

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE PART D REBATES FOR
PRESCRIPTIONS FILLED AT 340B
CONTRACT PHARMACIES**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



**Joanne M. Chiedi
Acting Inspector General**

July 2019
A-03-16-00002

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nation-wide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the healthcare industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: July 2019

Report No. A-03-16-00002

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

Congress created the 340B Drug Pricing Program to assist providers serving vulnerable patient populations by allowing them to purchase outpatient drugs at discounted prices. For drugs dispensed to Medicare Part D beneficiaries for payment under the Part D program, manufacturers may pay rebates based on rebate agreement terms negotiated between the manufacturers and the Part D prescription drug plan sponsors or their pharmacy benefit managers. Rebate agreement terms may prevent manufacturers from paying rebates for Part D prescriptions filled at 340B contract pharmacies.

Our objective was to determine the rebate amount that could have been generated had pharmaceutical manufacturers and Part D sponsors agreed that prescriptions for Part D beneficiaries filled at 340B contract pharmacies would generate rebates for those sponsors.

How OIG Did This Review

We reviewed 68 sponsors whose prescription drug events (PDEs) represented 75 percent of the 340B pharmacy PDEs in 2014 and requested a list of the 2014 Part D claims for which the manufacturer did not pay a rebate because the claim was filled at a 340B contract pharmacy. We requested that the sponsors calculate the rebate amounts that would have been paid for the 2014 contracts had the prescription been filled at a non-340B pharmacy.

Medicare Part D Rebates for Prescriptions Filled at 340B Contract Pharmacies

What OIG Found

We determined that tens of millions of dollars in rebates could have been generated had manufacturers and sponsors agreed that eligible prescriptions filled at 340B contract pharmacies would receive rebates. If the Part D prescriptions for the sponsors in our review had been filled at non-340B pharmacies, sponsors calculated that manufacturers would have paid rebates of up to \$74.7 million for 554,549 claims in 2014. The manufacturers did not pay these rebates because, as sponsors reported, rebate agreements did not require manufacturers to pay rebates for Part D drugs filled at a 340B contract pharmacy.

We also found that because there are no 340B identifiers on claims and PDE records, sponsors do not have the data to distinguish whether prescriptions dispensed at a 340B contract pharmacy were filled using 340B drugs. Therefore, the possible additional rebate amount of up to \$74.7 million is for both 340B and non-340B drugs filled at a 340B contract pharmacy for Part D beneficiaries.

There is an opportunity to potentially reduce Part D costs if sponsors were to negotiate similar net prices for both non-340B drugs dispensed by 340B contract pharmacies and drugs dispensed by non-340B pharmacies.

What OIG Recommends

This report contains no recommendations. We provide this report to inform congressional and administration decisionmakers of the impact that drugs dispensed at 340B contract pharmacies may have on the Part D program.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Review	1
Objective	1
Background	2
The Medicare Part D Program	2
The 340B Drug Pricing Program	3
How We Conducted This Review	5
RESULTS OF REVIEW	6
Some Manufacturer-Sponsor Rebate Agreements Prohibited Sponsors From Receiving Rebates for All Prescriptions Filled at a 340B Pharmacy	7
Sponsors Did Not Have Data To Identify When a 340B Drug Was Dispensed to a Part D Beneficiary	7
The Type of Pharmacy Used To Fill a Prescription Affected the Cost to the Part D Program When Rebate Agreements Contained 340B Rebate Prohibition Language.....	8
CONCLUSION.....	9
CMS AND HRSA COMMENTS	10
APPENDICES	
A: Audit Scope and Methodology	11
B: Related Office of Inspector General Reports.....	13

INTRODUCTION

WHY WE DID THIS REVIEW

Congress created the 340B Drug Pricing Program (340B program) to assist providers serving vulnerable patient populations by allowing the providers to purchase outpatient drugs at discounted prices. Medicare Part D is an optional program to help Medicare beneficiaries pay for prescription drugs. For drugs dispensed to Part D beneficiaries for payment under the Part D program, manufacturers may pay rebates based on rebate agreement terms negotiated between the manufacturers and the Part D prescription drug plan sponsors or their pharmacy benefit managers (PBMs).¹

