

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**STATE EFFORTS TO EXCLUDE  
340B DRUGS FROM  
MEDICAID MANAGED CARE  
REBATES**



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# **EXECUTIVE SUMMARY: STATE EFFORTS TO EXCLUDE 340B DRUGS FROM MEDICAID MANAGED CARE REBATES**

## **OEI-05-14-00430**

### **WHY WE DID THIS STUDY**

Manufacturer rebates for drugs paid through Medicaid managed care organizations (MCOs) are an increasingly important source of savings for both States and the Federal government. However, “duplicate discounts,” which occur when manufacturers pay Medicaid rebates on drugs sold at the already-discounted 340B price, are prohibited by law. Thus, for States to collect allowable rebates only and avoid duplicate discounts for drugs paid through MCOs, they must identify and exclude 340B drug claims. If a State does not accurately identify 340B drug claims, both duplicate discounts and forgone rebates—that is, unclaimed rebates to which States are legally entitled—may occur. Duplicate discounts result in manufacturers paying too much in rebates, while forgone rebates result in States paying too much for drugs.

### **HOW WE DID THIS STUDY**

We conducted structured interviews with States that pay for drugs through MCOs to determine how they identify 340B drug claims when collecting Medicaid rebates. We assessed States’ methods and identified potential vulnerabilities that could inhibit correct rebate collection. We did not attempt to determine whether duplicate discounts for MCO drugs had occurred.

### **WHAT WE FOUND**

We found that, to identify 340B drug claims and correctly collect rebates for MCO drugs, most States use methods that identify providers using 340B-purchased drugs. However, we found that these provider-level methods may not accurately identify all individual 340B drug claims, creating a risk of duplicate discounts and forgone rebates. By contrast, we found that methods that operate at the claim level can improve accuracy in identifying 340B drug claims, and thereby, help States correctly collect rebates.

### **WHAT WE RECOMMEND**

We recommend that the Centers for Medicare & Medicaid Services (CMS) require States to use claim-level methods to identify 340B claims. CMS did not concur with our recommendation, noting that while it agrees with the importance of claim-level methods, the statute does not contemplate such a requirement for States. We continue to recommend that CMS require the use of claim-level methods to improve accuracy in identifying 340B claims and thereby reduce the risk of duplicate discounts and forgone rebates.

We also recommend that the Health Resources and Services Administration (HRSA) clarify its guidance on preventing duplicate discounts for MCO drugs to align with this new requirement. HRSA concurred with our recommendation.

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## OBJECTIVES

1. To describe States' methods for identifying claims for 340B-purchased drugs paid through Medicaid managed care organizations (MCOs).
2. To identify potential vulnerabilities in States' methods for correctly collecting rebates and preventing duplicate discounts for drugs paid through MCOs.

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## BACKGROUND

Manufacturer rebates for drugs paid through MCOs are an increasingly important source of savings for both States and the Federal government. From 2011 to 2014, the proportion of States paying for prescription drugs through MCOs rose from under one-quarter to over two-thirds.<sup>1</sup> As more Medicaid drugs are paid through MCOs, the financial impact of States' collection of rebates for those drugs—or failure to collect such rebates—becomes increasingly significant.

States' methods for identifying claims for drugs purchased under the 340B Program have both direct and indirect effects on rebate collection. The 340B Program allows certain health care providers to purchase drugs at a discount. Duplicate discounts, which occur when manufacturers sell drugs at the discounted 340B price and later pay Medicaid rebates on the same drugs, are prohibited by law. To collect rebates correctly and prevent duplicate discounts, States must identify and exclude claims representing 340B-purchased drugs. If States' methods do not accurately identify 340B claims, however, States may end up forgoing rebates to which they are legally entitled. Moreover, manufacturer concerns about the effectiveness of States' methods to prevent duplicate discounts can contribute to rebate disputes, as demonstrated in previous OIG work.<sup>2</sup> Such disputes may impede or delay rebate payments, and require States to expend scarce resources to resolve them.

This study was conducted in response to a Congressional request.

### **Medicaid Prescription Drug Coverage**

All 50 States and the District of Columbia (hereinafter referred to as States) offer prescription drug coverage as part of their Medicaid benefit packages. Medicaid reimbursement for covered outpatient drugs totaled

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<sup>1</sup> Office of Inspector General (OIG), *States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations Has Improved*, OEI-05-14-00431, September 2015, p. 1.

<sup>2</sup> OIG, *Medicaid Drug Rebate Dispute Resolution Could Be Improved*, OEI-05-11-00580, August 2014.

approximately \$42 billion in 2014.<sup>3,4</sup> Covered outpatient drugs include drugs dispensed directly to patients at pharmacies (pharmacy drugs) and drugs administered by physicians or other medical practitioners to patients (physician-administered drugs).

States use two primary models to pay for drugs: fee-for-service (FFS) and MCOs. Under the FFS model, pharmacies and providers submit reimbursement claims for drugs directly to the State, and the State pays pharmacies and providers for those claims. Under the MCO model, States prospectively pay MCOs a fixed monthly amount for each Medicaid beneficiary, regardless of whether a beneficiary receives services during the month. Pharmacies and providers submit drug claims to MCOs under the MCO model. States may choose to use more than one payment model. For example, a State might pay for pharmacy drugs under the FFS model but pay for physician-administered drugs under the MCO model.

### **The Medicaid Drug Rebate Program**

The Omnibus Budget Reconciliation Act of 1990 established the Medicaid Drug Rebate Program.<sup>5</sup> The program requires that, for covered outpatient drugs (hereinafter referred to as drugs) to be eligible for Federal financial participation through Medicaid, manufacturers must pay rebates to States on these drugs when dispensed to Medicaid beneficiaries and paid for by Medicaid.<sup>6</sup> States essentially share a portion of these rebates with the Federal government.<sup>7</sup>

In 2010, the Affordable Care Act (ACA) expanded the Medicaid Drug Rebate Program to require payment of rebates for MCO drugs.<sup>8</sup> Prior to ACA, only FFS drugs were subject to rebates under the Medicaid Drug Rebate Program.

To collect rebates, States determine the amount of rebates owed to them for each quarter and send invoices to manufacturers. First, States determine the total number of units of each drug paid by Medicaid in the quarter. For FFS drugs, States calculate units from drug claims

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<sup>3</sup> The term “covered outpatient drug” is defined at 42 U.S.C. § 1396r-8(k)(2).

<sup>4</sup> OIG analysis of data from the Centers for Medicare and Medicaid Services’ (CMS) Medicaid Budget and Expenditure System (MBES) and Medicaid State drug utilization data, September 2015. We combined Medicaid fee-for-service expenditures from MBES and MCO expenditures from Medicaid State drug utilization data. This amount does not reflect rebates.

<sup>5</sup> The Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, § 4401; 42 U.S.C. § 1396r-8.

<sup>6</sup> 42 U.S.C. §§ 1396r-8(a)(1) and 1396r-8(b)(1).

<sup>7</sup> 42 U.S.C. § 1396r-8(b)(1).

<sup>8</sup> ACA, P.L. 111-148 § 2501(c); 42 U.S.C. § 1396b(m)(2) and 42 U.S.C. § 1396r-8(b)(1).

reimbursed directly by the State. For MCO drugs, States calculate units from drug claims data provided by their MCOs.<sup>9</sup> States then multiply the total number of units of each drug by the drug's unit rebate amount to determine the total quarterly amount of rebates owed.<sup>10</sup> Finally, States send invoices to manufacturers reflecting the total quarterly amount of rebates owed for the manufacturers' drugs.

