Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

THE MEDICARE CONTRACTORS FOR JURISDICTION 11 OVERPAID PROVIDERS FOR SELECTED OUTPATIENT DRUGS

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Office of Inspector General

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EXECUTIVE SUMMARY

The Medicare contractors for Jurisdiction 11 overpaid providers by $2.2 million for selected outpatient drugs over 3 years.

WHY WE DID THIS REVIEW

The Centers for Medicare & Medicaid Services (CMS) pays Medicare claims through the Medicare administrative contractor or fiscal intermediary (Medicare contractor) in each Medicare jurisdiction. From July 1, 2009, through June 30, 2012, Medicare contractors nationwide paid hospitals $11.5 billion for outpatient drugs, which also include biologicals and radiopharmaceuticals. Previous Office of Inspector General reviews of outpatient services have found that Medicare contractors overpaid providers for selected outpatient drugs. This report is part of a series of reports focusing on payments for selected outpatient drugs.

The objective of this review was to determine whether payments that the Medicare contractors for Jurisdiction 11 made to providers for selected outpatient drugs were correct.

BACKGROUND

Providers report the outpatient drugs administered to Medicare beneficiaries using standardized codes called Healthcare Common Procedure Coding System (HCPCS) codes and report units of service in multiples of the units shown in the HCPCS narrative description. Correct payments depend on accurate reporting of the HCPCS codes and units of service for each claim line item billed. CMS designed a series of automatic system edits that Medicare contractors use to review the units billed by providers, identify errors in billed amounts, and ensure that billed units that exceed the edit threshold for a likely dose are validated before the claim line items are paid. In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

Before May 16, 2011, Palmetto GBA, LLC, was the Medicare contractor for North Carolina and South Carolina, and National Government Services was the Medicare contractor for Virginia and West Virginia. Effective May 16, 2011, Palmetto GBA became the Medicare contractor for Jurisdiction 11 (North Carolina, South Carolina, Virginia, and West Virginia) and assumed responsibility for claims formerly paid by National Government Services. Accordingly, we have addressed our findings and recommendations to Palmetto GBA for review and comment.

During our audit period (July 1, 2009, through June 30, 2012), the Medicare contractors paid providers $977.3 million for 1.8 million line items for selected outpatient drugs. We reviewed 2,135 line items with total payments of $12.7 million that were at risk for overpayment.

WHAT WE FOUND

Payments that the Medicare contractors for Jurisdiction 11 made to providers for 900 of the 2,135 line items for outpatient drugs we reviewed were not correct. These incorrect payments resulted in overpayments of $2,169,751 and underpayments of $16,437 that the providers had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, providers

had refunded $1,674,240 of overpayments for another 672 line items. The remaining 563 line items were correct.

For the 862 incorrect line items with overpayments of $2,169,751 that had not been refunded, providers reported a combination of incorrect units of service and incorrect HCPCS codes, reported incorrect units of service, billed separately for an outpatient drug for which payment was packaged with the primary service, billed for noncovered use of a drug, did not provide supporting documentation, and used incorrect HCPCS codes. For the 38 incorrect line items with underpayments of $16,437 that had not been adjusted, we notified the providers of the underpayments so that they could decide whether to submit adjustment claims.

Providers attributed the incorrect billings to clerical errors and to provider billing systems that could not prevent or detect the incorrect billing of outpatient drug services. The Medicare contractors overpaid these providers because there were insufficient edits in place to prevent or detect the overpayments.

WHAT WE RECOMMEND

We recommend that Palmetto GBA:

- recover the $2,169,751 in identified overpayments,
- verify the payment of $16,437 in identified underpayments, and
- use the results of this audit in its on-going provider education activities.

PALMETTO GBA COMMENTS

In written comments on our draft report, Palmetto GBA concurred with our findings and recommendations and described corrective actions it had taken or planned to take to address them.

