

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MASSACHUSETTS CLAIMED
UNALLOWABLE FEDERAL
REIMBURSEMENT FOR SOME MEDICAID
PHYSICIAN-ADMINISTERED DRUGS**

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A-06-18-04001

Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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Report in Brief

Date: October 2020

Report No. A-06-18-04001

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



Why OIG Did This Audit

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. However, prior OIG audits found that States did not always invoice and collect all rebates due for drugs administered by physicians.

Our objective was to determine whether Massachusetts complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

How OIG Did This Audit

We reviewed claims for physician-administered drugs paid between January 2016 and December 2017.

We used the Centers for Medicare & Medicaid Services' (CMS's) Medicare Part B crosswalk and the CMS Medicaid Drug File to identify single-source and multiple-source drugs. Additionally, we determined whether the Healthcare Common Procedure Coding System codes were published in CMS's top-20 multiple-source drug listing.

Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs

What OIG Found

Massachusetts did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Massachusetts did not invoice manufacturers for rebates associated with \$11.4 million (Federal share) in physician-administered drugs. Of this amount, \$10.5 million was for single-source drugs, and \$883,000 was for top-20 multiple-source drugs. Of the \$11.4 million, \$9.7 million was related to claims identified as hospital outpatient. Massachusetts did not invoice for rebates for any physician-administered drug claims identified as hospital outpatient claims. In addition, some claims identified as physician claims were not invoiced for rebates. Because Massachusetts' internal controls did not always ensure that it invoiced manufacturers to secure rebates, Massachusetts improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, Massachusetts did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. Providers submitted claims totaling \$4.2 million (Federal share) that did not have National Drug Codes (NDCs) or had invalid NDCs. Furthermore, under the Medicaid drug rebate program, claims totaling \$783,000 (Federal share), which contained NDCs, could have been eligible for rebates.

What OIG Recommends and Massachusetts' Comments

We recommend that Massachusetts refund \$11.4 million and work with CMS to determine the proper resolution of the other claims in question. We also made procedural recommendations.

Massachusetts did not concur with all of our recommendations but stated that beginning with the October 2020 rebate cycle, it will invoice manufacturers for rebates for eligible physician-administered drugs paid through the outpatient hospital payment methodology, including eligible drugs covered by this audit, and remit the Federal share of any rebates collected. Massachusetts also issued additional guidance to providers to include NDCs in most instances when billing for physician-administered drugs.

After reviewing Massachusetts' comments, we maintain that our findings and recommendations are valid.

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INTRODUCTION

WHY WE DID THIS AUDIT

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset the Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, prior Office of Inspector General audits found that States did not always invoice and collect all rebates due for drugs administered by physicians.¹ (Appendix B lists previous audits of the Medicaid drug rebate program.) For this audit, we reviewed the Massachusetts Executive Office of Health and Human Services' (State agency's) invoicing for rebates for physician-administered drugs for the period January 1, 2016, through December 31, 2017.

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

Manufacturers are required to submit a list of all covered outpatient drugs to CMS and to report each drug's average manufacturer price and, where applicable, best price.² On the basis of this information, CMS calculates a unit rebate amount for each drug and provides the information to the States quarterly. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with such fields as National Drug Code (NDC), unit type, units per package size, and product name.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for invoicing manufacturers for rebates as described in section 1927 of the Act. To invoice for rebates, States capture drug utilization data that identifies, by NDC,

¹ *States' Collection of Medicaid Rebates for Physician-Administered Drugs* (OEI-03-09-00410), issued June 24, 2011.

² Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

the number of units of each drug for which the States reimbursed Medicaid providers and report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule. This schedule is part of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program report, which contains a summary of actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

Physician-Administered Drugs

Drugs administered by a physician are typically invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.³ For purposes of the Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.⁴

The Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source physician-administered drugs and for the top 20 multiple-source physician-administered drugs.⁵ Beginning on January 1, 2007, CMS was responsible for publishing annually the list of the top 20 multiple-source drugs by HCPCS codes that had the highest dollar volume dispensed. Before the DRA, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs enable States to identify the drugs and their manufacturers and to facilitate the collection of rebates for the drugs.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for paying claims and collecting Medicaid drug rebates for physician-administered drugs. The State agency uses a contractor⁶ to perform drug rebate processing and to submit invoices to manufacturers. The contractor uses claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to

³ HCPCS codes (sometimes referred to as J-Codes) are used throughout the health care industry to standardize coding for medical procedures, services, product, and supplies.

⁴ See, e.g., the Act § 1927(a)(7). In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated therapeutically equivalent by the Food and Drug Administration. See, e.g., the Act § 1927(k)(7). Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents.

⁵ The term "top 20 multiple-source drugs" is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid. The Act § 1927(a)(7)(B)(i).

⁶ Conduent was the State agency's contractor during the audit period.

invoice manufacturers quarterly. The State agency maintains the record of rebate accounts receivable due from the manufacturers and collects the rebates from the manufacturer.

In Massachusetts, there are two sources of claims for physician-administered drugs. Claims can come from hospital outpatient billings or physician billings.

HOW WE CONDUCTED THIS AUDIT

The State agency claimed \$46.6 million (\$23.3 million Federal share) for fee-for-service physician-administered drugs paid between January 1, 2016, and December 31, 2017.

We used CMS's Medicare Part B crosswalk⁷ to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We then used the CMS Medicaid Drug File to determine whether the identified NDCs were classified as single-source drugs or multiple-source drugs. Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing.⁸

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 contains the details of our audit scope and methodology.

FINDINGS

The State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

The State agency did not invoice manufacturers for rebates associated with \$22.8 million (\$11.4 million Federal share) in physician-administered drugs. Of this amount, \$21 million

⁷ The Medicare Part B crosswalk is published quarterly by CMS and is based on published drug and biological pricing data and information submitted to CMS by manufacturers. CMS uses this information along with pricing data submitted by manufacturers to calculate a volume-weighted sales price for each HCPCS code, which becomes the basis for the reimbursement rate the States pay to providers for the following quarter. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across health care programs.

⁸ We used CMS's last top 20 list, published in 2011, to determine the top-20 physician administered drug claims for our audit period. CMS stopped publishing the list in 2011 because it claimed that virtually all States do not limit NDC numbers on claims for only these drugs but require NDC submission for all physician-administered drugs. Available online at <https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/index.html>. Accessed May 4, 2020.

(\$10.5 million Federal share) was for single-source drugs, and \$1.8 million (\$882,892 Federal share) was for top-20 multiple-source drugs. Also, \$19.3 million (\$9.7 million Federal share) of the \$22.8 million was related to claims identified as hospital outpatient. The State agency did not invoice for rebates for any physician-administered drug claims identified as hospital outpatient claims. These claims were not imported into the Drug Rebate Analysis and Management System for rebate processing. In addition, some claims identified as physician claims were not invoiced for rebate. Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. Providers submitted claims totaling \$8.3 million (\$4.2 million Federal share) that did not have NDCs or had invalid NDCs. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims. Furthermore, under the Medicaid drug rebate program, claims totaling \$1.6 million (\$782,917 Federal share) containing NDCs could have been eligible for rebates.

FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. States must capture NDCs for single-source and top-20 multiple-source drugs (the Act § 1927(a)(7)). To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs for which a State has not required the submission of claims containing the NDCs (42 CFR § 447.520).

In a December 2011 policy update to Massachusetts Community Health Center providers, the State agency stated that effective January 1, 2012, all claims with dates of service on or after January 1, 2012, including without limitation claims for drugs purchased through the 340B program, will require NDC information.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME SINGLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of \$21 million (\$10.5 million⁹ Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates. Of the \$21 million, \$17.6 million was related to claims identified as hospital outpatient.

