that exceeded 340B ceiling prices in 2013 (see Table 2).^{24, 25} Of these 398 HCPCS codes, payment amounts for 149 codes exceeded 340B ceiling prices by between 25 percent and 49 percent, and payment amounts for 95 of the 398 HCPCS codes were more than double the 340B ceiling prices.

For 35 HCPCS codes, the difference between the Part B payment amount and the 340B ceiling price was so large that, in at least one quarter of 2013, the beneficiary’s coinsurance alone (i.e., 20 percent) was greater than the amount a covered entity spent to acquire the drug.²⁶ For example, covered entities spent \$737 per treatment in the first quarter of 2013 to acquire a drug that is used to treat bladder cancer; however, beneficiaries owed approximately \$831 per treatment—i.e., 13 percent more than the drug cost—through coinsurance paid to the covered entity. Meanwhile, in addition to receiving this coinsurance, the covered entities also received \$3,325 per treatment in reimbursement from Medicare.

Table 2: Median Differences between Part B Payment Amounts and 340B Ceiling Prices for HCPCS Codes with 340B Expenditures in 2013

Relation of Payment Amounts to 340B Ceiling Prices	Percentage Difference	Number of HCPCS Codes
Payment amounts less than 340B ceiling prices	Total	22
Payment amounts greater than 340B ceiling prices	Less than 25%	79
	25–49%	149
	50–79%	53
	80–100%	22
	More than 100%	95
	Total	398
Grand Total		420

Source: OIG analysis of 340B ceiling prices and Part B payment amounts.

²⁴ Of the 472 HCPCS codes under review, 52 did not have 340B expenditures in 2013.

²⁵ Of the 22 HCPCS codes with payment amounts that were less than 340B ceiling prices, 14 had payment amounts that were below 340B ceiling prices by 25 percent or less. Because we did not collect actual acquisition costs for 340B-purchased drugs, we could not determine whether covered entities were actually reimbursed less than their costs for these 22 drugs, or whether they instead paid less than the 340B ceiling price through the Prime Vendor Program or other non-340B distribution channels.

²⁶ In some instances, certain covered entities may waive all or part of the beneficiary’s coinsurance (*Medicare Benefit Policy Manual*, ch. 13 § 80.1). We did not confirm whether beneficiaries in fact paid the Part B coinsurance for 340B-purchased drugs.

Covered entities retained thousands more per beneficiary than noncovered entities for five high-expenditure cancer drugs in 2013

Because covered entities acquired most Part B drugs from manufacturers at lower prices than did other providers, they were able to retain a greater spread between Part B payment amounts and acquisition costs than noncovered entities. For example, providers not enrolled in the 340B Program retained less than \$1,000 per beneficiary treated with one of five high-expenditure cancer drugs in 2013. That same year, covered entities retained between \$5,749 and \$13,336 per beneficiary for the same drugs because they were able to acquire the drugs using 340B discounts (see Table 3).

Table 3: Acquisition Costs and Payment Differentials Per Beneficiary for Five High-Expenditure Cancer Drugs in 2013

Cancer Drug	Noncovered Entities			Covered Entities		
	2013 Part B Payment Per Beneficiary	2013 Acquisition Cost Per Beneficiary	Spread Between Payment and Acquisition Cost	2013 Part B Payment Per Beneficiary	2013 Acquisition Cost per Beneficiary	Spread Between Payment and Acquisition Cost
1	\$21,671	\$20,895	\$776	\$20,517	\$14,768	\$5,749
2	\$22,767	\$21,865	\$902	\$18,506	\$9,268	\$9,238
3	\$23,900	\$23,046	\$854	\$22,573	\$13,411	\$9,162
4	\$21,662	\$20,898	\$764	\$20,044	\$8,914	\$11,130
5	\$28,653	\$27,694	\$959	\$27,207	\$13,871	\$13,336

Source: OIG analysis of 2013 340B ceiling prices, Part B payment amounts, and NCH claims from the hospital outpatient, DME, and physician-office settings.
 Note: The term "noncovered entities" refers to providers not enrolled in the 340B Program.

Alternative payment methodologies could redistribute the financial benefits of the 340B program among covered entities, Medicare, and Medicare beneficiaries

Medicare and its beneficiaries paid covered entities \$3.5 billion (\$1.3 billion more than acquisition cost) for Part B drugs in 2013. Currently, Medicare and its beneficiaries do not share in the savings resulting from the 340B Program; covered entities retain the entire discount. In response to ongoing policy-level discussions regarding the intersection of 340B and other government programs, we developed three shared-savings scenarios that demonstrate the financial impact on covered entities, Medicare, and Medicare beneficiaries if policymakers were to decide to implement low, medium, or high levels of Medicare participation in 340B cost savings. Under these three scenarios, total Part B drug expenditures for Medicare and its beneficiaries could have been reduced by \$162 million to \$1.1 billion while allowing covered entities to retain from \$211 million to \$1.1 billion (see Table 4).

Payment scenario 1: 100 percent of ASP

Most Part B drugs are paid for at 106 percent of ASP. A cited reason for the 6 percent “add-on” above ASP is to ensure that providers are adequately reimbursed for drug costs.²⁷ If the current 6 percent add-on to ASP for 340B-purchased drugs were removed and Part B payments were instead set at ASP, Medicare expenditures would have been reduced by \$162 million (5 percent) in 2013; \$32 million of this total reduction would have been realized by beneficiaries in the form of reduced coinsurance.²⁸ Under this scenario, covered entities would have still retained \$1.1 billion in the spread between acquisition costs and Part B payments.