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INTRODUCTION

WHY WE DID THIS REVIEW

The Centers for Medicare & Medicaid Services (CMS) pays Medicare claims through the Medicare administrative contractor or fiscal intermediary (Medicare contractor[1]) in each Medicare jurisdiction. From July 1, 2009, through June 30, 2012, Medicare contractors nationwide paid hospitals $11.5 billion for outpatient drugs, which also include biologicals and radiopharmaceuticals.[2]

Previous Office of Inspector General reports have found that Medicare contractors overpaid providers by more than $122.4 million for outpatient drugs. We identified $4.6 million of these overpayments in reviews of selected outpatient drugs at 39 providers and $24.2 million in nationwide reviews of the drug Herceptin. We identified approximately $81.9 million of payments for outpatient drugs in reviews of payments that exceeded provider charges by at least $1,000 and identified approximately $11.7 million of payments for outpatient drugs in reviews of payments at high risk for overpayments.[3] (See Appendix A for a list of reports related to Jurisdiction 11.)

This report is part of a series of reports focusing on payments for selected outpatient drugs.

OBJECTIVE

Our objective was to determine whether payments that the Medicare contractors for Jurisdiction 11 made to providers for selected outpatient drugs were correct.

BACKGROUND

Medicare Part B

Part B of Medicare provides supplementary medical insurance, including coverage for the cost of outpatient drugs. CMS administers Part B and contracts with Medicare contractors to, among other things, determine reimbursement amounts and pay claims, conduct reviews and audits, and safeguard against fraud and abuse. Medicare contractors must establish and maintain efficient

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[1] Currently, Medicare administrative contractors pay Medicare claims. For some jurisdictions, fiscal intermediaries paid claims during some or all of our audit period. In this report, the term "Medicare contractor" means the fiscal intermediary or Medicare administrative contractor, whichever is applicable.

[2] Biologicals are medicinal preparations made from living organisms and their products (for example, serums, vaccines, antigens, and antitoxins); radiopharmaceuticals are radioactive drugs used for diagnostic or therapeutic purposes.

[3] Although the selected provider and Herceptin audits included only outpatient drugs, the payments-greater-than-charges audits, with overpayments totaling $106 million, and the excessive-claim-payments audits, with overpayments totaling $44 million, included all types of outpatient services. Some of the reviews of payments that exceeded provider charges covered amounts between $500 and $1,000. We considered high-risk payments as those that exceeded $10,000 for claims under Part B and exceeded $50,000 for claims for outpatient services. We estimated the total overpayment amount for selected outpatient drug services for these audits.

and effective internal controls.[4] These controls, including those over automatic data processing systems, are intended to prevent increased program costs caused by incorrect or delayed payments. Medicare contractors use the Common Working File (CWF) and Fiscal Intermediary Standard System (FISS) to validate providers' claims for outpatient services before paying the claims. Medicare contractors calculate the payment for each outpatient service using FISS's Hospital Outpatient Prospective Payment System (OPPS). These three systems can also detect certain improper payments.

Healthcare Common Procedure Coding System Codes

Medicare contractors pay providers using established rates for each hospital outpatient unit of service claimed, subject to any Part B deductible and coinsurance. Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted claim may contain multiple line items that detail most provided services.[5] Providers must use standardized codes, called Healthcare Common Procedure Coding System (HCPCS) codes, for drugs administered and report units of service in multiples of the units shown in the HCPCS narrative description. For example, if the description for the HCPCS code specifies 50 milligrams and 200 milligrams are administered, units are shown as 4.

Medicare Contractor Edits

To reduce payment errors, CMS introduced a number of claims-review initiatives that identify and address incorrect billing due to coverage or coding errors made by providers. One of these review initiatives, established in January 2007, is the "Medically Unlikely Edits" prepayment claims review program. Medically unlikely edits are developed and maintained by the CMS National Correct Coding Initiative contractor.[6]

Medically unlikely edits are automatic prepayment edits within the FISS that compare the billed units with the maximum units of service for a given HCPCS code. The maximum units of service are the maximum number of units that a provider would reasonably administer to a patient for that service on a single date of service. A medically unlikely edit denies line items for units of service that exceed the maximum units for the HCPCS code billed.

