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West Virginia Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs

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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.
- Prior OIG audits found that States did not always invoice and collect all rebates due for drugs administered by physicians.
- This audit is one of a series of audits in which we are reviewing compliance with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

What OIG Found

West Virginia did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

- West Virginia did not invoice for, and collect from manufacturers, rebates totaling $2.2 million (Federal share). Of this amount, $2.2 million (Federal share) was for single-source drugs and $14,514 (Federal share) was for top-20 multiple-source drugs.
- We also identified rebates totaling $488,185 (Federal share) for other multiple-source drugs for which we were unable to determine whether, in some cases, West Virginia was required to invoice for rebates.
- In addition, West Virginia did not invoice for, and collect from manufacturers, $65 million (Federal share) in rebates for physician-administered drugs invoiced on crossover claims, for which enrollees are eligible for both Medicare and Medicaid services.

What OIG Recommends

We make five recommendations to West Virginia, including that West Virginia:

1. refund to the Federal Government the $2.2 million (Federal share) for single-source drugs;
2. refund to the Federal Government the $14,514 (Federal share) for top-20 multiple-source drugs;
3. work with CMS to determine and refund the unallowable portion of the $488,185 (Federal share) for other multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement and consider invoicing drug manufacturers for rebates for those drugs;
4. strengthen internal controls for non-crossover claims going forward, to better use collected data to invoice manufacturers and collect rebates; and
5. consider revising West Virginia's payment methodology going forward for crossover claims.

The full recommendations are in the report.

West Virginia concurred with our first three (monetary) recommendations and described corrective actions that it planned to take. West Virginia did not concur with our fourth and fifth (procedural) recommendations.

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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 their 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 (OIG) audits found that States did not always invoice and collect all rebates due for drugs administered by physicians. (Appendix B lists previous OIG audits and reviews of the Medicaid drug rebate program.[1]) For this audit, we reviewed the West Virginia Bureau for Medical Services' (State agency's) invoicing for rebates for physician-administered drugs for the period January 1, 2019, through December 31, 2022 (audit period).

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 to CMS of all covered outpatient drugs 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 each quarter. 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

[1] OIG performed similar audits for rebates due for drugs administered by physicians to fee-for-service and Medicaid managed care organizations' enrollees. These audits are included in Appendix B.

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

1927(a)(7) of the Act. To invoice for rebates, States capture drug utilization data that identifies, by NDC, 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 (Form CMS-64), 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.

States' Collection of Rebates for 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] To collect rebates for drugs, States submit to the manufacturers the drug utilization data containing NDCs for the drugs. NDCs enable States to identify the drugs and their manufacturers to facilitate the collection of rebates for the drugs. Before the Deficit Reduction Act of 2005 (DRA), many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs.

The 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 the top 20 multiple-source physician-administered drugs.[4] For purposes of the Medicaid drug rebate program, single-source drugs are those covered outpatient drugs produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA).[5] Multiple-source drugs are defined, in part, as those covered outpatient drugs that have at least one other drug rated as therapeutically equivalent by the FDA.[6] Beginning on January 1, 2007, CMS was responsible for publishing the list of the top 20 multiple-source drugs by HCPCS codes that had the highest dollar volume dispensed.

[3] HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies. The HCPCS codes associated with physician-administered drugs generally begin with a "J" and are referred to as J-Codes. These physician-administered drugs include injectable drugs that ordinarily cannot be self-administered, such as chemotherapy drugs, immunosuppressive drugs, and inhalation solutions.

[4] 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)). CMS published lists of the top-20 multiple-source drugs (with respective HCPCS codes and NDCs) in 2006, 2009, 2010, and 2011 and then not again until 2021.

[5] Section 1927(k)(7) of the Act. Single-source drugs are commonly referred to as "brand-name" drugs.