⁹ The actual number is \$10,518,114.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of \$1.8 million (\$882,892 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates. Of the \$1.8 million, \$1.7 million was related to claims identified as hospital outpatient.

Before 2012, CMS published an annual listing of top-20 multiple-source HCPCS codes and their respective NDCs. However, the State agency did not always submit the utilization data for the top-20 multiple-source drugs to the drug manufacturers for rebate purposes.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these top-20 multiple-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON OTHER PHYSICIAN-ADMINISTERED DRUGS

We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other physician-administered drug claims.

Providers submitted some claims, totaling \$8.3 million (\$4.2 million¹⁰ Federal share), that did not have NDCs or had invalid NDCs. Of the \$8.3 million, \$8,281,068 was related to claims identified as hospital outpatient. For the claims that did not have NDCs or had invalid NDCs in the utilization data, we were unable to determine whether the State agency improperly claimed Federal reimbursement for the physician-administered drugs associated with these claims. Furthermore, under the Medicaid drug rebate program, claims totaling \$1.6 million (\$782,917 Federal share), which contained NDCs, could have been eligible for rebates. Of the \$1.6 million, \$1.4 million was related to claims identified as hospital outpatient. These claims related to drugs that were non-top-20 multiple-source physician-administered drugs with NDCs. The State agency's obligation to invoice these claims for rebate is unclear.

Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$8.3 million (\$4.2 million Federal share) of the claims that were submitted without NDCs or with invalid NDCs and (2) whether the remaining \$1.6 million (\$782,917 Federal share) of other physician-administered drug

¹⁰ The actual number is \$4,154,511.

claims should have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

RECOMMENDATIONS

We recommend that the Massachusetts Executive Office of Health and Human Services:

- refund to the Federal Government \$10,518,114 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$882,892 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;
- work with CMS to determine:
 - the unallowable portion of \$4,154,511 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs or with invalid NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and
 - whether the remaining \$782,917 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims;
- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2017; and
- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our third recommendation, partially concurred with our fifth recommendation, and did not concur with our remaining recommendations.

The State agency broadly agreed with our analysis that the State must invoice manufacturers for rebates relating to eligible physician-administered drugs paid through the State's outpatient

hospital payment methodology; however, the State agency disagreed that the rebating of invoices should have occurred prior to the audit because the State agency had sought guidance from CMS regarding the eligibility of these drugs for rebate and was instructed by staff at CMS not to invoice them pending a legal review. The State agency also disagreed with the wording of our recommendations and requested that they be restated in terms of the forgone Federal rebate rather than the entire Federal share of the claim.

Although not concurring with the first, second, and fourth recommendations, the State agency stated that beginning with the October 2020 rebate cycle, it will invoice manufacturers for rebates for eligible physician-administered drugs paid through the outpatient hospital payment methodology, including eligible drugs covered by this audit, and remit the Federal share of any rebates collected.

The State agency also issued additional guidance to providers to include NDCs in most instances when billing for physician-administered drugs.

The State agency's comments appear in their entirety as Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments, we maintain that our findings and recommendations are valid.

The State agency did not concur with our recommendations because of guidance it received from CMS to not invoice for rebate for physician-administered drugs paid through a specific payment methodology. However, the State was unable to provide us any documentation of this guidance from CMS. We also communicated with CMS about guidance provided to the State, and CMS could not provide any documentation instructing the State not to invoice the claims. In addition, CMS agreed that these types of claims should be invoiced for rebate.

We agree that if the State agency invoices the eligible drugs for rebates and returns the Federal share of rebates, it will not be required to return the Federal share of the claim payment. However, the State would need to reimburse the Federal share of any claims related to the first and second recommendations for which the State is unable to invoice rebates. Federal regulations specifically address the collection of rebates for physician-administered drugs and prohibit Federal reimbursement when proper steps to collect the rebates are not taken.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed \$46,612,453 (\$23,306,226 Federal share) for physician-administered drugs paid between January 1, 2016, and December 31, 2017.