Medically unlikely edits, which are updated each quarter, do not exist for all HCPCS codes. Before implementing new medically unlikely edits, CMS offers national health care organizations the opportunity to review and comment on the proposed edits. Medicare contractors must include the medically unlikely edits in their payment systems.[7]

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[4] CMS, *Medicare Financial Management Manual*, Pub. No. 100-06, chapter 7, section 10.

[5] Some claim line items included on outpatient claims do not identify the specific services provided but just identify the revenue code and billed charges. These line items are generally not paid because the services are bundled into other services that are specifically identified.

[6] The contractor, Correct Coding Solutions, LLC, provides a revised medically unlikely edit table to CMS each quarter. CMS then distributes the revised medically unlikely edit table with the revised national correct coding initiative table to the Medicare contractors.

[7] CMS makes the majority of medically unlikely edits publicly available on its Web site. However, CMS does not publish all medically unlikely edit values, particularly for outpatient drugs, because of fraud and abuse concerns.

Palmetto GBA, LLC

Before May 16, 2011, Palmetto GBA, LLC, was the Medicare contractor for North Carolina and South Carolina, and National Government Services was the Medicare contractor for Virginia and West Virginia. Effective May 16, 2011, Palmetto GBA became the Medicare contractor for Jurisdiction 11 (North Carolina, South Carolina, Virginia, and West Virginia) and assumed responsibility for claims formerly paid by National Government Services. Accordingly, we have addressed our findings and recommendations to Palmetto GBA for review and comment.

HOW WE CONDUCTED THIS REVIEW

During our audit period (July 1, 2009, through June 30, 2012), the Medicare contractors for Jurisdiction 11 paid providers $977.3 million for 1.8 million line items for selected outpatient drugs. We reviewed 2,135 line items[8] with total payments of $12.7 million that were at risk for overpayment. These line items were for outpatient drugs with payment status indicator code "G" or "K."[9] We used computer matching, data mining, and other analytical techniques to identify the line items potentially at risk for noncompliance with Medicare billing requirements. We evaluated compliance with selected billing requirements, but we did not use medical review to determine whether services were medically necessary.

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.

See Appendix B for the details of our scope and methodology.

FINDINGS

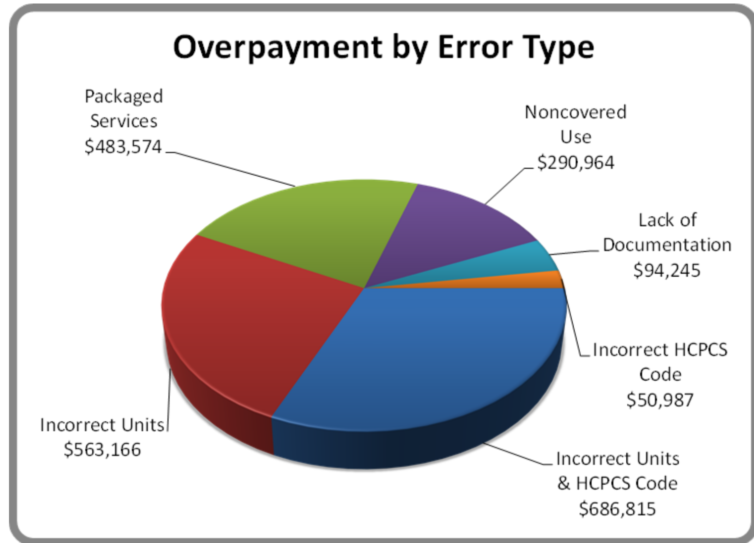
Payments that the Medicare contractors for Jurisdiction 11 made to providers for 900 of the 2,135 line items for outpatient drugs we reviewed were not correct. These incorrect payments resulted in overpayments of $2,169,751 and underpayments of $16,437 that the providers had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, providers had refunded $1,674,240 of overpayments for another 672 line items. The remaining 563 line items were correct.