Payment scenario 2: Equally shared savings

Paying for 340B-purchased drugs at ASP minus 14.4 percent would have allowed Medicare and covered entities to have equally shared the 340B discount in 2013. In other words, the savings attributable to the 340B prices would have been split evenly between covered entities and Medicare (and its beneficiaries). If Part B had reimbursed covered entities at ASP minus 14.4 percent in 2013, Medicare expenditures would have been reduced by \$638 million (18 percent) while covered entities would have retained \$638 million in the spread between drug acquisition costs and Part B payments. Of the \$638 million in total reduced spending, \$128 million would have been realized by beneficiaries in the form of reduced coinsurance.

Payment scenario 3: 340B ceiling price plus 6 percent of ASP

Under a methodology whereby 340B-purchased drugs would be paid for at the 340B ceiling price plus 6 percent of ASP, covered entities would receive approximately the same spread as they would receive on drugs not purchased at 340B prices (i.e., purchased outside of the 340B Program). The add-on above the ceiling price would be intended to ensure that covered entities are adequately reimbursed for drug costs and that there is not a disincentive for covered entities to provide 340B-purchased drugs to Medicare beneficiaries. Reimbursing covered entities at ceiling price plus 6 percent of ASP would have reduced Medicare expenditures by \$1.1 billion (31 percent) in 2013; \$213 million of this total reduction would have been realized by beneficiaries in the form of reduced

²⁷ U.S. Department of Health and Human Services, *Medicare Part B Reimbursement of Prescription Drugs*, June 2014.

²⁸ In most cases, Part B expenditures for a drug divided by the number of units reimbursed did not exactly equal the payment amount (i.e., 106 percent of ASP) in a given quarter. Therefore, potential expenditures under a “100 percent of ASP” payment scenario would not have been reduced by exactly 6 percent.

coinsurance. Covered entities would have retained \$211 million in the spread between acquisition costs and Part B payments.

Table 4: Potential 2013 Part B Expenditures Under Shared-Savings Payment Scenarios

Payment Scenario	Expenditures for 340B-Purchased Drugs	Reduction in Expenditures (Vs. Current Payment Methodology)	Percentage Reduction in Expenditures for 340B-Purchased Drugs	Beneficiaries' Share of Reduction	Amount Retained by Covered Entities
Current Payment (For Most Drugs, 106 Percent of ASP)	\$3,479,817,670	--	--	--	\$1,276,799,208
100 Percent of ASP	\$3,317,914,493	\$161,903,177	5%	\$32,380,635	\$1,114,896,031
Equal Sharing (ASP Minus 14.4 Percent)	\$2,841,421,124	\$638,396,546	18%	\$127,679,309	\$638,402,662
340B Ceiling Price Plus 6 Percent of ASP	\$2,414,247,516	\$1,065,570,154	31%	\$213,114,031	\$211,229,054

Source: OIG analysis of 2013 340B ceiling prices, Part B payment amounts, and NCH claims from the hospital outpatient, DME, and physician-office settings.

CONCLUSION

Congress created the 340B Program to assist providers serving vulnerable patient populations by allowing them to purchase outpatient drugs at discounted prices. Our findings illustrate the financial benefits that these discounts provide for participating entities. In 2013, covered entities retained \$1.3 billion in Part B payments because of the spread between Medicare payment amounts and 340B ceiling prices. The 340B statute does not restrict how covered entities may use these funds.

Proposals for restructuring the 340B Program have been a topic of significant debate, including the issue of whether Federal insurance programs and their beneficiaries should share in the benefits of the discounted prices. We examined a number of potential payment scenarios that show how Medicare and its beneficiaries, who together spent \$3.5 billion on 340B-purchased drugs in 2013, could share in 340B discounts—something that is not possible under the current design of the 340B Program and Part B payment rules. The payment scenarios explored in this report would have reduced Medicare expenditures for Part B drugs between \$162 million to \$1.1 billion in 2013 while still allowing covered entities to retain between \$211 million and \$1.1 billion in 340B discounts. It is important to note that our analysis was entirely financial. We did not examine the effect these changes would have on covered entities' ability to serve their communities.

OIG has produced an extensive body of work examining the 340B Program from various angles. As stakeholders debate the nature of 340B discounts and whether changes should be made to enable Medicare and/or Medicaid to share in these savings, this report presents an independent analysis to inform the ongoing discussion and to support congressional and Administration decisionmakers' efforts in striking a balance among the needs of these vital programs.

In implementing any changes, it would be essential for any payment methodology to provide enough financial incentives to ensure that covered entities continue to purchase Part B drugs through the 340B Program. Without such incentives, it may be more financially advantageous for covered entities to dispense non-340B drugs to Medicare patients, depriving both the entities and Medicare of the benefits of the 340B Program.

Furthermore, it is also necessary that any payment methodology specifically for 340B-purchased drugs addresses issues in identifying these drugs on Part B claims. Currently, there are no identifiers used on Part B claims that would allow Medicare to identify when a 340B-purchased drug was provided to a beneficiary. Because drugs purchased at 340B prices

are challenging to identify on Medicare claims, CMS may risk incorrectly including or excluding these drugs from a shared-savings payment methodology.