When a manufacturer, in good faith, believes that a State's rebate invoice for a given drug is based on erroneous utilization data, the manufacturer may dispute the invoiced amount for that drug.<sup>11</sup> Once a manufacturer initiates a dispute, it can withhold payment to States for the disputed invoiced amount.

### **The 340B Drug Pricing Program**

The Veterans Health Care Act of 1992 established the 340B Drug Pricing Program.<sup>12</sup> The 340B Program requires that, for drugs to be eligible for Federal financial participation through Medicaid, manufacturers must provide discounts on such drugs to certain eligible health care providers, known as covered entities.<sup>13, 14</sup> To participate, covered entities must register with HRSA, the agency responsible for administering the 340B Program. Covered entities generally bill their patients' insurance—including Medicaid, if applicable—for 340B-purchased drugs that they dispense or administer.

*340B-purchased drugs for Medicaid patients.* Covered entities may decide to use either 340B-purchased drugs or non-340B-purchased drugs

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<sup>9</sup> We refer to data on drug claims reimbursed directly by the State (for FFS drugs) or by MCOs (for MCO drugs) as drug utilization data.

<sup>10</sup> CMS uses drug pricing data provided by manufacturers to calculate the unit rebate amount for each drug according to a statutory formula. See 42 U.S.C. § 1396r-8(c).

<sup>11</sup> CMS, Sample Drug Rebate Agreement, § V(b). Accessed at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/SampleRebateAgreement.pdf> on October 27, 2015.

<sup>12</sup> Veterans Health Care Act of 1992, P.L. 102-585 § 602; Public Health Service Act § 340B; 42 U.S.C. § 256b.

<sup>13</sup> 42 U.S.C. § 1396r-8(a)(1), 42 U.S.C. § 1396r-8(a)(5), and 42 U.S.C. § 256b(a)(1).

<sup>14</sup> 42 U.S.C. § 256b(a)(4) enumerates the complete list of the types of entities eligible to become covered entities.

for their Medicaid patients.<sup>15, 16</sup> Covered entities might make the same decision for all of their Medicaid patients, or make different decisions for their FFS Medicaid patients and their MCO Medicaid patients.

*Contract pharmacy arrangements.* Covered entities may contract with one or more pharmacies, known as contract pharmacies, to dispense 340B-purchased drugs on their behalf.<sup>17</sup> Most contract pharmacies are retail pharmacies that serve the general public as well as patients of the covered entity or entities with which they contract. Contract pharmacies generally bill patients' insurance—including Medicaid, if applicable—on behalf of the covered entity for 340B-purchased drugs dispensed to its patients.

### **Duplicate Discounts**

Duplicate discounts occur when manufacturers sell drugs at a discount under the 340B Program and later pay Medicaid rebates on the same drugs. Duplicate discounts are prohibited by law for both FFS drugs and MCO drugs.<sup>18</sup> Figure 1 shows how duplicate discounts could occur in the Medicaid rebate process.

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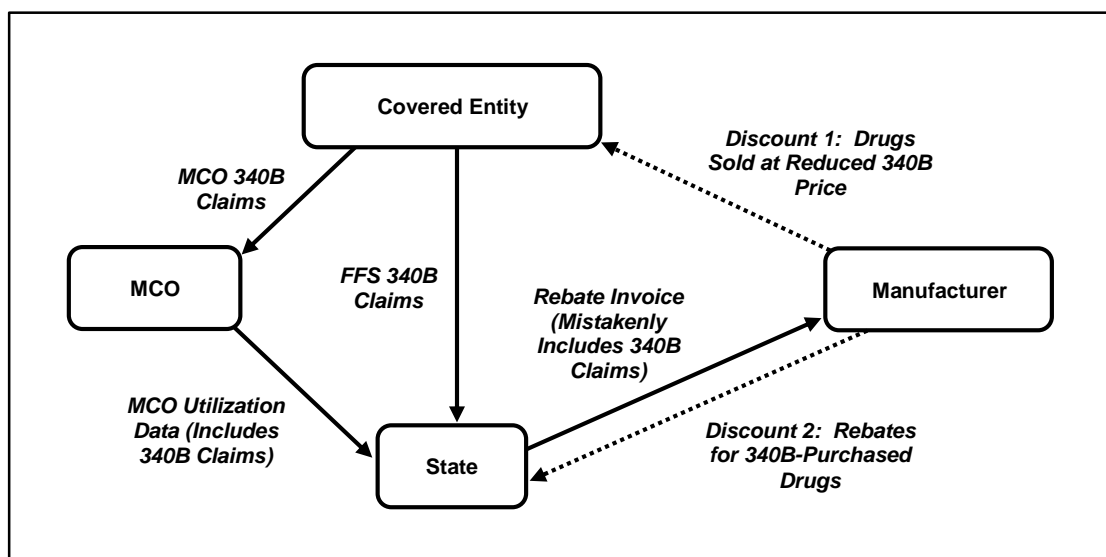
<sup>15</sup> The decision to use 340B-purchased drugs for Medicaid patients is often referred to as “carving in,” whereas the decision to use non-340B-purchased drugs for Medicaid patients is referred to as “carving out.” Covered entities may decide to use non-340B-purchased drugs for their Medicaid patients because payment rates make doing so more financially advantageous. State laws and/or billing rules may restrict covered entities' ability to make this decision.

<sup>16</sup> See, e.g., 65 Fed. Reg. 13983, 13984 (March 15, 2000). That guidance applies to FFS drugs because it was developed before the ACA expanded the Medicaid Drug Rebate Program to include MCO drugs. However, HRSA has proposed new guidance that would extend this policy to MCO drugs. See 80 Fed. Reg. 52300, 52309 (August 28, 2015).

<sup>17</sup> See, e.g., 75 Fed. Reg. 10272 (March 5, 2010). Covered entities are permitted to use multiple contract pharmacy arrangements as long as they comply with applicable guidance. *Id.* at 10277-10278.

<sup>18</sup> 42 U.S.C. § 256b(a)(5)(A)(i) and 42 U.S.C. § 1396r-8(j)(1).

**Figure 1: How Duplicate Discounts Could Occur in the Medicaid Drug Rebate Process**



States play a key logistical role in preventing duplicate discounts because they invoice manufacturers for rebates. To collect rebates correctly and prevent duplicate discounts, States must ensure that FFS and MCO utilization data used to invoice manufacturers do not include claims representing 340B-purchased drugs (hereinafter referred to as 340B claims). In general, States do so by identifying 340B claims in utilization data and excluding them before compiling rebate invoices.

*Methods for identifying 340B claims.* A number of different methods are available to States for identifying 340B claims and preventing duplicate discounts, but they generally correspond to one of two types:

- *Provider-level methods*, which identify covered entities that use 340B-purchased drugs for their Medicaid patients and exclude drug claims billed by those entities from utilization data. The most prominent provider-level method is HRSA’s Medicaid Exclusion File (MEF).
- *Claim-level methods*, which exclude individual drug claims that covered entities have explicitly identified as 340B claims from utilization data.

See Appendix A for detailed descriptions of methods to identify 340B claims and prevent duplicate discounts.

*Federal policies on duplicate discounts for MCO drugs.* Because duplicate discounts for MCO drugs are relevant to the 340B Program and the Medicaid Drug Rebate Program, both HRSA and CMS have been involved in developing Federal policies on the topic. HRSA provides



direction to covered entities related to their participation in the program, including their role in preventing duplicate discounts. Importantly, in December 2014, HRSA issued a notice clarifying that the MEF is available to help prevent duplicate discounts specifically for *FFS* drugs.<sup>19</sup> CMS provides direction to States regarding MCO drugs and rebate collection under the Medicaid Drug Rebate Program. See Appendix B for details on HRSA and CMS policies related to duplicate discounts for MCO drugs.