For the 862 incorrect line items with overpayments of $2,169,751 that had not been refunded, providers:

[8] In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

[9] "G" and "K" identify drugs that are separately paid by Medicare. "G" identifies drugs and biologicals paid using the OPPS that include a pass-through payment. (Pass-through payments are additional payments made for a short time to cover the cost for certain innovative medical devices, drugs, and biologicals that exceed Medicare's OPPS payment amount.) "K" identifies drugs, biologicals, therapeutic radiopharmaceuticals, brachytherapy sources of radiation, blood, and blood products paid using the OPPS without a pass-through payment.

- reported a combination of incorrect units of service and incorrect HCPCS codes on 326 line items, resulting in overpayments of $686,815;



- reported incorrect units of service on 167 line items, resulting in overpayments of $563,166;
- billed separately for an outpatient drug for which payment was packaged with the primary service on 145 line items, resulting in overpayments of $483,574;
- billed for the noncovered use of a drug on 164 line items, resulting in overpayments of $290,964;
- did not provide supporting documentation for 27 line items, resulting in overpayments of $94,245; and
- used incorrect HCPCS codes on 33 line items, resulting in overpayments of $50,987.

For the 38 incorrect line items with underpayments of $16,437 that had not been adjusted, we notified the providers of the underpayments so that they could decide whether to submit adjustment claims.

Providers attributed the incorrect billings to clerical errors and to provider billing systems that could not prevent or detect the incorrect billing of outpatient drug services. The Medicare contractors overpaid these providers because neither the CWF nor the FISS had sufficient edits in place to prevent or detect the overpayments.

FEDERAL REQUIREMENTS

The Social Security Act (the Act) and CMS Pub. No. 100-04, *Medicare Claims Processing Manual* (the Manual), provide overall requirements related to the billing and payment of hospital outpatient services. They require that providers submit accurate and complete bills to Medicare for allowable and covered services and identify the number of units of service for each outpatient drug administered to a Medicare beneficiary using the correct HCPCS code.[10]

See Appendix C for details on the Federal requirements related to Medicare contractor payment and provider billing for selected outpatient drugs.

[10] These requirements are found in the Act, section 1833(e), and the Manual, chapter 17, section 90.2.A.

OVERPAYMENTS TO PROVIDERS THAT BILLED INCORRECTLY OR DID NOT DOCUMENT THAT THE SERVICES BILLED HAD BEEN PERFORMED

Combination of Incorrect Number of Units of Service and Incorrect Healthcare Common Procedure Coding System Codes

Providers reported a combination of incorrect units of service and incorrect HCPCS codes on 326 line items. These errors resulted in overpayments of $686,815. The following are examples:

- One provider billed Medicare on 60 line items for 2 to 12 units of service for leuprolide acetate injections (HCPCS code J1950, 3.75 milligrams per unit), which is indicated for the treatment of endometriosis, uterine leiomyoma, and malignant neoplasm of the breast. However, the provider should have billed Medicare for 1 to 6 units of service for the leuprolide acetate injections (HCPCS code J9217, 7.5 milligrams per unit), which is indicated for the treatment of prostate cancer and was the dose actually administered. As a result of these errors, the Medicare contractor paid the provider $166,191 when it should have paid $34,268, an overpayment of $131,923.

- Another provider billed Medicare on one line item for units of service unrelated to the drug administered. The provider billed Medicare for 200 units of service for a pralatrexate injection (HCPCS code J9307), a cancer drug. However, the provider should have billed for 40 units of service for an epoetin alfa injection for non-end stage renal disease use (HCPCS code J0885). As a result of this error, the Medicare contractor paid the provider a total of $31,995 when it should have paid $302, an overpayment of $31,693.