APPENDIX A

Calculation of AMP, URA, and 340B Ceiling Prices

Under their Medicaid drug rebate agreements and pursuant to section 1927(b)(3) of the Act, manufacturers must provide CMS with the AMP for each of their NDCs on a monthly and quarterly basis.^{29, 30} Effective October 2010, ACA revised the definition of “AMP” to be the average price paid to the manufacturer for the drug in the United States by (1) wholesalers for drugs distributed to retail community pharmacies and (2) retail community pharmacies that purchase drugs directly from the manufacturer.

In the Medicaid drug rebate program, drugs are generally categorized as one of three types: single-source, innovator multiple-source, or noninnovator multiple-source. In general terms, a single-source drug would typically be a brand-name product with no available generic versions. An innovator multiple-source drug would typically be a brand-name product that has available generic versions. A noninnovator multiple-source drug would typically be a generic version of any innovator product. Manufacturers provide CMS with the drug category for each of their NDCs in conjunction with AMP data.

Manufacturers of single-source and innovator multiple-source drugs must also provide CMS with the “best price” for each NDC.³¹ “Best price” is defined in section 1927(c)(1)(C) of the Act as the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions. Manufacturers of noninnovator multiple-source drugs are not required to provide best prices for those NDCs.

For rebate purposes, manufacturers must provide AMP and best-price data to CMS within 30 days of the end of each quarter.³² CMS uses this information to calculate a URA every quarter for each NDC included in the Medicaid drug rebate program. Pursuant to section 1927(c) of the Act, the formula used to calculate the URA depends on the drug category

²⁹ For Federal financial participation to be available for covered outpatient drugs provided under Medicaid, manufacturers must enter into rebate agreements with the Secretary of Health and Human Services and pay quarterly rebates to State Medicaid agencies. Sections 1927(a)(1) and (b)(1) of the Act.

³⁰ Section 1927(b)(3) of the Act. See also 42 CFR § 447.510.

³¹ Section 1927(b)(3)(A)(i)(II) of the Act.

³² 42 CFR § 447.510(a).

reported by the manufacturer. The basic URA for a noninnovator multiple-source drug is 13 percent of the AMP. The basic URA for a single-source or innovator multiple-source drug is the greater of 23.1 percent of the AMP or the difference between the AMP and best price.³³ In addition, for drugs approved exclusively for pediatric indications and certain blood-clotting factors, the basic rebate is the greater of 17.1 percent of AMP or the difference between the AMP and the best price. If the AMP for a brand-name drug has risen faster than inflation, the drug's manufacturer must pay an additional rebate over and above the basic URA.³⁴

The AMP and URA used in the 340B ceiling price formula are based on the lowest identifiable amount of each drug, such as a tablet, capsule, or milliliter.³⁵ Therefore, the 340B ceiling price applies to each unit of the drug that the covered entity purchases—for example, \$1 per pill. To implement the 340B requirements in practice, the per-unit 340B ceiling price must be multiplied by the drug package size at which covered entities purchase drugs—for example, a bottle of 100 tablets.

HRSA calculates 340B ceiling prices each quarter. However, because of confidentiality provisions related to pricing data, the agency does not share 340B ceiling prices with covered entities; effectively, the covered entities must rely on manufacturers to charge the appropriate amount for eligible drug purchases.^{36, 37} If a manufacturer fails to sell eligible drugs to covered entities at or below the 340B ceiling price, it may be required to

³³ Section 1927(c) of the Act.

³⁴ Section 1927(c)(2) of the Act. To determine whether a brand-name drug is subject to the increased rebate amount, CMS compares the reported AMP for a given quarter to its inflation-adjusted baseline AMP. The baseline AMP for a drug is the AMP for the first quarter after the drug's initial market date. To adjust the baseline AMP for inflation, CMS first divides the baseline AMP by the baseline consumer price index for all urban consumers (consumer price index), which is the consumer price index for the first month prior to the first quarter after the drug's initial market date. The result of that calculation is then multiplied by the quarterly consumer price index, which is the consumer price index for the month prior to the quarter being calculated. If the reported AMP is greater than the inflation-adjusted baseline AMP, then the difference is added to the URA.

³⁵ *Sample Medicaid Drug Rebate Agreement*, Section I, accessed at <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/samplerbateagreement.pdf> on March 6, 2014. See 77 Fed Reg. 5318, 5328 (Feb. 2, 2012).

³⁶ Section 1927(b)(3)(D) of the Act.

³⁷ In May 2015, HRSA announced that covered entities will have access to a new 340B pricing system that would allow them to view 340B ceiling prices. See <http://www.hrsa.gov/opa/updates/2015/may.html>. At the time of our review, this system had not been implemented.

reimburse for discounts withheld and can be terminated from both the 340B Program and the Medicaid drug rebate program.³⁸

³⁸ 42 U.S.C. § 256b(d)(1)(B)(ii); Section 1927(b)(4)(B) of the Act.

APPENDIX B

Medicare Part B Payments for Prescription Drugs

Medicare beneficiaries can receive Part B drugs through hospital outpatient departments, physicians' offices, and DME suppliers.