### **Related Office of Inspector General Work**

In recent years, OIG has published an extensive body of work on the 340B Program and MCO rebates.

*OIG work on the 340B Program.* In June 2011, OIG published a review of States' *FFS* Medicaid reimbursement policies and oversight activities related to 340B-purchased drugs.<sup>20</sup> OIG found that over half of States had developed alternatives to MEF for correctly collecting rebates and preventing duplicate discounts for *FFS* drugs.

In February 2014, OIG published a review of 340B contract pharmacy arrangements.<sup>21</sup> OIG found that contract pharmacy arrangements create complications in preventing duplicate discounts.

In August 2014, OIG published a review of manufacturer dispute resolution under the Medicaid Drug Rebate Program, highlighting duplicate discount concerns.<sup>22</sup> OIG found that disputes between States and manufacturers related to 340B-purchased drugs occur frequently. OIG recommended that CMS inform States of the availability of 340B indicators, and CMS concurred with that recommendation.

*OIG work on MCO rebates.* In September 2015, OIG published a review of States' collection of MCO rebates.<sup>23</sup> That review was conducted in conjunction with this study. It was a follow-up to a September 2012 OIG report that found that less than half of States paying for drugs under the

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<sup>19</sup> The notice stated that it did not apply to the prevention of duplicate discounts for MCO drugs. See HRSA, *340B Drug Pricing Program Notice: Clarification on use of the Medicaid Exclusion File*, Release No. 2014-1, December 12, 2014, p. 3.

<sup>20</sup> OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011.

<sup>21</sup> OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, February 2014.

<sup>22</sup> OIG, *Medicaid Drug Rebate Dispute Resolution Could Be Improved*, OEI-05-11-00580, August 2014.

<sup>23</sup> OIG, *States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations Has Improved*, OEI-05-14-00431, September 2015.

MCO model had invoiced manufacturers for MCO rebates.<sup>24</sup> The 2015 review found that a greater number of States are now paying for drugs under the MCO model, and that almost all of them are collecting MCO rebates.

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## **METHODOLOGY**

### **Scope**

This report describes States' methods for identifying 340B claims for MCO drugs and assesses vulnerabilities in those methods with respect to correctly collecting rebates and preventing duplicate discounts. We did not attempt to determine whether duplicate discounts for MCO drugs had actually occurred.

### **Data Collection and Analysis**

To address our objectives, we administered electronic surveys, structured telephone interviews, and follow-up email inquiries with States between November 2014 and April 2015. From the survey results and analysis of additional CMS data sources, we identified 37 States that paid for drugs under the MCO model and collected rebates for those drugs. We conducted structured interviews and follow-up inquiries with those 37 States to determine what methods they use to identify 340B claims for MCO drugs. We then assessed the methods reported by States to identify potential vulnerabilities. See Appendix C for a detailed description of our methodology.

### **Limitations**

Our findings are based on survey and interview responses provided by States. We did not independently verify States' interview responses regarding their methods for identifying 340B claims for MCO drugs.

### **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.

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<sup>24</sup> OIG, *States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations*, OEI-03-11-00480, September 2012.

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## FINDINGS

Almost all (35) of the 37 States in our review reported having methods for identifying 340B claims for MCO drugs. Many of these 35 States reported using more than one method to do so. For example, some states used one method for MCO pharmacy drugs and another for MCO physician-administered drugs. Other states used one method as a primary and another as a secondary or backup.

One of the two remaining States reported that it did not have any methods for identifying 340B claims for MCO drugs at the time of our data collection, but planned to begin using a provider-level method. The other remaining State did not provide information regarding its method(s) for identifying 340B claims for MCO drugs.

### **Most States use provider-level methods to identify 340B claims for MCO drugs**

Thirty of the 35 States reported using provider-level methods in some capacity to identify 340B claims and prevent duplicate discounts for MCO drugs. Provider-level methods identify covered entities that use 340B-purchased drugs for their Medicaid patients and allow States to exclude drug claims billed by those entities from utilization data. For example, HRSA's MEF—the most commonly-used provider-level method—identifies all covered entities that have informed HRSA that they will use 340B-purchased drugs for their FFS Medicaid patients.

Of the 30 States that use provider-level methods, 22 reported using *only* provider-level methods to identify 340B claims for either all of their MCO drugs or a segment of their MCO drugs (e.g., MCO pharmacy drugs, MCO physician-administered drugs). The remaining 8 States reported using provider-level methods in conjunction with another type of method, such as a claim-level method, for all or a segment of their MCO drugs.

Fourteen of the 35 States reported using claim-level methods in some capacity to identify 340B claims and prevent duplicate discounts for MCO drugs. Claim-level methods allow States to exclude individual drug claims that covered entities have explicitly identified as 340B claims from utilization data. Of the 14 States, 9 reported using *only* claim-level methods for all or a segment of their MCO drugs, whereas 5 reported using claim-level methods in conjunction with another type of method for all or a segment of their MCO drugs.

Table 1 shows the number of States using different types of methods to identify 340B claims and prevent duplicate discounts for MCO drugs.

**Table 1: Types of Methods Used by States to Identify 340B Claims for MCO Drugs**

Type of Method	Number of States Using This Type in Some Capacity for MCO Drugs	Number of States Using This Type <i>Only</i> for Some or All MCO Drugs	Number of States Using This Type in Conjunction with Another Type for Some or All MCO Drugs
Provider-level	30	22	8
Claim-level	14	9	5
Other	6	2	4
Overlap	(15)		
<b>Total</b>	<b>35</b>		

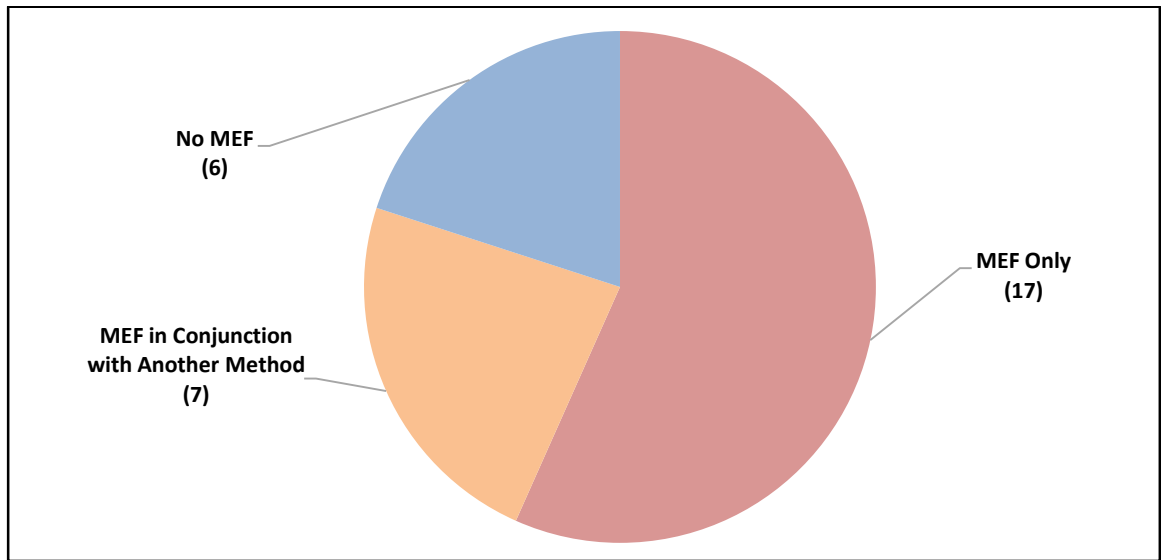
Source: OIG analysis of State interviews, 2015.