[6] Section 1927(k)(7) of the Act. According to the definition of "therapeutically equivalent" in the FDA glossary of terms, a therapeutically equivalent drug product can be substituted for another product to achieve the same clinical effect as the prescribed drug.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for invoicing and collecting Medicaid drug rebates for physician-administered drugs. The State agency is required to submit drug utilization data to manufacturers, detailing drug usage by Medicaid enrollees, within 60 days of the end of each quarter. During our audit period, the State agency contracted with a fiscal agent to handle the claims data. The fiscal agent processed and invoiced Federal rebates through its rebate administration system. The State agency collected the rebates and forwarded the amount of rebates received to the fiscal agent. The fiscal agent was also responsible for payment tracking and reconciliation as well as resolving disputes related to Federal rebates. The fiscal agent housed historic quarterly rebate data in its rebate management system.

HOW WE CONDUCTED THIS AUDIT

We reviewed physician-administered drug claims totaling $76,224,690 that the State agency paid between January 1, 2019, and December 31, 2022.

We used the quarterly CMS Medicaid Drug Rebate files and the Medicaid Drug Product files to determine whether the NDCs listed on the claims were classified as single-source drugs or multiple-source drugs. For claims submitted without an NDC, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.[7] Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug list.

We removed claims for drugs that either were not eligible for rebates or had been invoiced for rebates.

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.

[7] The Medicare Part B crosswalk is published quarterly by CMS and is based on drug and biological 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 State pays 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 (State Medicaid Director Letter No. 06-016 (July 11, 2006)).

FINDINGS

During our audit period, 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 for, and collect from manufacturers, rebates totaling $2,908,130 ($2,173,585 million Federal share) for physician-administered drugs. Of this amount, $2,888,681 ($2,159,071 Federal share) was for single-source drugs and $19,449 ($14,514 Federal share) was for top-20 multiple-source drugs. 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.

Furthermore, we were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other multiple-source physician-administered drug claims. Although the State agency generally collected the drug utilization data necessary to invoice manufacturers for rebates associated with these drugs, the State agency did not invoice the manufacturers for rebates associated with the claims totaling $653,333 ($488,185 Federal share) for these other multiple-source physician-administered drugs. Accordingly, we are recommending that the State agency work with CMS to determine the unallowable portion of the $488,185 (Federal share) for these claims and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

In addition, the State agency did not invoice for, and collect from manufacturers, $87,192,582 ($65,119,566 Federal share) in rebates for physician-administered drugs invoiced on crossover claims, for which enrollees are eligible for both Medicare and Medicaid services.

Although its policies required the collection of drug utilization data necessary to invoice for rebates on all physician-administered drug claims, the State agency's internal controls did not always ensure that the collected data were used to invoice manufacturers and collect rebates for physician-administered drugs for these claims.

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 NDCs (42 CFR § 447.520).

The State agency also requires providers of Medicaid services to include the NDCs on the claim form when submitting invoices to the State agency for payment (*BMS [Bureau for Medical Services] Provider Manual*, chapter 518.1, revised Oct. 1, 2015).

Appendix C contains Federal requirements and State agency guidance related to physician-administered drugs.

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

The State agency improperly claimed Federal reimbursement of $2,888,681 ($2,159,071 Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Because the State agency did not invoice manufacturers for rebates for these single-source drugs, these claims were not eligible for Federal reimbursement.

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 $19,449 ($14,514 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

CMS last provided the State agency with an annual list of top-20 multiple-source HCPCS codes and their respective NDCs in 2021 for use with claims paid on June 15, 2021, and after.[8] For claims paid in 2019 and 2020, and through June 14, 2021, CMS provided a list of top-20 multiple-source HCPCS codes and their respective NDCs in 2011 (footnote 4). We relied on these lists to identify top-20 multiple-source physician-administered drugs. However, the State agency did not always submit the utilization data for the drugs on the list to the drug manufacturers for rebate purposes.

Because the State agency did not invoice manufacturers for rebates for these top-20 multiple-source drugs, these claims were not eligible for Federal reimbursement.