Payments in the hospital outpatient setting. Medicare pays most hospital outpatient departments for Part B drugs on the basis of ASPs, but only when the drugs are considered "separately payable."^{39, 40} A drug is separately payable when (1) its estimated per-drug, per-day costs are greater than \$80 (for 2013), or (2) it has been granted "pass-through" status by CMS, regardless of whether the cost exceeds the \$80-per-day packaging threshold.^{41, 42, 43} In contrast, "packaged drugs" are inexpensive Part B drugs that do not exceed the packaging threshold and are also not pass-through drugs. CMS does not make separate payments for packaged drugs; it includes payment for these drugs as part of the payment for the treatment during which the drugs are administered.⁴⁴

The Act does not define a set payment methodology (e.g., 106 percent of ASP) for certain separately payable drugs administered in a hospital outpatient setting. Rather, through the rulemaking process, CMS annually updates the ASP-based payment methodology for separately payable drugs that are not pass-through drugs, and publishes a quarterly file on its Web site listing payment amounts for these drugs. For 2013, CMS set the Medicare payment amount for non-pass-through separately payable drugs

³⁹ CAHs; certain hospitals in Maryland; hospitals located outside one of the 50 States, the District of Columbia, and Puerto Rico; and hospitals of the Indian Health Service are not paid on the basis of ASPs. They are excluded from OPPS and are paid at cost. 42 CFR § 419.20(b).

⁴⁰ *Medicare Claims Processing Manual*, ch. 4 § 10.3.

⁴¹ 77 Fed. Reg. 68210, 68377 (Nov. 15, 2012).

⁴² Section 1833(t)(6)(A) of the Act provides for temporary additional payments, or "transitional pass-through payments," for certain drugs, including new drugs and "orphan" drugs. Section 1833(t)(6)(A)(i) of the Act defines orphan drugs as drugs that are used for a rare disease or condition with respect to which the drug has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act.

⁴³ The "packaging threshold" refers to the "packaging" of payment for dependent, ancillary, supportive, and adjunctive items and services into the payment for the primary independent service. In 2013, drugs with a per-day cost of less than or equal to \$80 were packaged under the service with which the drug was administered.

⁴⁴ CMS, *Hospital Outpatient Prospective Payment System*, December 2014.

at 106 percent of the volume-weighted ASP.⁴⁵ The payment method for pass-through drugs was equal to 106 percent of ASP in 2013.⁴⁶ Medicare beneficiaries are responsible for 20 percent of Medicare payments in coinsurance.

Payments in the physician-office and DME supplier settings. Medicare also pays physicians and DME suppliers for most Part B covered drugs using a methodology based on ASPs.⁴⁷ Payment amounts for most Part B drugs are statutorily set at 106 percent of the volume-weighted ASPs. Each quarter, CMS publishes on its Web site a payment-amount file that includes payment amounts for drugs that could be billed in the physician-office and/or DME setting. Likewise, DME Medicare Administrative Contractors (MACs) also publish each quarter on their Web sites payment-amount files for drugs that could be billed in the DME setting.

⁴⁵ 77 Fed. Reg. 68216 (Nov. 15, 2012). Part B claims dated on or after April 1, 2013, incur a 2-percent reduction in payment in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (i.e., sequestration). This mandatory payment reduction is applied after the beneficiary's coinsurance has been determined, resulting in a payment rate for most Part B drugs of 104.3 percent of the volume-weighted ASP. For further explanation, see <http://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/downloads/2013-03-08-standalone.pdf>.

⁴⁶ 77 Fed. Reg. 68210, 68367 (Nov. 15, 2012).

⁴⁷ Several Part B drugs, including certain vaccines, blood products, and DME infusion drugs, are paid for on the basis of AWP and not on the basis of ASPs. Sections 1847A(a)(1) and 1842(o)(1) of the Act. See also *Medicare Claims Processing Manual*, ch. 17 § 20.1.3.

APPENDIX C

Detailed Methodology

Data Sources and Collection

Part B Payment Amounts and ASPs. We used CMS's first-quarter 2013 through second-quarter 2014 payment amount files to obtain the ASP-based payment amounts in the hospital outpatient, DME, and physician-office settings and to calculate ASPs for Part B HCPCS codes.⁴⁸ We used CMS's 2013 quarterly payment amount files and DME MACs' quarterly 2013 payment files to obtain AWP-based payment amounts for each DME infusion HCPCS code under review.⁴⁹

ASP Data. We obtained from CMS the quarterly ASP background files for the third and fourth quarters of 2012 and the first and second quarters of 2013 on which 2013 ASP-based payment amounts were based.⁵⁰ The background files link ASP-based HCPCS codes to the related NDCs included in the ASP calculation, including a determination of how many units of a given NDC are represented by the HCPCS code. We also obtained from the background files the quarterly ASPs and number of units sold as reported by manufacturers for all NDCs associated with the relevant HCPCS codes. Because there is a two-quarter lag between the sales period for which ASPs are reported and the effective date of the Part B payment amounts, we obtained background files for the third and fourth quarters of 2012 and the first and second quarters of 2013.

Paid Part B Claims. On April 29, 2014, we obtained from the NCH all 2013 paid claims (i.e., claims from the hospital outpatient, physician-office, and DME settings) for all drug HCPCS codes to

⁴⁸ Because there is a two-quarter lag between the sales period for which ASPs are reported and the effective date of the Part B payment amounts, we obtained first-quarter and second-quarter 2014 payment amount files to calculate ASPs for the third quarter and fourth quarter of 2013.

⁴⁹ DME infusion drugs are paid for on the basis of ASPs if they were compounded or furnished incident to a professional service. Otherwise, they are paid on the basis of AWPs that were in effect on October 1, 2003. See section 1842(o)(1)(D)(i) of the Act and *Medicare Claims Processing Manual*, ch. 17 § 20.1.3.