See Appendix D for the specific method(s) used by each of the 35 States to identify 340B claims and prevent duplicate discounts for MCO drugs.

***Many States use the Medicaid Exclusion File to identify 340B claims for MCO drugs and continued to do so despite HRSA guidance***

Of the 30 States that use provider-level methods to identify 340B claims for MCO drugs, 24 reported using the MEF in some capacity. Of these 24 States, 17 reported using *only* the MEF for all or a segment of their MCO drugs, whereas 7 reported using the MEF in conjunction with another method, such as a different provider-level method or a claim-level method, for all or a segment of their MCO drugs. Chart 1 shows use of the MEF among the 30 States that use provider-level methods to identify 340B claims for MCO drugs.

**Chart 1: Use of the MEF Among 30 States That Use Provider-Level Methods for MCO Drugs**



Source: OIG analysis of State interviews, 2015.

In December 2014, HRSA issued a notice clarifying that the MEF is available to help prevent duplicate discounts specifically for *FFS* drugs.<sup>25</sup> The notice encouraged covered entities to work with their States to develop alternative strategies for preventing duplicate discounts for MCO drugs.

In April 2015, however, all 19 States that responded to our follow-up inquiries reported that they continued to use the MEF for MCO drugs. This included almost all (15 of 17) States that reported using *only* the MEF for all or a segment of their MCO drugs.

### **Provider-level methods may not accurately identify all 340B claims, creating a risk of duplicate discounts and forgone rebates**

States' use of provider-level methods may not accurately identify 340B claims for some covered entities. Provider-level methods generally treat all drug claims from a given covered entity in the same way—that is, as either 340B claims or non-340B claims—and do not allow covered entities to differentiate among specific claims. In practice, however, a covered entity may submit both 340B claims and non-340B claims to Medicaid. This may occur because a covered entity: (1) makes different decisions on use of 340B-purchased drugs for its FFS Medicaid patients and its MCO

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<sup>25</sup> HRSA, *340B Drug Pricing Program Notice: Clarification on use of the Medicaid Exclusion File*, Release No. 2014-1, December 12, 2014.

Medicaid patients; and/or (2) must make exceptions to its decision to use 340B-purchased drugs in certain situations.

For such covered entities, States’ use of provider-level methods creates a risk of duplicate discounts and forgone rebates. States using provider-level methods are likely to either erroneously include some 340B claims in rebate invoices (resulting in duplicate discounts) or erroneously exclude some non-340B claims from rebate invoices (resulting in forgone rebates).

Use of 340B-purchased drugs for FFS Medicaid patients and MCO Medicaid patients differs. Covered entities that decide to use 340B-purchased drugs for their FFS Medicaid patients but not for their MCO Medicaid patients—or vice versa—will submit both 340B claims and non-340B claims to Medicaid. Provider-level methods are generally insufficient to distinguish between such entities’ 340B and non-340B claims.

Consider, for example, the 17 States that reported using only the MEF to identify 340B claims and prevent duplicate discounts for all or a segment of their MCO drugs. The MEF was designed to identify covered entities that decide to use 340B-purchased drugs for their *FFS* Medicaid patients. By using the MEF for *MCO* drugs, States are effectively assuming that covered entities are making the same decision on use of 340B-purchased drugs for *all* of their Medicaid patients, which may not be the case. Table 2 illustrates how this can cause States to incorrectly identify 340B claims, resulting in duplicate discounts and/or forgone rebates.

**Table 2: Potential Duplicate Discounts and Forgone Rebates for States Using the MEF for MCO Drugs**

	Type of Drugs Used for FFS Medicaid Patients	Entity in MEF?	State’s Action for MCO Rebates, per MEF	Type of Drugs Used for MCO Medicaid Patients	Result
Entity A	340B	Yes	Exclude Claims	340B	✓ Duplicate Discount Prevented
Entity B	Non-340B	No	Include Claims	Non-340B	✓ Allowable Rebate Invoiced
Entity C	Non-340B	No	Include Claims	340B	* Duplicate Discount
Entity D	340B	Yes	Exclude Claims	Non-340B	* Forgone Rebate

Source: OIG analysis of State interviews, 2015.

For entities A and B, which make the same decision on use of 340B-purchased drugs for their FFS Medicaid patients and their MCO Medicaid patients, use of the provider-level MEF has the desired result: duplicate discounts are prevented for entity A, and allowable rebates are

invoiced for entity B. However, for entities C and D, which make different decisions on use of 340B-purchased drugs for their FFS Medicaid patients and their MCO Medicaid patients, use of the provider-level MEF is problematic: entity C's MCO claims are included in rebate invoices, resulting in duplicate discounts, and entity D's MCO claims are excluded from rebate invoices, resulting in forgone rebates.

In a May 2015 working paper, the National Association of Medicaid Directors (NAMD) also highlighted this vulnerability. Specifically, NAMD noted that, with respect to States' use of the MEF, covered entities that make different decisions on the use of 340B-purchased drugs for their FFS Medicaid patients and their MCO Medicaid patients present challenges for States.<sup>26</sup>

Some States that use provider-level methods have taken steps to address the risk of duplicate discounts and forgone rebates described above. Two States reported that they have begun efforts to track covered entities' decisions on the use of 340B- or non-340B-purchased drugs separately for FFS Medicaid patients and MCO Medicaid patients. Alternatively, one State reported that it requires covered entities to make the same decision on the use of 340B- or non-340B-purchased drugs for their FFS Medicaid patients and their MCO Medicaid patients.

Exceptions to decisions to use 340B-purchased drugs. Even if covered entities generally use 340B-purchased drugs for both FFS Medicaid patients and MCO Medicaid patients, they may still submit non-340B claims to Medicaid in certain situations. Covered entities are sometimes unable to obtain or use 340B-purchased drugs, due to circumstances such as manufacturer supply limitations or the 340B Program's orphan drug exclusion.<sup>27</sup> In such situations, covered entities will likely use non-340B-purchased drugs for Medicaid patients and thus submit non-340B claims to Medicaid. However, if a State's provider-level method indicates that the entities dispense 340B-purchased drugs to Medicaid (because they generally do so), the non-340B claims they submit will be incorrectly identified as 340B claims and excluded from rebate invoices, resulting in forgone rebates. While HRSA guidance recognizes

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<sup>26</sup> NAMD, *Medicaid and the 340B Program: Alignment and Modernization Opportunities*, May 13, 2015, p. 10.

<sup>27</sup> See, e.g., HRSA, *Clarification of Non-Discrimination Policy*, Release No. 2011-1.1, May 23, 2013 and 42 U.S.C. § 256b(e).

that these situations might occur, it does not provide specific policies to address the risk of forgone rebates.<sup>28</sup>

NAMD's May 2015 working paper addresses this vulnerability as well. Specifically, NAMD stated that covered entities that generally use 340B-purchased drugs for Medicaid patients do use non-340B-purchased drugs in certain situations. Moreover, NAMD noted that for States that use the MEF, no mechanism is in place for covered entities to notify States of these situations.<sup>29</sup>

### **Claim-level methods can improve accuracy in identifying 340B claims**

Use of claim-level methods can help States more accurately identify 340B claims and thus reduce the risk of duplicate discounts and forgone rebates associated with provider-level methods. Unlike provider-level methods, claim-level methods allow covered entities to differentiate among specific claims—that is, to identify some of their drug claims as 340B claims and others as non-340B claims. For example, a covered entity that decides to use 340B-purchased drugs for MCO Medicaid patients only can use a State's claim-level method to identify its MCO claims—but not its FFS claims—as 340B claims. Likewise, a covered entity that generally uses 340B-purchased drugs for its Medicaid patients, but is unable to do so in certain situations, can use a State's claim-level method to identify its drug claims as non-340B claims in those situations. In both cases, the State can correctly identify 340B claims and exclude them from its rebate invoices while including all other (non-340B) claims, thereby preventing both duplicate discounts and forgone rebates.