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

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

Although the State agency generally collected the drug utilization data necessary to invoice manufacturers for rebates associated with these multiple-source physician-administered drugs, the State agency did not invoice the manufacturers for rebates associated with these drugs,

[8] Top 20 Multiple Source Covered Outpatient Physician Administered Drugs, June 15, 2021, https://www.medicaid.gov/medicaid/prescription-drugs/downloads/top20-covered-oms-drugs.pdf. Accessed on Sept. 19, 2024.

which were not identified as top-20 multiple-source drugs. Providers submitted claims totaling $653,333 ($488,185 Federal share) that were not used to obtain Medicaid drug rebates. Under the Medicaid drug rebate program, these claims could have been eligible for rebates.

Accordingly, we set aside $653,333 ($488,185 Federal share) for the remaining multiple-source drug claims and are recommending that the State agency work with CMS to determine the unallowable portion of these claims and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

Although its policies require the collection of drug utilization data necessary to invoice for rebates on all physician-administered drug claims, the State agency's internal controls did not always ensure that the State agency used data it had collected to invoice manufacturers and collect rebates for physician-administered drugs for these claims.

THE STATE AGENCY HAS AN OPPORTUNITY TO IMPROVE ITS PAYMENT METHODOLOGY FOR CROSSOVER CLAIMS TO OBTAIN REBATES FOR PHYSICIAN-ADMINISTERED DRUGS

The State agency did not invoice for, and collect from manufacturers, $87,192,582 ($65,119,566 Federal share) in rebates for physician-administered drugs invoiced on crossover claims. The term "crossover claims" refers to Medicaid claims for Federal reimbursement that involve enrollees who are eligible for both Medicare and Medicaid services (also known as "dual-eligible" enrollees). For crossover claims, health care providers invoice Medicare, which calculates its payment first and then submits an invoice containing any applicable coinsurance or deductible amounts to the State agency.

As part of the invoice process for crossover claims, Medicare submits two sets of data for services rendered to dual-eligible enrollees: (1) the line-item level, which shows each individual service, such as physician-administered drugs, and (2) the header level, which consolidates the services to show a combined total amount for all the services on the claims. For a claim to be eligible for rebate, the State agency must make a payment for the physician-administered drug(s) at the line-item level.

After receiving crossover claims data from Medicare, the State agency calculates the payment it will make to the provider.[9] However, as a consequence of the State agency's payment methodology, the State agency did not pay any portion of the amounts not covered by Medicare on any crossover claims during our audit period.

For example, a provider administered an alteplase recombinant injection to a dual-eligible enrollee on July 1, 2022; the provider subsequently submitted a claim to Medicare for

[9] Under § 1902(n)(2) of the Act, "[A] State is not required to provide . . . payment for deductibles, coinsurance, or copayments for [M]edicare cost-sharing to the extent that payment . . . for the service would exceed the payment amount that otherwise would be made under the State plan . . . for such service . . . ."

reimbursement in the amount of $44,112.[10] Medicare paid the claim at the header level, and then submitted a claim to the State agency, asking it to pay the Medicaid amount or lesser. The State agency denied Medicare's claim and did not pay any of the amount not covered by Medicare. However, if the State agency's payment methodology had allowed a payment of even a nominal amount, the State agency could have collected $13,807 ($10,220 Federal share) in rebates for this claim. In conformance to its payment methodology, the State agency did not pay for these crossover claims, which resulted in the State agency forgoing rebates for physician-administered drugs.

We acknowledge that, according to the Act, the State agency was not required to make a payment on these crossover claims; however, we believe the State agency has an opportunity to improve its administration of the Medicaid drug rebate program insofar as crossover claims are concerned. If its payment methodology would have required the State agency to pay an amount on the cost-sharing of these crossover claims, the State agency could have invoiced for additional rebates totaling $87,192,582 ($65,119,566 Federal share) during our audit period.

RECOMMENDATIONS

We recommend that the West Virginia Bureau for Medical Services:

- refund to the Federal Government $2,159,071 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $14,514 (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 $488,185 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable;

- strengthen internal controls for non-crossover claims going forward, to better use collected data to invoice manufacturers and collect rebates for all eligible physician-administered drugs; and

- consider revising its payment methodology going forward regarding payments for crossover claims, thereby allowing collection of manufacturers' rebates for associated physician-administered drugs.