⁵⁰ Because Medicare Part B reimbursement for outpatient drugs is based on HCPCS codes rather than on NDCs and more than one NDC may meet the definition of a particular HCPCS code, CMS has developed the background file and the crosswalk file to "crosswalk" NDCs to their matching HCPCS codes. Both files are released quarterly by CMS and CMS uses information in these files to calculate volume-weighted ASPs for covered HCPCS codes; however, the background file is not publicly available because it contains manufacturer-reported information on ASPs and units sold.

determine quarterly utilization and spending.^{51, 52} To identify the providers who billed and received payments, we obtained provider identifiers listed on each claim (i.e., NPIs and TINs).⁵³

Covered Entities Database. We obtained the covered entities database from HRSA on April 3, 2014, and used it to identify covered entities eligible to purchase drugs at 340B prices in 2013. The 340B Program requires each location (i.e., covered entity site) to be registered individually in HRSA's covered entities database.⁵⁴ We obtained NPIs, Medicare Provider Numbers, Medicaid Provider Numbers, and HRSA-assigned identification numbers for covered entity sites listed in the covered entities database.

For each covered entity site, we used the covered entities database to obtain the participation start and termination dates and the codes for covered entity type (e.g., CAH, DSH).⁵⁵

Medicaid Exclusion File. We obtained the Medicaid Exclusion File from HRSA on May 26, 2015, to identify covered entity sites that should not use 340B-purchased drugs for their Medicaid patients (i.e., covered entities that use the “carve out” approach), including for Medicare/Medicaid dual-eligibles.

Medicare Enrollment Database. We obtained the Medicare beneficiary enrollment database from CMS to identify dual-eligible beneficiaries.

Medicare Provider Enrollment, Chain, and Ownership System. We used the Medicare Provider Enrollment, Chain, and Ownership System

⁵¹ Previous OIG work showed that the number of units listed in claims for blood-clotting factors often underrepresent the actual number of HCPCS units reimbursed by a substantial margin. We calculated the correct number of Medicare units by dividing the total Part B spending in each setting by the Part B payment amount in each quarter in that particular setting. See OIG, *Medicare Could Collect Billions if Pharmaceutical Manufacturers Were Required to Pay Rebates for Part B Drugs*, OEI-12-12-00260, September 2013.

⁵² Hospital outpatient claims refer to any claims in the NCH institutional outpatient file, which includes not only hospitals but also entities such as clinics or health centers. We only included hospital outpatient claims if they were paid under OPSS. Therefore, CAHs; certain hospitals in Maryland; hospitals located outside one of the 50 States, the District of Columbia, and Puerto Rico; and hospitals of the Indian Health Service were excluded from our analysis because they are excluded from OPSS.

⁵³ The NPI is a unique 10-digit identification number for health care providers (both individual providers and organizational providers). On DME and physician claims, the TIN represents the entity that received payment from Medicare.

⁵⁴ HRSA, *340B Hot Topics*. Accessed at <http://www.hrsa.gov/opa/updates/august2014.html> on February 18, 2015.

⁵⁵ HRSA, *340B Program Acronyms for Covered Entity Types and/or Grantees*. Accessed at <http://opanel.hrsa.gov/opa/CoveredEntityAcronyms.aspx> on February 18, 2015.

(PECOS) to obtain the names and addresses of organizations associated with TINs listed on paid drug claims from DME and physician-office settings.

National Plan and Provider Enumeration System. We used the National Plan and Provider Enumeration System (NPPES) to identify NPIs that had been “crosswalked” to Medicare Provider Numbers and Medicaid Provider Numbers listed in the covered entities database.⁵⁶

340B Ceiling Price, AMP, and URA Data. For every NDC associated with the HCPCS codes under review, we obtained from HRSA the 340B ceiling prices that were in effect in each quarter of 2013. We also obtained from HRSA and CMS the manufacturer-reported AMPs and Medicaid URAs on which 340B ceiling prices were based.

Data Analysis

Selection of NDCs Used in Payment Amount Calculations. A total of 636 HCPCS codes paid for on the basis of ASPs were listed in CMS’s 2013 quarterly payment amount files. Using CMS’s quarterly ASP background files, we selected the NDCs that were used to calculate the ASP-based Part B payment amounts for 2013 for each of the 636 HCPCS code under review. We removed 68 HCPCS codes because none of the associated NDCs had ASPs that were included in payment-amount calculations.⁵⁷

Calculation of HCPCS Code 340B Ceiling Prices. 340B ceiling prices (i.e., the maximum amount that covered entities pay for 340B-purchased drugs) are calculated for the entire package of a drug represented by the NDC. Because units of a drug represented by an NDC often differ from the units of a drug represented by a HCPCS code, we converted the 340B ceiling price for each NDC under review to HCPCS code units.⁵⁸ We first divided HRSA’s per-package 340B ceiling price by the package size to calculate a per-unit 340B ceiling price for each NDC. If HRSA-reported 340B ceiling prices were not available, we used manufacturer-reported AMPs and URAs to calculate the NDC’s per-unit 340B ceiling price using the statutory formula (i.e. AMP minus URA). We then multiplied the

⁵⁶ CMS issued NPIs beginning in 2005 to meet a requirement of the Health Insurance Portability and Accountability Act of 1996. The NPI was implemented as a single national identifier for use in standard electronic health care transactions; it was meant to replace Medicaid Provider Numbers, Medicare Provider Numbers, and other identifiers that providers use to bill specific health plans.

⁵⁷ The ASPs associated with these NDCs were either not reported by manufacturers or were deemed unusable by CMS.