Rebate agreements may include terms that excuse manufacturers from having to pay rebates to sponsors or their PBMs for drugs if those manufacturers already provided a discount for those drugs under the 340B program. However, Part D claims and prescription drug event (PDE) records lack information that would help sponsors and manufacturers identify whether the specific drug units dispensed to a Part D beneficiary were purchased under the 340B program. In addition, rebate agreements may exclude payment of rebates for all drugs dispensed by a 340B covered entity's in-house or contract pharmacy) instead of prohibiting rebates for just 340B drugs.² This audit reviews the extent to which Part D sponsors did not receive Part D rebates due to these agreements because prescriptions were filled by 340B pharmacies for contract year 2014.^{3,4}

OBJECTIVE

Our objective was to determine the rebate amount that could have been generated had pharmaceutical manufacturers and Part D sponsors agreed that prescriptions for Part D beneficiaries filled at 340B contract pharmacies would generate rebates for those sponsors.

¹ Commonly referred to as the non-interference clause, section 1860D-11(i) of the Social Security Act prohibits the Department of Health and Human Services (HHS) Secretary from interfering with the negotiations between drug manufacturers, pharmacies, and Part D sponsors and from instituting a price structure for reimbursement of covered Part D drugs.

² 340B drugs are drug units purchased at a discounted price under the 340B program.

³ The Office of Inspector General (OIG) has published a series of reviews on 340B pricing, but none of the previous reviews focused on Medicare Part D. See Appendix B for a listing of previous OIG reports on the 340B program.

⁴ This work, conducted from June 2016 through January 2017, pre-dates the publication on February 6, 2019, of the Department's Notice of Proposed Rulemaking entitled "Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Services Fees" (84 F.R. 2340 (Feb. 6, 2019)). As of the date of publication of this report, this proposed rule has not been finalized.

BACKGROUND

The Medicare Part D Program

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act by establishing the Medicare Part D prescription drug program. Under Part D, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage.

To provide prescription drug benefits under Part D, the Centers for Medicare & Medicaid Services (CMS) contracts with private entities called sponsors that act as payers and insurers. Sponsors provide a minimum set of prescription benefits through a stand-alone prescription drug plan or as part of a managed care plan known as a Medicare Advantage prescription drug plan.

Relationships Between Part D Sponsors and Pharmacies

Under Part D, sponsors may contract with PBMs to manage or administer the drug benefit on the sponsor's behalf. Sponsors or their PBMs establish a pharmacy network and negotiate pharmacy reimbursement rates. Reimbursement to pharmacies is usually based on an average wholesale price less a negotiated percentage; the price the pharmacy pays for these drugs is usually based on the wholesale acquisition cost and is generally not accounted for in the reimbursement price.

Relationships Between Part D Sponsors and Drug Manufacturers

Sponsors or their PBMs often negotiate rebates with manufacturers to reduce drug costs. The rebates are not required by law, but manufacturers typically negotiate and pay the rebates to secure preferred placement on a sponsor's drug formulary. Rebates are often paid based on utilization of the manufacturer's product, and the rebate amount is typically based on the wholesale acquisition cost.

Sponsors report rebates annually to CMS on their Direct and Indirect Remuneration Report (DIR report).⁵ CMS uses the DIR report and other sponsor-submitted data to determine the total cost of Part D drugs to sponsors. CMS then reconciles the cost of drugs to the sponsor with payments the Government made to the sponsor for Part D. Because the Federal Government shares Part D risk with sponsors, the higher a sponsor's Part D costs are, the higher the Federal Government's Part D costs will generally be.

⁵ CMS requires sponsors to report all rebates, including those retained by the PBM, on the DIR report. CMS also requires sponsors to report all rebate amounts on its annual bid. Bid amounts are the basis for beneficiary premiums and Government subsidies.