Our audit objective did not require an understanding or assessment of the complete internal control structure of the State agency. We limited our internal control review to obtaining an understanding of the State agency's processes for reimbursing physician-administered drug claims and its process for claiming and obtaining Medicaid drug rebates for physician-administered drugs.

We conducted our audit work, which included contacting the State agency in Boston, Massachusetts, from July 2018 to April 2020.

METHODOLOGY

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs.
- We reviewed State agency regulations and guidance to providers, including invoicing instructions for physician-administered drugs.
- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs.
- We obtained listings of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk, and the CMS Medicaid Drug File for our audit period.
- We obtained claim details from the State agency for all physician-administered drugs for the period January 1, 2016, through December 31, 2017.
- We removed drug claims totaling \$13,935,584 (\$6,967,792 Federal share) that either were not eligible for a drug rebate or contained an NDC and were invoiced for rebate.
- We reviewed the remaining drug claims totaling \$32,676,868 (\$16,338,434 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically:

- We identified single-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We used the CMS Medicaid Drug File to determine whether these NDCs were classified as single-source drugs.
- We identified the top 20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug listing.
- We identified the remaining drugs (those not identified as single-source or as top-20 multiple-source drugs) as other outpatient physician-administered drugs.
- We discussed the results of our review with State agency officials.

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>Vermont Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-19-06086</u>	9/18/2020
<i>Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-18-06079</u>	9/14/2020
<i>Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-05-17-00017</u>	8/25/2020
<i>Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician Administered Drugs</i>	<u>A-09-19-02001</u>	7/21/2020
<i>New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-02-18-01016</u>	4/7/2020
<i>New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-18-01011</u>	2/19/2020
<i>New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-02-16-01011</u>	8/30/2019
<i>Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-06-17-04001</u>	8/21/2019
<i>Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates</i>	<u>A-07-18-06078</u>	8/16/2019
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-18-00030</u>	6/18/2019
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-16-01012</u>	5/9/2019
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-17-00038</u>	4/5/2019
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02031</u>	2/16/2018
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-16-00018</u>	2/12/2018
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-13-06046</u>	12/22/2017
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00004</u>	12/12/2017

Report Title	Report Number	Date Issued
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-16-00013	11/1/2017
<i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02028	9/26/2017
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02029	9/26/2017
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02027	9/12/2017
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	A-07-16-06065	5/5/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-16-00014	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06050	1/5/2017
<i>Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-03-15-00202	12/30/2016
<i>Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-03-15-00201	12/22/2016
<i>California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	A-09-15-02035	12/8/2016
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-07-15-06060	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06057	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-15-06063	3/31/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-15-06059	2/9/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-15-06062	1/14/2016
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-15-06058	1/13/2016

Report Title	Report Number	Date Issued
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	A-09-14-02038	1/7/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-14-06056	9/18/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06049	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-06-12-00060	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06051	4/13/2015
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-13-02037	3/4/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-14-00031	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00205	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-13-06040	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	A-09-12-02079	4/30/2014
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	A-09-12-02080	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00200	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-12-00059	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	A-06-10-00011	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	OEI-03-09-00410	6/24/2011

APPENDIX C: FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 (which added section 1927 to the Act), became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services (HHS) and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

Section 6002 of the DRA added section 1927(a)(7) to the Act to require that States capture information necessary to secure rebates from manufacturers for certain covered outpatient drugs administered by a physician. In addition, section 6002 of the DRA amended section 1903(i)(10) of the Act to prohibit Medicaid Federal share for covered outpatient drugs administered by a physician unless the States collect the utilization and coding data described in section 1927(a)(7) of the Act.

Section 1927(a)(7) of the Act requires States to provide for the collection and submission of such utilization data and coding (such as J-codes and NDCs) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top 20 multiple-source drugs effective January 1, 2008. Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Section 1927(a)(7)(D) of the Act allowed HHS to delay any of the above requirements to prevent hardship to States that required additional time to implement the physician-administered drug reporting requirements.