⁵⁸ Because 340B ceiling prices are the maximum price a manufacturer should charge covered entities, they serve as a proxy for covered entities’ drug acquisition costs.

per-unit 340B ceiling price by the total number of units of a drug contained in the HCPCS code to calculate a 340B ceiling price per HCPCS unit for each NDC.

We removed 74 HCPCS codes because none of their associated NDCs had a 340B ceiling price, AMP, or URA. We removed an additional four HCPCS codes because of concerns about the accuracy of pricing data.

We then calculated a weighted 340B ceiling price for each of the 490 remaining HCPCS codes. We used CMS's 2013 quarterly ASP background files to determine the percentage of total sales that each associated NDC represented within a HCPCS code (i.e., one NDC represented 10 percent of total sales, another NDC represented 15 percent), and then weighted each NDC's 340B ceiling price by this percentage to determine an overall 340B ceiling price for each HCPCS code in every quarter.

Identifying Covered Entities Enrolled in the 340B Program. Using the participation start and termination end dates listed in HRSA's covered entities database, we removed covered entity sites that were not enrolled in the 340B Program in at least one quarter of 2013. There were 25,039 covered entity sites that participated in the 340B Program for at least one quarter of 2013.⁵⁹

Identifying Hospital Outpatient Claims Associated With Covered Entities. We obtained paid hospital outpatient claims for the 490 HCPCS codes under review. Because Part B claims do not identify whether the claim is for a 340B-purchased drug, we obtained the NPIs of covered entity sites from HRSA's database. If a covered entity site did not have an NPI listed in HRSA's database, we used NPDES to crosswalk its Medicare Provider Numbers and Medicaid Provider Numbers (i.e., alternate identifiers) to NPIs. A Medicaid Provider Number or Medicare Provider Number may be associated with multiple NPIs, and a covered entity may not use all NPIs to bill Medicare for 340B-purchased drugs. Because there was no way to identify the specific NPI that a covered entity site uses to bill Medicare for 340B-purchased drugs, we kept covered entity sites in our analysis of 340B hospital expenditures only if they were associated with a single NPI.

Because some covered entities (typically nonhospitals) are not required to provide their NPIs or alternate identifiers to HRSA upon applying to participate in the 340B Program, 7,688 covered entity sites enrolled in the 340B Program in 2013 did not have an NPI or alternate identifier listed in

⁵⁹ We included a covered entity site in our analysis in a particular quarter if it was enrolled in the 340B Program for the *entire* quarter.

the covered entities database. After we removed covered entity sites with identifiers that crosswalked to multiple NPIs, covered entity sites with identifiers that did not crosswalk to any NPIs, and covered entity sites with no identifiers listed in the database, 14,878 covered entity sites remained in our analysis of 340B hospital outpatient expenditures (see Table 5). We matched the NPIs associated with these covered entity sites to hospital outpatient claims.

Table 5: Summary of Covered Entities Included in 340B Hospital Outpatient Expenditure Analysis

Whether Included in Analysis	Reason	Number of Covered Entity Sites
Included in analysis	NPI listed in database	9,014
	Alternate identifier crosswalked to a single NPI	5,864
	Total included in analysis	14,878
Not included in analysis	Alternate identifier crosswalked to multiple NPIs	1,772
	Alternate identifier not crosswalked to any NPIs	701
	No NPI or alternate identifier listed in database	7,688
	Total excluded from analysis	10,161
TOTAL ENROLLED IN THE 340B PROGRAM IN 2013		25,039

Source: OIG analysis of NPPES and HRSA's covered entities database downloaded on April 3, 2014.

Identifying DME and Physician-Office Claims Associated With Covered Entities. We obtained paid DME and physician claims for the 490 HCPCS codes under review. Resource constraints required that we select a sample of claims. Therefore, we selected all claims for providers that constituted 95 percent of spending in the physician-office setting and claims for providers that constituted 98 percent of spending in the DME setting.

Although physicians are not considered covered entities, a previous study found that physicians associated with covered entities may bill Part B with their personal NPIs and organizational TINs instead of the covered entities' NPIs (i.e., the physician performs the service, but the entity receives the payment).^{60, 61} Because physicians do not individually register with the 340B Program, their personal NPIs would not be in HRSA's database of covered entities. To identify drug claims submitted by

⁶⁰ OIG, *Medicare Could Collect Billions if Pharmaceutical Manufacturers Were Required to Pay Rebates for Part B Drugs*, OEI-12-12-00260, September 2013.

⁶¹ On Part B physician and DME claims submitted by a physician or supplier associated with a covered entity, the TIN represents the entity that received payment from Medicare.

covered entities in nonhospital outpatient settings, we obtained the organizational TIN on each physician-office and DME drug claim included in our analysis. We then matched the TINs to PECOS to obtain the associated name and address of the organization for which the physician is an employee. Finally, we matched the name and address of the organization to HRSA’s covered entities database to determine whether each organization that submitted a paid claim is a covered entity. We manually checked each match to ensure that the TIN represents a covered entity.

Identifying Claims for Drugs Not Eligible for 340B Pricing. After removing HCPCS codes with no paid Part B claims in our sample, we identified claims submitted by “carve-out” covered entities for dual-eligible beneficiaries. Drugs listed on these claims should not have been purchased at 340B prices. We first matched hospital outpatient, DME, and physician-office claims submitted by covered entities to the Medicaid Exclusion File using HRSA-assigned identification numbers associated with each provider for covered entity sites. Covered entities not listed in the Medicaid Exclusion File are carve-out covered entities. We then identified whether the claims submitted by carve-out covered entities were for dual-eligible beneficiaries by matching Medicare Health Insurance Claim Numbers (HICs) on the claims to the Medicare beneficiary enrollment database.