The 340B Drug Pricing Program

The Veterans Health Care Act of 1992 established the 340B program in section 340B of the Public Health Service Act. Congress created the 340B program to allow eligible providers serving vulnerable patient populations to purchase outpatient drugs at discounted prices.⁶ HRSA, the agency that administers the 340B program, estimates that in 2016, 340B program sales totaled \$16 billion, and that covered entities saved between 25 and 50 percent of the price they would have otherwise paid for covered outpatient drugs.⁷ Congress intended for the savings from 340B drugs to enable “covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”⁸

Manufacturers that participate in the 340B program agree to sell covered outpatient drugs at or below statutorily defined discount prices, known as 340B ceiling prices, to covered entities.⁹ To encourage manufacturers to participate in the 340B program, Congress made Medicaid coverage of a manufacturer’s drugs conditional upon that manufacturer’s participation in the 340B program. However, the Medicaid program also requires that manufacturers offer rebates on all covered outpatient drugs under the Medicaid program. To protect manufacturers from paying both a 340B discount and a Medicaid rebate on the same drug, Congress established a statutory prohibition on “duplicate discounts” for 340B drugs dispensed to Medicaid beneficiaries.

Medicare Part D has no similar prohibition on manufacturers paying duplicate discounts for 340B drugs dispensed to Part D beneficiaries. Therefore, manufacturers may sell drugs at a discount to 340B covered entities under the 340B program and later pay a rebate to the Part D sponsor for the same drugs. Part D does not define how rebate agreements should be structured; rather, it allows manufacturers and sponsors to negotiate any rebates for drugs.¹⁰ As a result, CMS is not involved in the negotiations regarding rebates between manufacturers and sponsors, and CMS does not define how such rebates are structured.

⁶ These eligible providers are known as covered entities. To participate in the 340B program, covered entities must register with HHS’s Health Resources and Services Administration (HRSA) and comply with all 340B program requirements.

⁷ HHS, *HRSA FY 2019 Budget Justification*, p. 265.

⁸ HRSA, “340B Drug Pricing Program.” Available online at <https://www.hrsa.gov/opa/index.html>. Accessed on November 19, 2018.

⁹ 42 U.S.C. § 256b(a)(1).

¹⁰ The Social Security Act § 1860D-11(i).

Covered Entities and 340B-Eligible Patients

Covered entities include disproportionate share hospitals (DSHs),¹¹ family planning clinics, federally qualified health centers, and hemophilia treatment centers.¹² Covered entities may only provide drugs purchased at a discount through the 340B program to eligible patients of the covered entity. Discounted drugs may be dispensed to an eligible patient regardless of the patient's payer status and whether the drug is intended for self-administration or administration by a clinician. The 340B program does not prohibit covered entities from providing 340B drugs to individuals with private insurance or Part D as long as the individual is a 340B-eligible patient and the drug is not subject to a duplicate discount under Medicaid.

In general, an individual is an eligible patient of a covered entity if:

- the individual has established a relationship with the covered entity such that the covered entity maintains records of the individual's healthcare;
- the individual receives healthcare services from either a healthcare professional who is employed by the covered entity or a healthcare professional who provides healthcare under contractual or other arrangements (e.g., a referral for consultation such that responsibility for the care provided remains with the covered entity); and
- the individual receives from the covered entity a healthcare service or a range of healthcare services consistent with the service or range of services for which grant funding or federally qualified health center look-alike¹³ status has been provided to the entity.¹⁴

340B Contract Pharmacies

Covered entities may either dispense 340B drugs themselves or contract with pharmacies to dispense the drugs on their behalf. Most 340B contract pharmacies are retail pharmacies that serve both the general public and the patients of the covered entities with which they contract. Contract pharmacies include both independent retail pharmacies and large chain pharmacies. Covered entities often utilize contract pharmacies to increase patient access to 340B drugs.

¹¹ A DSH is a hospital with a disproportionately large share of low-income patients.

¹² The Patient Protection and Affordable Care Act (42 U.S.C. §§ 256b(a)(4) and 7101) added five new eligible entity types: certain children's hospitals, certain free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. All other eligible entities can be found at 42 U.S.C. § 256b(a)(4).