Alternatively, States may be able to achieve claim-level specificity through existing provider-level methods by directing covered entities to use a separate provider identifier for 340B claims. Specifically, each covered entity could use two separate provider identifiers (NPIs or Medicaid billing numbers) to bill Medicaid—one for 340B claims and one for non-340B claims. States could, in turn, ensure that their provider-level methods are configured to exclude claims from rebate invoices *only* when

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<sup>28</sup> HRSA's December 2014 notice states only that covered entities must "have a mechanism in place to notify the State Medicaid agency" that non-340B-purchased drugs were used in such circumstances. See HRSA, *340B Drug Pricing Program Notice: Clarification on use of the Medicaid Exclusion File*, Release No. 2014-1, December 12, 2014, p. 2. HRSA's proposed omnibus guidance reiterated this expectation, but did not provide additional detail. See 80 Fed. Reg. 52300, 52320 (August 27, 2015).

<sup>29</sup> NAMD, *Medicaid and the 340B Program: Alignment and Modernization Opportunities*, May 13, 2015, p. 8-9.



billed using a covered entity's 340B-specific provider identifier. If covered entities and States perform this process correctly, both duplicate discounts and forgone rebates could be effectively prevented.<sup>30</sup> However, covered entities' use of multiple provider identifiers solely for the purpose of identifying individual 340B claims may create complications for other State and Federal oversight activities.

***States may be able to use claim-level methods to identify 340B-purchased drugs dispensed through contract pharmacies***

Per HRSA guidance, covered entities should not dispense 340B-purchased drugs to Medicaid patients through their contract pharmacies, unless they have an arrangement to prevent duplicate discounts.<sup>31</sup> If contract pharmacies do not dispense 340B-purchased drugs to Medicaid patients, States can collect rebates for the pharmacies' drug claims without causing duplicate discounts to occur.

Ten States reported that if covered entities do dispense 340B-purchased drugs to MCO Medicaid patients through contract pharmacies, the States' use of claim-level methods can accurately identify 340B claims and prevent duplicate discounts.<sup>32</sup> Eight of these 10 States referenced their use of 340B indicators, whereas two States referenced their use of alternative claim-level methods.

Seven of the eight States that referenced their use of claim-level 340B indicators reported that contract pharmacies, like all of their State's covered entities, should use 340B indicators if they submit 340B claims to

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<sup>30</sup> HRSA guidance contemplates this type of "separate identifier" arrangement, but not as a means of achieving claim-level specificity through provider-level methods. Rather, HRSA addresses this arrangement only with respect to multi-site covered entities that wish to have some sites use 340B-purchased drugs for Medicaid patients and other sites use non-340B-purchased drugs for Medicaid patients (i.e., by using a separate provider identifier for each site). See, e.g., HRSA, *340B Drug Pricing Program Notice: Clarification on use of the Medicaid Exclusion File*, Release No. 2014-1, December 12, 2014, p. 2 and 80 Fed. Reg. 52300, 52308-52309 (August 27, 2015).

<sup>31</sup> HRSA guidance allows contract pharmacies to dispense 340B-purchased drugs to Medicaid patients only if "the covered entity, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts" and report the arrangement to HRSA. See 75 Fed. Reg. 10272, 10278 (March 5, 2010). That guidance applies to FFS drugs because it was developed before the ACA expanded the Medicaid Drug Rebate Program to include MCO drugs. However, HRSA has proposed new guidance that would extend this policy to MCO drugs. See 80 Fed. Reg. 52300, 52309 (August 28, 2015).

<sup>32</sup> Previous OIG work found some covered entities whose contract pharmacies were dispensing 340B-purchased drugs to Medicaid patients but did not have arrangements to prevent duplicate discounts. See OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, February 2014, p. 13-14.

MCOs. The one additional State reported using 340B indicators exclusively for contract pharmacies wishing to dispense 340B-purchased drugs to MCO Medicaid patients. By including 340B indicators, contract pharmacies allow the States to identify and exclude their 340B claims from rebate invoices to ensure correct rebate collection and prevent duplicate discounts.

The structure of many contract pharmacy arrangements, however, creates technical challenges regarding the use of claim-level 340B indicators. Drugs dispensed by contract pharmacies on behalf of covered entities are often determined to be 340B-eligible retroactively—that is, after they have been dispensed to patients and billed. Contract pharmacies that operate this way cannot use 340B indicators when billing because they do not know the drug’s 340B eligibility status at that time.<sup>33</sup>

Six of the eight States reported that they expect contract pharmacies to work around these technical challenges. Specifically, these States reported that if contract pharmacies determine 340B eligibility retroactively but still wish to dispense 340B-purchased drugs to MCO Medicaid patients, they should reverse any claims retroactively determined to be 340B-eligible and re-submit them with 340B indicators.<sup>34</sup>

By contrast, two States reported developing alternative claim-level methods to accommodate contract pharmacies’ technical challenges. Specifically, these two States instruct contract pharmacies to regularly submit spreadsheets identifying all previously-billed claims that are retroactively determined to be 340B-eligible. To correctly collect rebates and prevent duplicate discounts, the States then remove all 340B claims identified in the spreadsheets from rebate invoices.<sup>35</sup> Because contract pharmacies send the spreadsheets to the State *after* the drugs have been dispensed to patients and billed, they are able to identify drug claims retroactively determined to be 340B-eligible. However, this process requires greater effort and involvement by State staff.

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<sup>33</sup> Ibid, p. 9, 14. See also NAMD, *Medicaid and the 340B Program: Alignment and Modernization Opportunities*, May 13, 2015, p. 11.

<sup>34</sup> While some States reported that they were aware of the NCPDP Telecommunication standard’s N1 transaction—which allows providers to add 340B indicators to previously-submitted claims without reversing and re-submitting them—none reported using it.

<sup>35</sup> The States may need to adjust previous quarters’ rebate invoices—instead of removing 340B claims prior to invoicing—due to timing issues.

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## CONCLUSION AND RECOMMENDATIONS

Effective methods for identifying 340B claims are needed to ensure compliance with the statutory prohibition on duplicate discounts, but are also a critical component of States' ability to achieve savings under the Medicaid Drug Rebate Program. If States' methods do not accurately identify 340B claims, States can end up forgoing rebates to which they are entitled. They also may be more likely to face rebate disputes that require additional resources and impede or delay rebate payments.

Nevertheless, we found that most States use provider-level methods—which may not accurately identify all 340B claims—for MCO drugs. Moreover, we found that many States continued to use the MEF to identify 340B claims for MCO drugs, even after HRSA's December 2014 notice clarified that the MEF is available to help prevent duplicate discounts specifically for *FFS* drugs.

Accordingly, we recommend that CMS:

### **Require the use of claim-level methods to identify 340B claims**

CMS should require that States use claim-level methods to identify claims for 340B-purchased drugs. As described in the findings of this report, claim-level methods can help States more accurately identify 340B claims, and thus reduce the risk of duplicate discounts and forgone rebates associated with provider-level methods.