We also removed claims for six vaccine HCPCS codes because vaccines are not eligible for 340B pricing.⁶² Claims for 472 HCPCS codes accounting for 86 percent (\$19 billion) of total Part B drug expenditures in 2013 remained in our analysis (see Table 6).

Table 6: Summary of Part B Drug HCPCS Codes Included in Analysis

Description	Number of HCPCS Codes
HCPCS codes paid on the basis of ASPs in at least one setting	636
After removing NDCs excluded from payment amount calculations	568
After removing HCPCS codes for which 340B ceiling prices could not be calculated	494
After removing NDCs with potentially inaccurate pricing data	490
HCPCS codes with Part B expenditures in our sample	478
After removing 6 HCPCS codes representing vaccines	472

⁶² Vaccines are not considered to be covered outpatient drugs for purposes of the Medicaid drug rebate program. See, e.g., Section 1927(k)(2) of the Act. Accordingly, they are not subject to the 340B program. 42 U.S.C. § 256b(b)(2).

Source: OIG analysis of quarterly 2013 Part B payment amount files, CMS and HRSA pricing data, and 2013 NCH claims from the hospital outpatient, DME, and physician-office settings.

Summarizing Part B Spending for 340B-Purchased Drugs. We divided claims for the 472 HCPCS codes into two groups based on whether the claims represented 340B or non-340B purchases. We compared 2013 hospital outpatient, DME, and physician-office expenditures for 340B-purchased drugs and non-340B drugs.

Comparison of 340B Ceiling Prices to Part B Payment Amounts. For each HCPCS code with 340B expenditures, we calculated the percentage difference between the code's quarterly payment amount in each setting (i.e., hospital outpatient, DME, and physician office) and its 340B ceiling price. We then calculated a median difference across all quarters to determine the annual percentage difference between Part B payment amounts and 340B ceiling prices for each individual HCPCS code.

For each quarter, we also estimated the aggregate difference between 340B ceiling prices and Medicare payment amounts among all codes by multiplying each HCPCS code's 340B utilization by its 340B ceiling price (i.e., the estimated drug acquisition cost for covered entities), summing the quarterly estimates, and comparing the result to Part B 340B expenditures.

Comparing Estimated Acquisition Costs Per Beneficiary For HCPCS Codes Representing High-Expenditure Cancer Drugs. We examined the highest expenditure Part B HCPCS codes in 2013 and determined that 7 of the 11 highest expenditure drugs are used in chemotherapy. Therefore, we selected a purposive sample of five high-expenditure HCPCS codes representing cancer drugs.⁶³ For each HCPCS code, we compared the acquisition costs for covered entities to those for other providers. To estimate how much covered entities spent per beneficiary to acquire the cancer drugs, we multiplied each HCPCS code's quarterly 340B ceiling price by the number of 340B units and divided the result by the total number of beneficiaries who received the 340B-priced drug in 2013.^{64, 65}

We also estimated how much providers not participating in the 340B Program (i.e., noncovered entities) paid to acquire the same high-expenditure drugs. Because ASPs are based on actual sales in the marketplace, we concluded that they provide a reasonable estimate of acquisition costs for noncovered entities. For each quarter, we divided

⁶³ Expenditures for each HCPCS code were at least \$300 million in 2013.

⁶⁴ To avoid duplication, when calculating per-beneficiary acquisition costs and per-beneficiary Part B expenditures, we removed claims for beneficiaries who received the drug from both a covered entity and a provider not enrolled in the 340B Program.

⁶⁵ Average units per beneficiary were approximately equal between covered entities and providers not enrolled in the 340B Program.

each HCPCS code's quarterly ASP-based payment amount by 1.06 to calculate ASPs.⁶⁶ We then multiplied each HCPCS code's quarterly ASP by non-340B utilization and divided the result by the number of beneficiaries who received the nondiscounted drug to estimate how much noncovered entities spent per beneficiary to acquire the drug. We conducted this analysis for each quarter of 2013 and summed the quarterly results. For each HCPCS code, we calculated the difference between acquisition costs for covered entities and noncovered entities.

We then estimated the difference between Part B payments and acquisition costs for covered entities and noncovered entities for each cancer drug. We calculated how much covered entities received per Medicare beneficiary for the cancer drugs by dividing 340B expenditures for each HCPCS code by the number of beneficiaries that received the 340B-priced drug. We calculated how much noncovered entities received per Medicare beneficiary by dividing non-340B expenditures for each HCPCS code by the number of beneficiaries that received the non-discounted drug.

Calculation of Spending Reductions Under a "Shared Savings" Model.

We determined pricing point options that would have allowed Medicare to share varying portions of the 340B discount in 2013 while keeping with the ASP-based payment methodology framework in Part B. We calculated the following pricing point scenarios under a "shared savings" model: (1) volume-weighted ASP (i.e., 100 percent of ASP), (2) volume-weighted ASP minus 14.4 percent, and (3) 340B ceiling price plus 6 percent of volume-weighted ASP.