FEDERAL REGULATIONS

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specify that no Federal share is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to invoice a manufacturer for rebates (42 CFR § 447.520).

STATE AGENCY GUIDANCE

The State agency publishes provider bulletins to clarify and explain new and existing programs and policies for providers. The MassHealth Community Health Center Bulletin 69, December 2011, states that effective January 1, 2012, all claims with dates of service on or after January 1, 2012, including without limitation claims for drugs purchased through the 340B program, will require NDC information. The Provider Bulletin adds that claims that do not have the required NDC information will be denied or be subject to recoupment.

APPENDIX D: STATE AGENCY COMMENTS



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September 14, 2020

Patricia Wheeler
Regional Inspector General for Audit Services
Office of Audit Services, Region VI
1100 Commerce Street, Room 632
Dallas, TX 75242

RE: Massachusetts Executive Office of Health and Human Services Response to U.S.
Department of Health and Human Services, Office of the Inspector General Draft Report No:
A-06-18-04001

Dear Ms. Wheeler:

The Massachusetts Executive Office of Health and Human Services ("EOHHS") is writing to respond to the U.S. Department of Health and Human Services, Office of the Inspector General's ("OIG") draft report titled *Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs* (No. A-06-18-04001; dated July 29, 2020) ("the Report"). Thank you for your consideration of EOHHS's comments on the Report.

As described below, EOHHS broadly agrees with the OIG's analysis that EOHHS must invoice manufacturers for rebates relating to eligible physician-administered drugs paid through EOHHS's outpatient hospital payment methodology. **EOHHS disagrees, however, that it should have invoiced manufacturers previously for such drugs because, unrelated to the OIG's audit, EOHHS had sought confirmatory guidance from CMS regarding the eligibility of certain drugs for rebate and was expressly instructed by staff at the Center of Medicare and Medicaid Services ("CMS") not to invoice manufacturers for such drugs pending further CMS legal review.** However, EOHHS has notified CMS that beginning with the October 2020 rebate cycle, it will invoice manufacturers for rebates for eligible physician-administered drugs paid through the outpatient hospital payment methodology, including the eligible drugs covered by this audit, and remit the Federal share of any rebates collected.

The substantial majority of claims for which the OIG found that EOHHS had improperly claimed Federal reimbursement were claims for hospital outpatient drugs paid through a methodology called the adjudicated payment per episode of care (“APEC”). EOHHS had transitioned to this payment methodology near the beginning of the OIG’s audit period. Due to complexities and nuances of this payment methodology and the Federal statute and regulations governing covered outpatient drugs, EOHHS engaged in a lengthy analysis as to whether drugs paid through that methodology met the definition of covered outpatient drugs and that EOHHS was therefore required to be rebated. EOHHS ultimately determined that it was required to invoice manufacturers for these drugs.¹ However, because of the complexities involved, EOHHS sought confirmatory guidance from CMS before invoicing manufacturers for rebates for clinician-administered drugs paid for through the APEC.

Specifically, EOHHS notified CMS of its intention to invoice for rebates for physician-administered drug claims paid through the APEC in a phone conversation between pharmacy staff at CMS and EOHHS in July 2018. Subsequently, Dan Tsai, Assistant Secretary for MassHealth had an additional conversation with senior staff at CMS in September 2018 to further explain EOHHS’s position that it was required to invoice for rebates for such drugs. EOHHS followed with a letter from the MassHealth pharmacy director to the Director of the CMS Pharmacy Division in June 2019, noting that it intended to submit invoices and describing in detail the legal basis for its determination that EOHHS was required to invoice manufacturers for rebates on such drugs. In November 2019, Dan Tsai, the Assistant Secretary for MassHealth again discussed this issue with senior staff at CMS. In response to this outreach, CMS instructed EOHHS not to invoice manufacturers for these rebates pending further CMS legal review. EOHHS was left in a difficult position. Its own analysis indicated it was required to invoice for rebates on physician-administered drugs paid through the APEC, but CMS requested that EOHHS not do so. Absent these instructions from CMS, EOHHS would have invoiced for rebates for eligible physician-administered drugs paid through the APEC for the period January 1, 2016 through December 31, 2017. Based on EOHHS’ understanding of CMS’ current view of this issue in the course of this OIG review, EOHHS has notified CMS that it intends to invoice manufacturers for these drugs beginning with the October 2020 rebate cycle, including the eligible claims covered by this audit. EOHHS respectfully requests that OIG acknowledge this situation in its final report, and reduce its findings accordingly.