CMS could afford States flexibility in complying with this requirement. States could use claim-level 340B indicators (specific data elements on claims transactions), for example, as a number of States already do for MCO drugs. States could instead opt to use alternative claim-level methods, such as spreadsheets identifying individual 340B claims, to avoid the technical challenges that 340B indicators pose for many contract pharmacy arrangements.

OIG acknowledges that methods to identify 340B claims may not be needed in States that require covered entities to use non-340B-purchased drugs for their Medicaid patients.

We also recommend that HRSA:

### **Clarify its guidance on preventing duplicate discounts for MCO drugs**

In finalizing its August 2015 proposed omnibus guidance, HRSA should clarify that, for MCO drugs, covered entities must follow State instructions to facilitate States' claim-level identification of 340B-purchased drugs. As proposed, HRSA's omnibus guidance suggests creating a new exclusion file (a provider-level method) to account for

covered entities' decisions on the use of 340B- or non-340B-purchased drugs for their MCO Medicaid patients. However, as we recommend above, CMS should instead require States to use claim-level methods to identify 340B claims. Accordingly, a new MCO-specific exclusion file would not be necessary for States to correctly collect rebates and prevent duplicate discounts for MCO drugs. While HRSA's proposed omnibus guidance does note that covered entities may be required to follow State-specific billing rules<sup>36</sup>, we recommend that HRSA further emphasize this point for MCO drugs and remove references to a new MCO-specific exclusion file.

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<sup>36</sup> 80 Fed. Reg. 52300, 52309 (August 28, 2015).

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## **AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

CMS did not concur with our first recommendation to require the use of claim-level methods to identify 340B claims. CMS stated that it agrees with the importance of claim-level methods, but that the statute does not contemplate such a requirement for States. CMS noted that States may develop their own billing instructions as a way to comply with the requirement to prevent duplicate discounts. Finally, CMS stated that it will continue to provide technical assistance to States as needed.

OIG continues to recommend that CMS require the use of claim-level methods to identify 340B claims. We believe that claim-level methods can improve accuracy in identifying 340B claims, and thereby reduce the risk of duplicate discounts and forgone rebates. We acknowledge that the statute does not explicitly direct CMS to require States' use of claim-level methods. However, as CMS notes, States have the primary role of identifying and excluding 340B claims to correctly collect rebates and prevent statutorily-prohibited duplicate discounts.

HRSA concurred with our recommendation to clarify its guidance on preventing duplicate discounts for MCO drugs. However, HRSA stated that it will need to consider public comments received on its proposed omnibus guidance prior to implementing our recommendation.

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## APPENDIX A

### Descriptions of Methods to Identify 340B Claims and Prevent Duplicate Discounts

*Provider-level methods.* Provider-level methods identify covered entities that use 340B-purchased drugs for their Medicaid patients and exclude drug claims billed by those entities from utilization data.

The most prominent provider-level method is the Medicaid Exclusion File (MEF). The MEF, which is maintained by HRSA and published quarterly, contains provider identifiers, such as national provider identifiers (NPIs) and Medicaid billing numbers, for all covered entities that have informed HRSA they will use 340B-purchased drugs for their FFS Medicaid patients for the relevant quarter.<sup>37</sup> Accordingly, States can compare provider identifiers on drug claims for a quarter to the provider identifiers contained in that quarter's MEF, and exclude all matching claims from utilization data when compiling rebate invoices.

Self-developed lists of covered entities are another type of provider-level method. These lists generally contain provider identifiers for covered entities that have been identified as using 340B-purchased drugs for their Medicaid patients, and can be applied in a similar manner as the MEF to exclude 340B claims from rebate invoices. Unlike the MEF, however, these lists are compiled and maintained independently by States, rather than HRSA.

*Claim-level methods.* Claim-level methods exclude individual drug claims that covered entities have explicitly identified as 340B claims from utilization data.

In the most common claim-level method, States direct covered entities to include specific data elements (hereinafter referred to as 340B indicators) on drug claims, in accordance with industry-accepted transaction standards, to identify them as 340B claims. For pharmacy drugs, the National Council on Prescription Drug Programs (NCPDP) Telecommunication standard contains a “submission clarification code”

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<sup>37</sup> The Veterans Health Care Act of 1992 directed the Secretary to develop a mechanism to prevent duplicate discounts. See 42 U.S.C. § 256b(a)(5)(A)(ii). HRSA developed MEF as that mechanism. See 58 Fed. Reg. 34058 (June 23, 1993) and HRSA, *340B Drug Pricing Program Notice: Clarification on use of the Medicaid Exclusion File*, Release No. 2014-1, December 12, 2014.

field that can be populated with a value of “20” to identify a 340B claim.<sup>38</sup> For physician-administered drugs, the American National Standards Institute’s (ANSI) Accredited Standards Committee (ASC) X12 837P standard contains a “UD” modifier value that can be added to identify a 340B claim.<sup>39</sup> Accordingly, States can exclude drug claims with 340B indicators from utilization data when compiling rebate invoices.

States also can employ claim-level methods using alternative mechanisms. For example, States can require covered entities that use 340B-purchased drugs for their Medicaid patients to compile and submit spreadsheets identifying individual 340B claims. States can exclude the drug claims identified in such spreadsheets from utilization data when compiling rebate invoices.

*Other methods.* Other methods attempt to correctly collect rebates by ensuring that utilization data contains no 340B claims that need to be excluded.

For example, States can require covered entities to use non-340B-purchased drugs for their Medicaid patients (i.e., “carve out”). If all of a State’s covered entities correctly do so, the State’s utilization data will not include any 340B claims. Accordingly, the State can compile rebate invoices for manufacturers from its utilization data without causing duplicate discounts to occur.

Alternatively, for MCO drugs, States can delegate the process of excluding 340B claims from utilization data to MCOs. If MCOs correctly exclude 340B claims from their utilization data before providing such data to States, States can compile rebate invoices for manufacturers from MCO utilization data without causing duplicate discounts for MCO drugs to occur.

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<sup>38</sup> The submission clarification code field can be populated with a value of 20 on the initial drug claim (“B1”) transaction, as well as on a subsequent information reporting (“N1”) transaction, which allows providers to amend or revise information from a previously-submitted B1 transaction. See NCPDP, *340B Information Exchange Reference Guide Version 1.0*, July 2011.

<sup>39</sup> While not explicitly defined by ANSI ASC X12 as identifying 340B claims, the UD modifier is often used for this purpose. See, e.g., Apexus 340B Prime Vendor Program, *340B & Medicaid*, p. 1. Accessed at [https://docs.340bpvp.com/documents/public/resourcecenter/340B\\_Medicaid.pdf](https://docs.340bpvp.com/documents/public/resourcecenter/340B_Medicaid.pdf) on January 20, 2016.

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## APPENDIX B

### HRSA and CMS Policies Related to Duplicate Discounts for MCO Drugs

*HRSA's existing guidance on use of the Medicaid Exclusion File.* HRSA guidance states that the Medicaid Exclusion File (MEF) is the official data source regarding covered entities that bill FFS Medicaid for 340B-purchased drugs, but that it is not applicable to MCO drugs.

When HRSA first established the MEF in 1993, the Medicaid Drug Rebate Program applied only to FFS drugs. Accordingly, HRSA's pre-ACA guidance did not distinguish between FFS drugs and MCO drugs.<sup>40</sup> In 2010, the ACA expanded the Medicaid Drug Rebate Program to include MCO drugs.