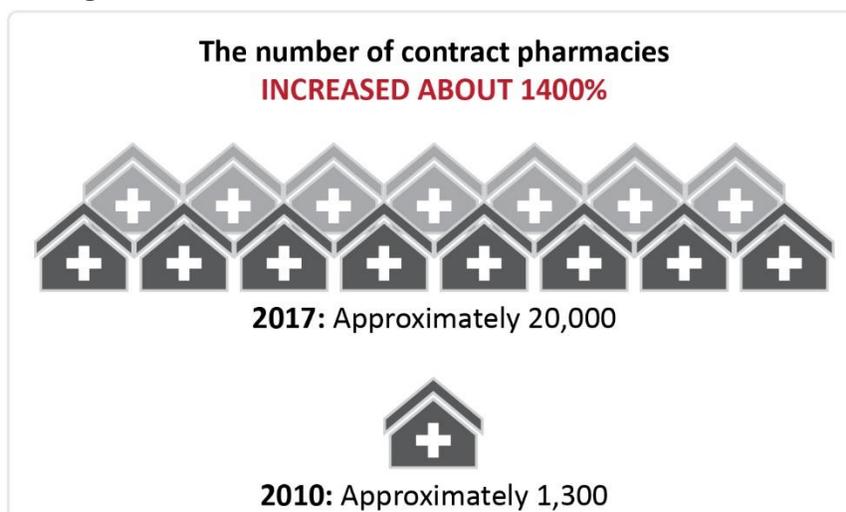
¹³ Federally qualified health center look-alikes are community-based healthcare providers that meet the requirements to become a federally qualified health center but do not receive HRSA funding. They operate under a governing board that includes patients and provide primary care on a sliding fee scale based on ability to pay.

¹⁴ DSHs are exempt from this requirement (61 Fed. Reg. 55157, 55158 (Oct. 24, 1996)).

However, earlier OIG work¹⁵ has shown that contract pharmacy arrangements create complications in identifying when prescriptions for 340B-eligible patients are filled, in preventing diversion of 340B drugs to patients not eligible for the 340B program, and in preventing duplicate discounts under Medicaid.

In March 2010, HRSA issued final guidance that allowed a covered entity to contract with an unlimited number of contract pharmacies and provided guidance to ensure compliance with program requirements.¹⁶ Since then, the number of pharmacies serving as 340B contract pharmacies has grown significantly. According to the same OIG report, the number of unique pharmacies serving as 340B contract pharmacies grew by 770 percent between March 2010 and May 2013. More recently, the Government Accountability Office reported that the number of contract pharmacies increased significantly from about 1,300 at the beginning of 2010 to about 20,000 in 2017¹⁷ (Figure).

Figure: 2010–2017 Increase in 340B Contract Pharmacies



HOW WE CONDUCTED THIS REVIEW

We reviewed manufacturer contracts associated with rebates provided to Part D sponsors for drugs dispensed to Part D beneficiaries. We reviewed 929 manufacturer-sponsor rebate agreements associated with these manufacturer contracts to identify agreement terms that prohibited rebates for prescriptions filled by 340B pharmacies.

¹⁵ *Contract Pharmacy Arrangements in the 340B Program* ([OEI-05-13-00431](#)), Feb. 4, 2014.

¹⁶ 75 Fed. Reg. 10277, 10278 (March 5, 2010).

¹⁷ *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (GAO-18-480), issued on Jun. 21, 2018.

We identified 248 sponsors associated with 340B pharmacies that submitted Part D PDE data in contract year 2014 (January 1, 2014, through December 31, 2014).¹⁸ Of those 248 sponsors, we selected for our review 68 sponsors who had approximately 55 million PDEs, which was 75 percent of the total 340B pharmacy PDEs in 2014. We contacted those 68 sponsors¹⁹ and requested a listing of the 2014 Medicare Part D claims for which the pharmaceutical manufacturer did not pay a rebate because the claim was filled at a 340B pharmacy.²⁰ We requested that the sponsors calculate the rebate amounts that would have been paid according to rebate agreement terms had the prescription been filled at a non-340B pharmacy. Although we relied on sponsors to identify the claims for which rebates were not paid, we note that, for those claims, the manufacturer-sponsor rebate agreements generally contained language precluding rebates from being paid.

We did not review sponsors' reimbursement to the pharmacies or the pharmacy drug purchase price. After our audit work, we asked 59 of the 68 sponsors or their PBMs if, when negotiating reimbursement contracts with pharmacies and deciding whether to reduce the pharmacy's reimbursement, they took into consideration whether a pharmacy is a 340B pharmacy and can dispense drugs purchased at the 340B drug price. We did not evaluate how potential additional rebates would have affected the DIR reports and therefore Part D payments to sponsors. However, rebates reported on the DIR report are applied in reconciliation to reduce the drug costs.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A describes our audit scope and methodology.