¹ EOHHS’s analysis is as follows: A Federal statute defines a covered outpatient drug as a drug that “may be dispensed only upon a prescription.” 42 USC 1396r–8(k)(3); see also 42 CFR 447.502. Specific limitations apply to the general rule, and the statutory definition excludes “any drug . . . provided as part of or incident to and in the same setting as any of [certain other medical services, including outpatient hospital services] (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug).” 42 USC 1396r–8(k)(3); see also 42 CFR 447.502. The exclusion makes clear that drugs administered in outpatient settings, like those paid for through the APEC, *can* be covered outpatient drugs. Importantly, such drugs are not *per se* excluded from the definition simply based on the setting in which they are administered. The provider’s billing method is not determinative either. The relevant consideration for determining whether a drug is a covered outpatient drug, therefore, is whether a state’s method of payment provides “direct reimbursement for the drug.” See Covered Outpatient Drugs Final Rule with Comment, 81 F.R. 5169, 5187-88 (Feb. 1, 2016) (“[A] drug which is billed as part of a bundled service . . . meets the definition of a [covered outpatient drug] if the state authorizes and provides a direct payment for the drug.”). EOHHS determined that APEC, with its identifiable amounts attributable to drugs and other components within a payment for an episode of care, pays for drugs *as incident* to services provided in an episode of care, but not *as part* of those service, and that accordingly it is required to invoice manufacturers for rebates on drugs paid for through its APEC.

EOHHS also believes that the OIG has significantly overstated its conclusions, by framing its findings in terms of allegedly improper claims and by recommending that EOHHS return the entire federal share of such claims. Particularly in light of the conflicting federal guidance EOHHS received from CMS regarding these claims, EOHHS believes OIG more appropriately should frame its finding and recommendations in terms of the forgone federal share of the rebate. Indeed, in discussions with OIG staff during the course of the audit, EOHHS has stated its intention to invoice manufacturers for rebates for eligible drugs once CMS had updated its guidance to EOHHS, and OIG staff have indicated that doing so would “cure” their audit findings. EOHHS respectfully requests that OIG reframe its findings and recommendations accordingly in its final report.

EOHHS has the following responses to the specific OIG recommendations:

EOHHS Responses to OIG Recommendations

OIG Recommendation 1: The OIG recommends that EOHHS refund to the Federal Government \$10,518,114 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.

EOHHS Response: EOHHS does not concur with this recommendation. EOHHS disagrees that these drugs were ineligible for federal reimbursement in light of the guidance that EOHHS received from CMS at the time, as described above. Rather, EOHHS believes this recommendation should be restated in terms of the foregone Federal rebate rather than entire Federal share of the claim.

Instead of refunding to the Federal government the claims that OIG claims were ineligible for Federal reimbursement, EOHHS intends to invoice manufacturers for rebates on any eligible drugs. In the event EOHHS does not have sufficient information to invoice for rebate on a particular claim, EOHHS will seek to obtain the additional information necessary to invoice for rebates. EOHHS will remit the Federal share of the manufacturers’ rebates for those claims to the Federal Government.