In December 2014, HRSA issued a notice clarifying that the MEF is available to help prevent duplicate discounts specifically for *FFS* drugs. The notice encouraged covered entities to work with their States to develop alternate strategies for preventing duplicate discounts for MCO drugs.<sup>41</sup>

*HRSA's existing guidance on contract pharmacies and Medicaid.* HRSA guidance allows contract pharmacies to dispense 340B-purchased drugs to FFS Medicaid patients only if “the covered entity, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts” and report the arrangement to HRSA.<sup>42</sup>

HRSA's December 2014 notice did not provide any additional guidance on contract pharmacy requirements related to preventing duplicate discounts specifically for MCO drugs.

*HRSA's proposed omnibus guidance.* In August 2015, HRSA issued proposed omnibus guidance on the 340B Program that explicitly addressed the issue of duplicate discounts for MCO drugs, among other topics.<sup>43</sup> In that proposed guidance, HRSA suggested creating a new exclusion file to account for covered entities' decisions on use of 340B- or non-340B-purchased drugs for their MCO Medicaid patients, but the operational details are yet to be defined. The proposed guidance continues

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<sup>40</sup> See 58 Fed. Reg. 27293 (May 7, 1993), 58 Fed. Reg. 34058 (June 23, 1993), and 65 Fed. Reg. 13983 (March 15, 2000).

<sup>41</sup> HRSA, *340B Drug Pricing Program Notice: Clarification on use of the Medicaid Exclusion File*, Release No. 2014-1, December 12, 2014.

<sup>42</sup> 75 Fed. Reg. 10272, 10278 (March 5, 2010).

<sup>43</sup> 80 Fed. Reg. 52300, 52309 (August 28, 2015).



to encourage covered entities, States, and MCOs to work together on preventing duplicate discounts for MCO drugs.

The proposed guidance would also explicitly apply HRSA's existing guidance on contract pharmacies and Medicaid to MCO drugs as well as FFS drugs.<sup>44</sup>

*CMS's final rule on covered outpatient drugs.* In February 2016, CMS issued a final rule on covered outpatient drugs that discussed duplicate discounts for MCO drugs; however, it did not implement any new regulations on the topic.<sup>45</sup> In the preamble of that final rule, CMS noted that States are responsible for ensuring that duplicate discounts for MCO drugs do not occur. CMS also stated that States should ensure that their MCOs have procedures in place to exclude 340B claims from utilization data. Finally, CMS encouraged States to work with their MCOs and covered entities on preventing duplicate discounts for MCO drugs.

*CMS's final rule on MCOs.* In May 2016, CMS issued a final rule on MCOs that included provisions relating to duplicate discounts for MCO drugs.<sup>46</sup> The final rule mandated that State contracts require MCOs to establish procedures for excluding 340B claims from utilization data provided to States.<sup>47</sup> However, the final rule did not specify what method(s) MCOs should use to do so.

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<sup>44</sup> See 80 Fed. Reg. 52300, 52309 (August 28, 2015). While HRSA's existing guidance on contract pharmacies and Medicaid does not distinguish between FFS drugs and MCO drugs, its proposed omnibus guidance addresses dispensing of 340B-purchased drugs to "Medicaid FFS and/or MCO patients" through contract pharmacies.

<sup>45</sup> 81 Fed. Reg. 5170 (February 1, 2016).

<sup>46</sup> 81 Fed. Reg. 27498 (May 6, 2016).

<sup>47</sup> See 42 C.F.R. § 438.3(s)(3) at 81 Fed. Reg. 27498, 27857 (May 6, 2016). This requirement does not apply to States that require submission of MCO claims data from covered entities directly.

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## APPENDIX C

### Detailed Methodology

*State surveys.* In November 2014, we surveyed all 51 States to identify States that paid for drugs under the MCO model. We sent the surveys to State Medicaid pharmacy directors with instructions to delegate to other State staff as appropriate.<sup>48</sup> We asked whether States paid for either pharmacy drugs or physician-administered drugs through MCOs from July 1, 2013 to June 30, 2014, and whether they had invoiced and collected rebates for those drugs. We received responses from all 51 States for a 100-percent response rate. Of the 51 States, 42 reported that they paid for all or some drugs through MCOs between July 1, 2013 and June 30, 2014, whereas 9 States reported that they did not pay for drugs through MCOs.

We confirmed survey responses of the nine States that reported that they did not pay for drugs through MCOs using three CMS data sources. We checked these data sources for any evidence suggesting that the States had paid for drugs through MCOs. Specifically, we checked CMS's National Summary of State Medicaid Managed Care Programs report from 2012 for any listed plans with outpatient drug coverage.<sup>49</sup> We also checked CMS-64 expenditure data and Medicaid drug utilization data, which States send to CMS, for any dollar amounts associated with drugs paid through MCOs. If we found any such evidence, we contacted the State to resolve the discrepancy and confirm that it did not pay for drugs through MCOs.

We excluded 5 of the 42 States that paid for drugs through MCOs from our analysis. These five States reported that they do not collect any MCO rebates; accordingly, they do not need methods for identifying 340B claims for MCO drugs. Four of the five States reported that they paid for only a small volume of drugs through MCOs (e.g., for a small number of beneficiaries enrolled in Program of All Inclusive Care for the Elderly (PACE) plans). These four States reported that they do not collect MCO rebates because it is not cost-effective to do so for such a small volume of drugs. The fifth State reported that its only MCO was an integrated health system that is itself a covered entity. Accordingly, the State considers all drugs paid through the MCO to be 340B-purchased and thus not subject to rebates.

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<sup>48</sup> In many cases, States had their rebate vendors—i.e., private contractors that assist States in the process of compiling drug utilization data, invoicing manufacturers, and/or collecting rebate payments—respond to some or all survey questions. Throughout this report, we attribute survey and interview responses from rebate vendors to the relevant State.

<sup>49</sup> This was the most current available version of the report.

State interviews. In November and December 2014, we conducted structured interviews with staff from the remaining 37 States. We asked States to describe their methods for identifying 340B claims to collect rebates correctly and prevent duplicate discounts for MCO drugs. We also asked specifically about any differences in the States' methods for pharmacy MCO drugs and physician-administered MCO drugs, as well as MCO drugs dispensed by contract pharmacies.

State follow-up inquiries. In April 2015, we sent follow-up email inquiries to 23 of the 24 States that reported using the MEF to identify 340B claims for MCO drugs. We did so because HRSA's December 2014 notice clarified that the MEF was not intended for use in identifying 340B claims and preventing duplicate discounts for MCO drugs. We did not send a follow-up email inquiry to the one additional State because we did not initially identify it as having reported use of the MEF for MCO drugs. In the follow-up inquiries, we asked States whether they were still using the MEF in the same capacity for MCO drugs.

Identification of potential vulnerabilities. After completing the structured interviews and follow-up inquiries, we assessed the methods reported by States to identify any potential vulnerabilities. Specifically, we assessed whether, and in what circumstances, the methods reported by States could allow duplicate discounts and/or forgone rebates to occur.