- Volume-weighted ASP. We multiplied each HCPCS code's ASP by its 340B utilization to determine how much would have been spent if payments for 340B-purchased drugs had been set at 100 percent of the HCPCS code's volume-weighted ASP.⁶⁷
- ASP minus 14.4 percent. Under the current Part B payment methodology, covered entities retain the entire savings attributable to the 340B Program. We examined expenditures under a payment model that would allow Medicare and covered entities to equally share in the 340B discounts. We first divided in half the spread between total Part B payments for 340B-purchased drugs and

⁶⁶ There is a two-quarter lag between the time when ASP sales occur and when Medicare payment amounts reflect those sales. As a result, ASPs in a given quarter were calculated using ASP-based payment amounts from two quarters later (e.g., fourth-quarter 2013 ASPs were calculated by dividing second-quarter 2014 payment amounts by 1.06).

⁶⁷ We calculated ASPs by dividing 2013 payment amounts by 1.06. In a small number of instances (six per quarter, at most), a drug's ASP-based payment amount was set at 103 percent of the average manufacturer price rather than at 106 percent of the ASP. In these cases, we divided the payment amount by 1.03.

acquisition costs for those drugs to estimate how much covered entities would retain under a payment model for equal sharing of savings. We determined that Medicare would need to pay covered entities for 340B-purchased drugs at ASP minus 14.4 percent to achieve this new spread. We calculated each HCPCS code's quarterly payment amount under the ASP minus 14.4 percent methodology using CMS's payment amount file and multiplied the revised payment amount by the HCPCS code's 340B utilization for each quarter of 2013.

- 340B ceiling price plus 6 percent of ASP. We estimated how much Part B would pay for 340B-purchased drugs if it had paid at the 340B price plus the same add-on that noncovered entities receive for Part B drugs. For each quarter, we calculated each HCPCS code's quarterly payment amount under the 340B ceiling price plus 6 percent of ASP by multiplying each HCPCS code's ASP by .06 and adding the result to the HCPCS code's ceiling price.⁶⁸ We then multiplied each HCPCS code's revised payment amount by its 340B utilization for each quarter of 2013.

We conducted this analysis for each quarter and then summed the results to estimate potential 2013 expenditures under each pricing point. We calculated the difference between potential expenditures under each pricing point and actual Part B 340B expenditures to determine how much total Part B spending for 340B-purchased drugs could have been reduced by in 2013. We calculated 20 percent of potential spending reductions to estimate how much beneficiaries' total coinsurance payments could have been lowered under each pricing point. Finally, we estimated how much above cost Part B would have paid covered entities under each pricing point by subtracting total acquisition costs from potential expenditures.

Limitations

We did not review Part B claims, pricing data, or covered entity enrollment data for accuracy. Because there is no identifier on Part B claims indicating that a drug was purchased through the 340B Program, we could not confirm that claims submitted by covered entities were in fact for drugs purchased at or below the 340B discount price.

We eliminated from our analysis of 340B expenditures in the hospital outpatient setting more than 10,000 covered entity sites listed in the covered entities database because we could not identify the NPIs with which covered entities would bill Part B in the hospital outpatient setting.

⁶⁸ Because we did not have access to actual 340B prices paid by covered entities, we used 340B ceiling prices as proxies for the drug costs.

As a result, any claims for 340B-purchased drugs potentially made by these covered entities were not included in our estimates. Furthermore, we used 340B ceiling prices (i.e., the maximum amount that a covered entity paid a manufacturer to acquire a drug) instead of actual 340B prices in our calculations. For example, covered entities that participate in the Prime Vendor Program purchase drugs at an average discount of 10 percent below the 340B ceiling price.⁶⁹ As a result, we may have overestimated covered entities' acquisition costs and underestimated potential payment reductions under a shared-savings methodology by approximately 10 percent.

Under the PHS Act, drugs with “orphan” designations are excluded from the 340B Program for newly eligible covered entity types (certain children’s hospitals, certain freestanding cancer hospitals, CAHs, rural referral centers, and sole community hospitals).⁷⁰ At the time of our review, the Act was interpreted to require manufacturers to offer certain covered entities 340B pricing on drugs that had received an orphan designation when those drugs were used to treat conditions other than those for which they received their orphan designation.⁷¹ Because (1) we could not determine the indication for which a drug was administered, (2) there are complexities in crosswalking the names of orphan drugs to the 420 drug HCPCS codes with 340B expenditures in 2013, and (3) payments to the newly eligible covered entity types did not account for a significant portion of Part B drug spending, we did not remove orphan drugs from our analysis for these types of covered entities.

Under sequestration, the effective payment rate for Part B drugs was reduced between 1 and 2 percent after April 1, 2013.⁷² Neither the published payment amounts nor expenditure data reflect these reductions. Therefore, we did not take any sequestration-related payment reductions into account when comparing 340B ceiling prices to Part B payment amounts or when estimating expenditure decreases under a revised payment methodology for 340B-purchased drugs.

We included 472 HCPCS codes accounting for 86 percent (\$19 billion) of total Part B expenditures in our review. Findings related to the purposive

⁶⁹ U.S. Department of Health and Human Services, *HRSA FY2015 Budget Justification*.

⁷⁰ Section 340B(e) of the PHS Act. (For more on “orphan” drugs, see footnote 42, p. 15.)

⁷¹ HRSA, *Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program*. HRSA’s interpretation was struck down in Federal court on October 14, 2015, and the interpretive rule has been vacated.

⁷² CMS, “Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program—‘Sequestration’,” *CMS Medicare FFS Provider e-News*, March 8, 2013. Accessed at <http://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/downloads/2013-03-08-standalone.pdf> on April 10, 2015.

sample of 472 HCPCS codes cannot be generalized to all Part B drug HCPCS codes.

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