RESULTS OF REVIEW

We determined that tens of millions of dollars in rebates could have been generated for sponsors or their PBMs had manufacturers and sponsors agreed that eligible prescriptions filled at 340B pharmacies would receive rebates. If the Part D prescriptions for the sponsors in our review had been filled at non-340B pharmacies, sponsors calculated that manufacturers would have paid rebates of up to \$74,745,353 for 554,549 claims in 2014. The manufacturers did not

¹⁸ When we initiated our review, CY 2014 Part D data were the most current, complete data available. In 2014, CMS contracted with 292 Medicare Part D sponsors.

¹⁹ Most sponsors used a PBM to provide services such as establishing a pharmacy network, paying claims, and negotiating rebates with manufacturers. For those Part D sponsors that used a PBM, we also contacted the PBM to gather information for our review.

²⁰ Although sponsors would not know whether a prescription was filled using a drug purchased through the 340B program, sponsors would be able to identify whether a prescription was filled at a 340B pharmacy.

pay these rebates because, as sponsors reported, rebate agreements did not require manufacturers to pay rebates for Part D drugs filled at a 340B pharmacy. We also found that because there are no 340B identifiers on claims and PDE records, sponsors do not have the data to distinguish whether prescriptions dispensed at a 340B pharmacy were filled using 340B drugs. Therefore, the possible additional rebate amount of up to \$74,745,353 is for both 340B and non-340B drugs filled at 340B pharmacies for Part D beneficiaries.

SOME MANUFACTURER-SPONSOR REBATE AGREEMENTS PROHIBITED SPONSORS FROM RECEIVING REBATES FOR ALL PRESCRIPTIONS FILLED AT A 340B PHARMACY

Rebate terms varied considerably among the agreements that we reviewed. However, of the 929 rebate agreements that we reviewed, 425 included language stating that Part D rebates would not be paid if a prescription was filled at a 340B pharmacy. For example, some rebate agreements stated that the manufacturers will not pay Part D rebates for any claims for prescriptions of the manufacturer's products if the manufacturer already provided a rebate or discount under any Federal or State contract, plan, or program, including the 340B program. Other rebate agreements stated that the manufacturer would not be obligated to pay the sponsor Part D rebates for utilization of a product if the product was dispensed by a 340B pharmacy, regardless of whether the drug received a 340B discount. In addition, we found that manufacturers may only include this 340B rebate prohibition language in some rebate agreements. For example, agreements involving one manufacturer included the 340B rebate prohibition language in 8 of the 14 rebate agreements that we reviewed but did not include the language in the remaining 6 rebate agreements.

Covered entities that participate in the 340B program may purchase drugs at a lower cost than those that do not participate in the program could. However, Part D sponsors and their PBMs generally indicated that they did not take those lower acquisition costs into consideration when negotiating reimbursement rates with 340B pharmacies. Of the 59 sponsors we asked, all but 1 disclosed that they or their PBMs did not negotiate lower reimbursement amounts based on a pharmacy's 340B status. In particular, one sponsor indicated that its PBM does not factor pharmacies' 340B status into all negotiations but may negotiate a lower reimbursement rate for individual 340B pharmacies that are not chain pharmacies.

Because sponsors or their PBMs generally did not negotiate different pharmacy reimbursement terms for 340B and non-340B pharmacies, sponsors may have had higher drug costs for those instances in which manufacturers did not pay rebates for drugs dispensed by 340B pharmacies. In general, when sponsors have higher drug costs, it increases the amount of the Federal Government's costs for the Part D program.

SPONSORS DID NOT HAVE DATA TO IDENTIFY WHEN A 340B DRUG WAS DISPENSED TO A PART D BENEFICIARY

Although there are no statutory restrictions on duplicate discounts for 340B drugs dispensed to Part D beneficiaries, the rebate agreements we reviewed often included terms that did not require manufacturers to pay Part D rebates for drugs that were purchased under the 340B

program. These agreements included these terms to ensure that manufacturers did not pay rebates for drugs that were already sold at a discounted price. However, although sponsors and manufacturers can readily identify whether claims were for drugs dispensed at a 340B pharmacy, there are no identifiers on a claim or PDE record that would allow sponsors to identify whether a 340B pharmacy dispensed a discounted 340B drug or a regular, non-340B drug to a Part D beneficiary. Because a 340B pharmacy can dispense both 340B drugs and non-340B drugs, some Part D beneficiaries may receive 340B drugs (if the beneficiary is a 340B-eligible patient), while others may receive non-340B drugs (if the beneficiary is not a 340B-eligible patient).