[10] Alteplase recombinant is an injection used to dissolve blood clots that have formed in the blood vessels. This drug is administered immediately after a patient has experienced symptoms of a heart attack in order to improve the patient's chances of surviving and recovering.

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 first three recommendations and described corrective actions that it planned to take. The State agency did not concur with our fourth and fifth recommendations.

For our first and second recommendations, the State agency said that it would work with CMS to determine whether the physician-administered drugs on the claims we identified should have been included for rebating. The State agency added that if so, it would "process those drugs as part of a rebate invoicing cycle."

For our third recommendation, the State agency said that it would work with CMS to determine the unallowable portion of the multiple-source physician-administered drugs we identified. The State agency added that it would consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

The State agency did not concur with our fourth recommendation because, it said, it has "controls in our medical billing system that deny fee-for-service claims when there is an invalid NDC/HCPCS match based on a crosswalk of NDCs that is updated routinely." The State agency also stated that its medical billing system would deny claims "if there are missing NDCs, HCPCS codes, and/or quantity amounts" on those claims. In addition, the State agency said that on review of these claims, it had "verified that the coding and crosswalk were accurate at the time of adjudication."

The State agency also did not concur with our fifth recommendation, which involved crossover claims. The State agency stated that after Medicare paid its portion of a crossover claim, the claim would cross over to Medicaid to adjudicate the remaining balance. In addition, the State agency stated: "If Medicare paid more than Medicaid would have allowed, then Medicaid pays zero. If there is no Medicaid payment on a fee-for-service claim, then the drug on the claim cannot be included for rebate processing." The State agency added that it pays crossover claims at the header level.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments on our draft report, we maintain that all of our recommendations remain valid. We commend the State agency for the corrective actions it described in its comments on our first three recommendations.

For our fourth recommendation, our report acknowledges that the State agency has policies regarding the collection of drug utilization data as well as internal controls regarding the

invoicing of manufacturers and the collection of rebates for physician-administered drugs. However, the amounts conveyed in our monetary recommendations suggest that the State agency has the opportunity to strengthen these internal controls.

For our fifth recommendation, we agree with the State agency's description of the payment protocols for crossover claims. We also acknowledge that because the State agency did not make a payment on these claims at the line-item level, the claims were not eligible for rebate. However, although the State agency did not concur with this recommendation, we believe that the State agency has the opportunity to improve its administration of the Medicaid drug rebate program. For instance, if the State agency's payment methodology were to require it to pay an amount on the cost-sharing of crossover claims, the State agency could invoice for and obtain significantly more Medicaid drug rebates, as our report's final finding suggests.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed physician-administered drug claims that the State agency paid between January 1, 2019, and December 31, 2022 (audit period). During our audit period, the State agency paid $76,224,690 associated with physician-administered drugs.

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 procedures for and controls over invoicing for Medicaid rebates for physician-administered drugs, as well as its payment methodology for crossover claims.

We conducted our audit work, which included contacting the State agency in Charleston, West Virginia, from May 2023 to September 2024.

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 requirements, policies, and procedures for rebates 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 lists of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk (footnote 7), the CMS Medicaid Drug Rebate File, and the CMS Medicaid Drug Product File for our audit period.

- We asked the State agency to identify 340B entities, which are drug claims associated with 340B entities and which are therefore not eligible for rebate.[11]

[11] Under the 340B drug pricing program (set forth in 42 U.S.C. § 256b), a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers; examples of 340B entities are disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug assistance programs. Drugs subject to discounts under the 340B drug pricing program are not subject to rebates under the Medicaid drug rebate program. Section 1927(j) of the Act and 42 U.S.C. § 256(a)(5)(A).