## APPENDIX D

### State-Specific Methods to Identify 340B Claims and Prevent Duplicate Discounts for MCO Drugs

State	Description of Methods Used for MCO Drugs
Arizona	Provider-level: self-developed list of covered entities
California	Provider-level: MEF Claim-level: 340B indicators
Delaware	Provider-level: self-developed list of covered entities
Florida	Provider-level: MEF
Georgia	Provider-level: MEF; self-developed list of covered entities
Hawaii	Claim-level: spreadsheet
Illinois	Claim-level: 340B indicators
Indiana	Provider-level: MEF
Iowa	Provider-level: MEF Claim-level: 340B indicators
Kansas	Provider-level: MEF
Kentucky	Provider-level: MEF
Louisiana	Provider-level: MEF
Maryland	Provider-level: self-developed list of covered entities (physician-administered drugs) Claim-level: 340B indicators (pharmacy drugs)
Massachusetts	Claim-level: 340B indicators
Michigan	Provider-level: MEF; self-developed list of covered entities Other: list of specific drugs for certain types of covered entities
Minnesota	Provider-level: MEF Claim-level: 340B indicators (exclusively for contract pharmacies)
Mississippi	Provider-level: MEF
Nebraska	Provider-level: self-developed list of covered entities
Nevada	Provider-level: MEF Other: delegation to MCOs
New Hampshire	Other: required use of non-340B-purchased drugs for Medicaid
New Jersey	Provider-level: MEF
New Mexico	Provider-level: MEF; self-developed list of covered entities Claim-level: 340B indicators
New York	Provider-level: MEF Claim-level: 340B indicators

## State-Specific Methods to Identify 340B Claims and Prevent Duplicate Discounts for MCO Drugs (Continued)

State	Description of Methods Used for MCO Drugs
North Dakota	Provider-level: self-developed list of covered entities Other: required use of non-340B-purchased drugs for Medicaid
Ohio	Provider-level: MEF
Oregon	Provider-level: MEF; self-developed list of covered entities Claim-level: spreadsheet (exclusively for contract pharmacies)
Pennsylvania	Provider-level: MEF
South Carolina	Provider-level: MEF
Tennessee	Provider-level: MEF
Texas	Provider-level: MEF (physician-administered drugs) Claim-level: 340B indicators (pharmacy drugs)
Utah	Claim-level: 340B indicators (pharmacy drugs) Other: required use of non-340B-purchased drugs for Medicaid (physician-administered drugs)
Virginia	Provider-level: MEF Claim-level: 340B indicators
Washington	Provider-level: MEF
West Virginia	Provider-level: self-developed list of covered entities (physician-administered drugs) Claim-level: 340B indicators (pharmacy MCO drugs)
Wisconsin	Provider-level: MEF Other: delegation to MCOs

Source: OIG analysis of State interviews, 2015.

## APPENDIX E

### Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

APR - 1 2016

200 Independence Avenue SW  
Washington, DC 20201

**TO:** Daniel R. Levinson  
Inspector General

**FROM:** Andrew M. Slavitt *Andrew M. Slavitt*  
Acting Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates" (OEI-05-14-00430)

The Centers for Medicare and Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of the Inspector General's (OIG) draft report. CMS takes seriously its responsibility for the accountability, fiscal integrity, and funding of the Medicaid program.

The Medicaid Drug Rebate Program was established by the Omnibus Budget Reconciliation Act of 1990 to help offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. It requires that, for covered outpatient drugs to be eligible for Federal financial participation through Medicaid, manufacturers must pay rebates to states on these drugs when dispensed to Medicaid beneficiaries and paid for by Medicaid. States are responsible for determining the amount of rebates owed and sending invoices to manufacturers for each quarter. In addition, the 340B Drug Pricing Program, established by the Veterans Health Care Act of 1992, requires drug manufacturers to enter into agreements which allows them to provide outpatient drugs to eligible health care providers, known as covered entities, at significantly reduced prices if those drugs are to be eligible for Federal financial participation through Medicaid. Together these programs serve as an increasingly important source of savings for both states and the Federal government.

CMS recognizes the importance of avoiding duplicate discounts and of working with states to establish processes to prevent duplicate discounts. CMS provides technical assistance to states regarding drugs covered under managed care organizations and the Department of Health and Human Services' Health Resources and Services Administration provides the "Medicaid Exclusion File", which identifies covered entities that participate in the 340B program specifically for drugs covered under fee-for-service. As OIG notes, states play a key logistic role in preventing duplicate discounts because they invoice manufacturers for rebates. They have the primary role of identifying 340B claims in utilization data and excluding them before sending manufacturers' a rebate invoice. States use both provider-level and/or claim-level methods to exclude 340B drugs from invoices and have significant flexibility to use a variety of methods to prevent duplicate discounts. In some cases, states may place certain requirements on covered entities regarding the prevention of duplicate discounts. CMS will continue to work with the

states to make sure that utilization data excludes any claims for 340B drugs and address any issues, if necessary.

OIG's recommendation and CMS' response is below:

**OIG Recommendation**

**The OIG recommends that CMS require the use of claim-level methods to identify 340B claims**

**CMS Response**

CMS does not concur with this recommendation. While CMS agrees with the importance of claim-level methods to identify 340B claim, statute does not contemplate that CMS require this from states, covered entities, or contract pharmacies. However, states may develop their own billing instructions as a way to comply with the requirement to prevent duplicate discounts and CMS will continue to provide technical assistance to states, as needed.



**TO:** Deputy Inspector General for Evaluations and Inspections  
Office of Inspector General (OIG)

**FROM:** Acting Administrator

**DATE:** MAR 25 2016

**SUBJECT:** General Comments to OIG Draft Report: State Efforts to Exclude 340B Drugs  
from Medicaid Managed Care Rebates (OEI 05-14-00340)

Attached are HRSA's general comments to OIG's final draft report: State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates (OEI 05-14-00340). If you have any questions, please contact Nettie Richards in HRSA's Office of Planning, Analysis and Evaluation, at (301) 443-2469.



James Macrae

Attachments



**GENERAL COMMENTS OF THE HEALTH RESOURCES AND SERVICES  
ADMINISTRATION (HRSA) ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT  
REPORT "STATE EFFORTS TO EXCLUDE 340B DRUGS FROM MEDICAID  
MANAGED CARE REBATES" (OEI-05-14-00430)**

The Health Resources and Services Administration (HRSA) has reviewed the draft for report OEI-05-14-00430, and appreciates the opportunity to review and comment.

In its report, OIG examines states' methods for identifying claims for 340B-purchased drugs paid through Medicaid Managed care organizations (MCO) and any potential vulnerabilities in states' methods with respect to correctly collecting rebates and preventing duplicate discounts for drugs paid through MCOs. OIG made a recommendation for both the Centers for Medicare & Medicaid Services (CMS) and HRSA. OIG recommends that CMS require states to use claim-level methods to identify 340B claims. OIG recommends that HRSA clarify its guidance on preventing duplicate discounts for MCO drugs. OIG further specifies that in finalizing its August 2015 proposed 340B Omnibus Guidance, HRSA should clarify that for Medicaid MCO drugs, covered entities must follow state instructions to facilitate states' claim-level identification of 340B-purchased drugs. Finally, the OIG recommends that HRSA remove references in the final Omnibus Guidance to a new MCO-specific exclusion file, as it would not be necessary in order for states to correctly collect rebates and prevent duplicate discounts for MCO drugs if states were required by CMS to utilize claims-level methods to identify these drugs.

HRSA concurs with OIG's recommendation to clarify guidance on preventing duplicate discounts for MCO drugs. However, HRSA is currently in the process of reviewing and analyzing the comments received from the public on the proposed 340B Omnibus Guidance. HRSA will need to consider OIG's specific recommendations regarding 340B and Medicaid MCO drugs in conjunction with the comments received by the public as we move forward to finalize the Guidance.

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## **ACKNOWLEDGMENTS**

This report was prepared under the direction of Thomas Komaniecki, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Laura Kordish, Deputy Regional Inspector General.

Adam Freeman and Kelly Waldhoff served as team leaders for this study. Central office staff who provided support include Althea Hosein, Meghan Kearns, and Joanne Legomsky.

# Office of Inspector General

<http://oig.hhs.gov>

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