Because there are no identifiers to indicate which drugs dispensed by a 340B pharmacy were purchased at a discount under the 340B program, sponsors and manufacturers are unable to determine whether a drug dispensed to a Part D beneficiary will result in a duplicate discount between the 340B and Part D programs. As a result, some manufacturers did not pay Part D rebates for non-340B drugs that otherwise may have been eligible to receive a rebate under the terms of the rebate agreement. Some sponsors submitted all claims to the manufacturer for rebates and let the manufacturer determine whether the claim was from a 340B pharmacy. Other sponsors did not submit for rebates any claims from 340B pharmacies. In general, the uncollected rebates on non-340B drugs dispensed at 340B pharmacies raised the cost of drugs to both the sponsors and the Part D program.

THE TYPE OF PHARMACY USED TO FILL A PRESCRIPTION AFFECTED THE COST TO THE PART D PROGRAM WHEN REBATE AGREEMENTS CONTAINED 340B REBATE PROHIBITION LANGUAGE

For those rebate agreements that prohibit Part D rebates if any prescription is filled at a 340B pharmacy, the type of pharmacy that fills a Part D beneficiary's prescription affects the overall cost of the Part D program, even if the drug dispensed is not a 340B drug. If a sponsor receives a Part D manufacturer rebate for a drug, that sponsor has a reduced drug cost. Sponsors record direct and indirect remunerations, including rebates, in their annual DIR reports. CMS uses the sponsors' DIR reports to determine the sponsors' drug costs, and lower sponsor drug costs result in lower costs to the Federal Government. The following example demonstrates how the type of pharmacy that dispenses a drug affects the cost to the Part D program if the rebate agreement prohibits rebates for all prescriptions filled at a 340B pharmacy.

Example: Claim for a Prescription Filled at a 340B Pharmacy if the Manufacturer-Sponsor Rebate Agreement Has a 340B Pharmacy Exclusion

A Part D beneficiary had a prescription for Drug A filled at a 340B pharmacy. The 340B pharmacy filled the prescription using non-340B drug inventory. The pharmacy submitted a claim to the sponsor and received reimbursement for the prescription ingredient cost of \$369.73. Under the terms of the manufacturer-sponsor rebate agreement, the sponsor did not receive a manufacturer rebate for this claim because the prescription was filled at a 340B pharmacy.

The sponsor had a higher drug cost because it did not receive a manufacturer rebate for this and possibly other drugs. Because the sponsor had higher costs overall for Part D, the Federal Government would likely have had higher costs for Part D.

If the Part D beneficiary had received that same prescription for Drug A filled at a non-340B pharmacy, the sponsor would have reimbursed the pharmacy the same ingredient cost of \$369.73. However, under the terms of the manufacturer-sponsor rebate agreement, the sponsor would have received a manufacturer rebate of \$144.20 for this claim.

The sponsor would have had a lower drug cost because the rebate would have reduced the sponsor's cost for Drug A by \$144.20. The sponsor would have recorded this rebate and any others in its DIR report. Because the sponsor would have had lower costs overall for Part D, the Federal Government also would likely have had lower costs for Part D.

If the Part D prescriptions for the sponsors in our review had been filled at non-340B pharmacies, sponsors calculated that manufacturers would have paid rebates to sponsors or their PBMs of up to \$74,745,353 for 554,549 claims in 2014.

CONCLUSION

As described in this report, rebate agreement terms vary between manufacturers and sponsors, and manufacturers sometimes have different rebate terms in agreements with different sponsors or their PBMs. Some rebate agreements prohibit manufacturers from paying Part D rebates for all claims originating at 340B pharmacies regardless of whether the drugs were discounted under the 340B program. Other rebate agreements only prohibit Part D rebates specifically for 340B-discounted drugs.

In other work, OIG has identified a lack of transparency about drugs purchased under the 340B program as a problem in both Medicaid and Part B and has recommended that CMS increase transparency by requiring State Medicaid agencies to identify 340B drugs at the claim level.²¹ As this report shows, this lack of transparency about 340B drugs is also a problem in Part D.