- We obtained from the State agency a detailed list of physician-administered drug claims paid between January 1, 2019, through December 31, 2022. In response to this request, the State agency provided data associated with claims totaling $76,224,690. We took the following steps:

    - We identified single-source drugs based on the classification of the drugs in the quarterly CMS Medicaid Drug Rebate File and the CMS Medicaid Drug Product File. If the claims data did not include an NDC, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify all of the NDCs associated with each HCPCS code. Because in each of these cases the NDC was unknown, we used the most conservative drug classification for the NDCs associated with the HCPCS code.

    - 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 list.

    - We identified other multiple-source drugs eligible for rebate that were not single-source or top-20 multiple-source drugs.

- We followed up with State agency officials for an explanation of eligible claims that had not been invoiced for rebate.

- We identified the physician-administered drugs invoiced on crossover claims that would have been eligible for a drug rebate if the State agency had made payments on the line-item level and, to estimate the finding amount, we took the following steps:

    - We calculated the State agency's percentage of rebates collected (that is, the total drug rebates received as a percentage of the total drug costs, as reported on Forms CMS-64) for the audit period (footnote 9).

    - We multiplied the percentage of rebates collected for each year of our audit period (calculated as explained in the subbullet just above) by the allowed amount from the claims data.

- We discussed the results of our audit 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
South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-22-07010	8/28/2024
State Agencies Could Be Obtaining Hundreds of Millions in Additional Medicaid Rebates Associated With Physician-Administered Drugs	A-07-23-06111	5/9/2024
Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-21-06103	10/18/2023
Alabama Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs	A-04-21-08090	9/21/2023
Kentucky Did Not Always Invoice Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-04-22-07102	9/12/2023
Georgia Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs	A-04-21-08089	3/13/2023
Florida Did Not Invoice Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-04-21-07098	3/3/2023
North Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-21-07002	2/7/2023
Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-21-06101	10/27/2022
Tennessee Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-21-06096	9/14/2022
South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-21-07003	8/10/2022
Colorado Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-17-06075	9/8/2021

Report Title	Report Number	Date Issued
New Mexico Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-06-16-00001	6/2/2021
Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-18-04001	10/22/2020
Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-05-17-00018	10/21/2020
Vermont Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-19-06086	9/18/2020
Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-18-06079	9/14/2020
Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-05-17-00017	8/25/2020
Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-09-19-020f01	7/21/2020
New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-02-18-01016	4/7/2020
New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-02-18-01011	2/19/2020
New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-02-16-01011	8/30/2019
Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-06-17-04001	8/21/2019
Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates	A-07-18-06078	8/16/2019
Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-18-00030	6/18/2019
New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-02-16-01012	5/9/2019

Report Title	Report Number	Date Issued
Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-17-00038	4/5/2019
Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02031	2/16/2018
Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-16-00018	2/7/2018
Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-13-06046	12/22/2017
Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations	A-06-16-00004	12/12/2017
Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-16-00013	11/1/2017
Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02028	9/26/2017
Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02029	9/26/2017
Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02027	9/12/2017
Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations	A-07-16-06065	5/5/2017
Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-16-00014	3/23/2017
Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06050	1/5/2017
Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-03-15-00202	12/30/2016

Report Title	Report Number	Date Issued
Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-03-15-00201	12/22/2016
California Did Not Bill Manufacturers for Rebates For Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations	A-09-15-02035	12/8/2016
Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-15-06060	8/18/2016
Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06057	5/26/2016
Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06063	3/31/2016
South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06059	2/9/2016
Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06062	1/14/2016
North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06058	1/13/2016
California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-14-02038	1/7/2016
Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-14-06056	9/18/2015
Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06049	7/22/2015
Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-12-00060	5/4/2015
Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06051	4/13/2015
Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-13-02037	3/4/2015

Report Title	Report Number	Date Issued
Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-14-00031	2/10/2015
The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00205	8/21/2014
Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-13-06040	8/7/2014
Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs	A-09-12-02079	4/30/2014
Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-12-02080	4/24/2014
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00200	11/26/2013
Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-12-00059	9/19/2013
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	8/12/2011
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	6/24/2011

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

FEDERAL REQUIREMENTS

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 that 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 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 a 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 that States shall provide for the collection and submission of such utilization data and coding 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.[12] 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)).