In total, the Medicare contractor paid 33 providers $847,607 when it should have paid $160,792, an overpayment of $686,815.

Incorrect Number of Units of Service

Providers reported incorrect units of service on 167 line items, resulting in overpayments of $563,166. The incorrect units of service involved 38 different outpatient drugs. The following are examples:

- One provider administered 600 milligrams of infliximab to a patient and billed for 600 units of service. Using the HCPCS description (injection, infliximab, 10 milligrams), the correct number of units of service to bill for 600 milligrams was 60. On five separate occasions, this type of error occurred, and as a result, the Medicare contractor paid the provider $114,116 when it should have paid $9,559, an overpayment of $104,557.

- Another provider administered 260 mg of bevacizumab to a patient and billed for 1,200 units of service. Bevacizumab is provided in 100-milligram single-use vials. Using the HCPCS description (injection, bevacizumab, 10 milligrams), each single-use vial is billable as 10 units of service. Therefore, the correct number of units of service to bill for 260 milligrams was 30. As a result, the Medicare contractor paid the provider $66,628 when it should have paid $1,353, an overpayment of $65,275.

In total, the Medicare contractor paid 54 providers $1,140,774 when it should have paid $577,608, an overpayment of $563,166.

Billed Separately for Packaged Services

For selected outpatient drugs that have multiple HCPCS codes, providers billed Medicare on 145 line items using the HCPCS code that Medicare pays separately instead of the HCPCS code that Medicare does not pay separately, resulting in overpayments of $483,574. These line items involved three different packaged outpatient drugs.

Medicare pays for outpatient drugs that are considered primary procedures but does not pay separately for outpatient drugs when their payment is packaged in the payment of a primary procedure. Medicare has different HCPCS codes for similar drugs to distinguish which are paid separately and which are not paid separately.

For example, one provider billed Medicare for dexamethasone intravitreal implant injection (HCPCS code J7312) rather than dexamethasone sodium phosphate injection (HCPCS code J1100), the drug actually administered. During the dates of service that the provider administered this drug, Medicare packaged the sodium phosphate formulation in the payment for related services and did not provide for separate reimbursement under the OPPS. On 119 separate occasions, this error occurred; as a result, the Medicare contractor paid the provider $394,127 when it should have paid $0, an overpayment of $394,127.

In total, the Medicare contractor paid four providers $483,574 for packaged drugs when it should have paid $0, an overpayment of $483,574.

Noncovered Use of a Drug

Providers billed Medicare for the noncovered use of an outpatient drug on 164 line items. These errors resulted in overpayments of $290,964.

For example, four providers billed Medicare for the noncovered use of the drug reteplase (HCPCS code J2993, 18.1 milligrams per unit). Reteplase is approved by the Food and Drug Administration (FDA) to treat cardiac conditions using a single-use dose. However, each provider split a single dose into multiple doses and used them as a thrombolytic agent to clean dialysis patient catheters.[11] Each provider then billed Medicare for one or more single-use doses of reteplase for each multiple dose administered.

Providers must identify on their claims that the billed service was for the unlabeled use of a drug.[12] However, each of the four providers submitted these line items as if the single-use dose had been administered for the covered use. Consequently, the Medicare contractor did not know that the 162 line items were for a small amount of the covered dose and were given for an

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[11] The Manual, chapter 8, section 60.2.1.1, identifies thrombolytics as drugs "used to declot central venous catheters" during the treatment of a patient's renal condition. During the audit period, thrombolytics were separately billable drugs.

[12] Providers should indicate the unlabeled use of a drug or biological (*Medicare Benefit Policy Manual,* CMS Pub. No. 100-02, chapter 15, § 50.4.2). Providers use the remarks section of the claim for this purpose.

unlabeled use that required a case-by-case payment determination. The Medicare contractor paid the four providers a total of $286,640 when it should have paid $0, an overpayment of $286,640.