²¹ State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates (OEI-05-14-00430), issued Jun. 6, 2016, and Part B Payments for 340B Purchased Drugs (OEI-12-4-00030), issued Nov. 23, 2015.

There is currently no identifier on the claim or in the Part D PDE record for sponsors to easily determine whether pharmacies dispensed drugs using discounted 340B drug inventory or regular non-340B drug inventory. Without this identifier, many rebate agreements effectively prohibit rebates for all drugs dispensed at 340B pharmacies rather than for only those drugs purchased at the 340B discount. This lack of transparency may have caused Part D sponsors to miss opportunities to receive rebates they might otherwise have obtained from drug manufacturers for drugs purchased outside the 340B program.

For 2014, rebate agreements led to non-payment of \$74,745,353 in rebates that would have been reported by sponsors had beneficiaries filled these drugs at non-340B pharmacies. Had sponsors received the additional rebates for Part D prescriptions filled at 340B pharmacies, they would have been required to report these rebates in their DIR reports, and the reported rebates would have potentially resulted in a reduction in Part D program costs.

Our analysis is based on 2014 data. Since then, the number of 340B pharmacies has continued to increase. Therefore, the potential costs to the Part D program may also be increasing. We provide this report to inform congressional and administration decisionmakers of the impact that non-340B drugs dispensed at 340B pharmacies may have on the Part D program. This report contains no recommendations.

CMS AND HRSA COMMENTS

CMS and HRSA provided technical comments on this report, which we addressed as appropriate.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed information for 554,549 claims for contract year 2014 (January 1, 2014, through December 31, 2014) identified by 68 sponsors. We reviewed the rebate amounts that the manufacturer did not pay for each claim because the prescription was filled at a 340B pharmacy. We totaled the rebate amounts and found that sponsors did not receive \$74,745,353 for the 554,549 claims. The sponsors identified the claims for which manufacturers did not pay rebates because the prescriptions were filled at 340B pharmacies.

As part of our survey work, we also reviewed claims for contract year 2012 (January 1, 2012, through December 31, 2012) at a covered entity with one 340B pharmacy. We reviewed 929 rebate agreements between manufacturers and sponsors to identify rebate agreement terms prohibiting rebates for prescriptions filled by 340B pharmacies. We also reviewed the rebate amounts that manufacturers paid for covered entities' claims. If a manufacturer did not pay a rebate to a sponsor, we reviewed the reason that it did not pay a rebate. We used rebate agreement terms to determine the rebate amount that would have been paid if a prescription had not been filled at the 340B pharmacy.

We conducted our audit from June 2016 through January 2017.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials about Federal requirements and guidance governing DIR reports and rebates;
- obtained the covered entity daily report and the 340B pharmacy daily report from the HRSA Office of Pharmacy Affairs 340B Database;
- identified National Provider Identifier numbers (NPI) for 340B pharmacies listed in HRSA's 340B database;
- identified 248 sponsors associated with 340B pharmacy NPIs that had Part D PDEs in contract year 2014;
- selected 68 sponsors whose PDEs represented 75 percent of the 340B PDEs in 2014;
- contacted sponsors and PBMs to request that each provide a list of 2014 Medicare Part D claims for which the pharmaceutical manufacturer did not pay a rebate because the claim was filled at a 340B pharmacy;

- reviewed manufacturer-sponsor rebate agreements to identify agreement terms that prohibited rebates for prescriptions filled at 340B pharmacies;
- requested that sponsors provide the rebate amount that would have been paid, according to rebate agreement terms, had prescriptions been filled at pharmacies that do not contract with 340B entities;
- reviewed a judgmental selection of claims provided by sponsors and PBMs to ensure that the claims were from pharmacies in the HRSA 340B database; and
- reviewed the information provided by sponsors and determined the rebate amounts that were not paid by pharmaceutical manufacturers because the prescriptions were filled at a 340B pharmacies.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>State Efforts to Exclude 340B Drugs From Medicaid Managed Care Rebates</i>	<u>OEI-05-14-00430</u>	6/6/2016
<i>Part B Payments for 340B Purchased Drugs</i>	<u>OEI-12-14-00030</u>	11/23/2015
<i>Contract Pharmacy Arrangements in the 340B Program</i>	<u>OEI-05-13-00431</u>	2/4/2014