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specifically state 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 bill a manufacturer for rebates (42 CFR § 447.520).

[12] 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 FDA. See, e.g., section 1927(k)(7) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents. Further, 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)).

STATE AGENCY GUIDANCE

According to the State agency's *BMS Provider Manual*, chapter 518.1, revised Oct. 1, 2015, providers are required to include the NDC when invoicing the State agency for physician-administered drugs.

STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

Cynthia A. Persily, Ph.D.
Cabinet Secretary

Cynthia Beane, MSW, LCSW
Commissioner

November 6, 2024

Report Number: A-07-23-06109

James I. Korn
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General
Office of Audit Services, Region VII
1201 Walnut Street, Suite 1338
Kansas City, MO 64106

Dear Mr. Korn,

The West Virginia (WV) Department of Human Services, Bureau for Medical Services (BMS), has received and reviewed the Department of Health and Human Services, Office of Inspector General (OIG) draft report *West Virginia Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs.* This draft report included five recommendations from the OIG to WV. Please find below our responses to each of the recommendations.

Recommendation 1: Refund to the Federal Government $2,159,071 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement

BMS concurs with the recommendation. We plan to work with CMS to determine if the drugs on claims that were excluded from rebate invoicing, for reasons such as invalid National Drug Code (NDC) and Healthcare Common Procedure Coding System (HCPCS) Code match or a billed Current Procedural Terminology (CPT) code, should have actually been included for rebating. Once this is determined, we will process those drugs as part of a rebate invoicing cycle. We will also work with CMS to determine the amount and method of payment for the remaining refund.

Recommendation 2: Refund to the Federal Government $14,514 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement

BMS concurs with the recommendation. We plan to work with CMS to determine if the drugs on claims that were excluded from rebate invoicing, for reasons such as invalid National Drug Code

(NDC) and Healthcare Common Procedure Coding System (HCPCS) Code match or a billed Current Procedural Terminology (CPT) code, should have actually been included for rebating. Once this is determined, we will process those drugs as part of a rebate invoicing cycle. We will also work with CMS to determine the amount and method of payment for the remaining refund.

Recommendation 3: Work with CMS to determine the unallowable portion of $488,185 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable

BMS concurs with the recommendation. We will work with CMS to determine the unallowable portion of the federal share for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount in a CMS-specified method, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

Recommendation 4: Strengthen internal controls for non-crossover claims going forward, to better use collected data to invoice manufacturers and collect rebates for all eligible physician-administered drugs

BMS does not concur with the recommendation. We have controls in our medical billing system that deny fee-for-service claims when there is an invalid NDC/HCPCS match based on a crosswalk of NDCs that is updated routinely. The system will also deny claims if there are missing NDCs, HCPCS codes, and/or quantity amounts on the applicable drug claims. Upon reviews, we verified that the coding and crosswalk were accurate at the time of adjudication.

Recommendation 5: Consider revising its payment methodology going forward regarding payments for crossover claims, thereby allowing collection of manufacturers' rebates for associated physician-administered drugs

BMS does not concur with the recommendation. According to policy, when a member is eligible for both Medicaid and Medicare, the provider bills the claim to Medicare. Once Medicare adjudicates the claim, the claim crosses over to Medicaid to adjudicate the remaining balance. If Medicare paid more than Medicaid would have allowed, then Medicaid pays zero. If there is no Medicaid payment on a fee-for-service claim, then the drug on the claim cannot be included for rebate processing. WV Medicaid pays cross-over claims at the header level.

It has been a pleasure to work with the auditing staff. We welcome ideas to improve the function of our programs. If you have any questions, feel free to contact us.

Sincerely,

/s/Cynthia Beane, MSW, LCSW

Cynthia Beane, MSW, LCSW
Commissioner

Cc: Vicki Cunningham, Pharmacy Director
Gail Goodnight, Drug Rebate Program Manager

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