OIG Recommendation 2: The OIG recommends that EOHHS refund to the Federal Government \$882,892 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;

EOHHS Response: EOHHS does not concur with this recommendation. EOHHS disagrees that these drugs were ineligible for federal reimbursement in light of the guidance that EOHHS received from CMS at the time, as described above. Rather, EOHHS believes this recommendation should be restated in terms of the foregone Federal rebate rather than entire Federal share of the claim.

Instead of refunding to the Federal government the claims that OIG claims were ineligible for Federal reimbursement, EOHHS intends to invoice manufacturers for rebates on any eligible drugs. In the event EOHHS does not have sufficient information

to invoice for rebate on a particular claim, EOHHS will seek to obtain the additional information necessary to invoice for rebates. EOHHS will remit the Federal share of the manufacturers' rebates for those claims to the Federal Government.

OIG Recommendation 3: The OIG recommends that EOHHS work with CMS to determine:

- o the unallowable portion of \$4,154,511 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs or with invalid NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and

- o whether the remaining \$782,917 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims;

EOHHS Response 3: EOHHS concurs with the first subpart of this recommendation to the extent that it recommends that EOHHS work with CMS to determine whether claims were submitted that should be invoiced for rebate. EOHHS intends to work internally and with CMS to determine whether these claims for covered outpatient physician-administered drugs should have included NDCs. If so, EOHHS intends to invoice manufacturers for rebates for any eligible drugs. EOHHS will remit the Federal share of the manufacturers' rebates for those claims to the Federal Government.

EOHHS concurs with the second subpart of this recommendation. EOHHS will work with CMS to determine if these could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, remit the Federal share of the manufacturers' rebates for those claims.

OIG Recommendation 4: The OIG recommends that EOHHS work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2017.

EOHHS Response: EOHHS does not concur with this recommendation. EOHHS did not invoice manufacturers for certain physician-administered drugs because of the guidance it received from CMS at the time. In light of the apparent updated guidance, EOHHS will invoice manufacturers for rebates on physician-administered drugs paid through APEC, as it currently does for physician-administered drugs paid through the traditional fee schedule. EOHHS will remit the Federal share of the manufacturers' rebates for those claims to the Federal Government.

OIG Recommendation 5: The OIG recommends that EOHHS strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

EOHHS Response: To the extent this recommendation refers to EOHHS's internal controls related to invoicing for rebates for eligible drugs paid through its outpatient

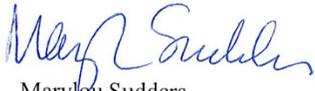
hospital methodology, EOHHS does not concur with this recommendation. OIG's findings in this area are primarily attributable to the instructions EOHHS received from CMS rather than weakness in internal controls. As previously noted, EOHHS will invoice manufacturers for rebates on physician-administered drugs paid through APEC, as it currently does for physician-administered drugs paid through the traditional fee schedule. EOHHS will remit the Federal share of the manufacturers' rebates for those claims to the Federal Government.

To the extent this recommendation refers to the collection of NDCs, EOHHS agrees with the recommendation and notes that it has already issued additional guidance to providers, including MassHealth Acute Outpatient Hospital Provider Bulletin 34 issued in December 2019 clarifying providers' obligations to include NDCs associated with physician-administered drugs in most instances.

EOHHS reiterates that its overall position is consistent with the OIG's analysis: physician-administered drugs paid through EOHHS's outpatient hospital payment methodology should generally be invoiced for rebate. EOHHS requests that OIG recognize that EOHHS was specifically instructed by CMS not to invoice manufacturers for such drugs. Furthermore, in light of CMS's apparent updated guidance, EOHHS will invoice for rebates for eligible drugs paid through its outpatient hospital methodology beginning with the October 2020 rebate cycle and remit the Federal share of the manufacturers' rebates for those claims to the Federal Government.

Thank you for your consideration of EOHHS' comments.

Sincerely,



Marylou Sudders

cc: Dan Tsai
Amanda Cassel Kraft
Leslie Darcy, EOHHS Chief of Staff