In total, the Medicare contractor paid six providers $290,964 for the noncovered use of drugs when it should have paid $0, an overpayment of $290,964.

Lack of Supporting Documentation

Sixteen providers billed Medicare on 27 line items for which the providers did not provide any documentation to support that a patient had received the drug service billed. The providers agreed to cancel the claims associated with these line items or file adjusted claims and refund the combined $94,245 in overpayments that they received.

Incorrect Healthcare Common Procedure Coding System Codes

Providers used incorrect HCPCS codes on 33 line items, resulting in overpayments of $50,987. For example, 1 provider billed Medicare on 5 line items for 12 units of service unrelated to the drug administered. The provider incorrectly billed HCPCS code J1950 (leuprolide acetate injection). The provider should have billed for HCPCS code J9065 (cladribine injection) the drug actually administered. As a result of these errors, the Medicare contractor paid the provider $30,170 when it should have paid $1,090, an overpayment of $29,080.

In total, the Medicare contractor paid 14 providers $61,691 when it should have paid $10,704, an overpayment of $50,987.

UNDERPAYMENTS TO PROVIDERS THAT BILLED INCORRECTLY

Providers billed Medicare on 38 line items for outpatient drug services that included incorrect units of service, incorrect HCPCS codes, or a combination of incorrect units of service and incorrect HCPCS codes, resulting in underpayments of $16,437. We identified these underpayments and notified the providers so that they could decide whether to submit adjustment claims for the underpayment amounts.

CAUSES OF INCORRECT MEDICARE PAYMENTS

The providers attributed the incorrect billings to clerical errors and to provider billing systems that could not prevent or detect the incorrect billing of outpatient drug services. These billing systems errors included chargemaster[13] errors and other system errors.

The Medicare contractors overpaid these providers because neither the CWF nor the FISS had sufficient edits in place to prevent or detect the overpayments. In effect, CMS relied on

[13] A provider's chargemaster is an automatic data processing system that providers use as part of their billing systems. The chargemaster contains data on every chargeable item or procedure that the provider offers, including (1) a factor that converts a drug's dosage to the number of units to bill and (2) whether to charge for waste.

providers to notify the Medicare contractor of incorrect payments and on beneficiaries to review their *Medicare Summary Notice* and disclose any overpayments.[14]

Other required edits in the CWF and FISS did not detect the errors that we found because the edits suspended only those payments that exceeded a payment amount threshold but did not flag payments that exceeded maximum billing units. Medically unlikely edits, which deny line items for excessive units of service billed, do not exist for all HCPCS codes.

RECOMMENDATIONS

We recommend that Palmetto GBA:

- recover the $2,169,751 in identified overpayments,
- verify the payment of $16,437 in identified underpayments, and
- use the results of this audit in its on-going provider education activities.

PALMETTO GBA COMMENTS

In written comments on our draft report, Palmetto GBA concurred with our findings and recommendations and described corrective actions it had taken or planned to take to address them. Palmetto GBA's comments are included in their entirety as Appendix D.

[14] The Medicare contractor sends a *Medicare Summary Notice*—an explanation of benefits—to the beneficiary after the provider files a claim for services. The notice explains the services billed, the approved amount, the Medicare payment, and the amount due from the beneficiary.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS: JURISDICTION 11

Report Title	Report Number	Date Issued
Medicare Contractors' Payments to Providers in Jurisdiction 11 for Full Vials of Herceptin Were Often Incorrect	A-03-11-00013	08/10/2012
Virginia Commonwealth University Medical Center Incorrectly Billed Medicare for the Biological Drug Myozyme	A-03-12-00009	06/19/2012
Review of Medicare Payments Exceeding Charges by $500 to $1,000 for Outpatient Services Processed by National Government Services but Transitioned to Palmetto GBA, LLC, in Jurisdiction 11 for the Period January 1, 2006, Through June 30, 2009	A-03-11-00005	11/30/2011
Review of Medicare Payments Exceeding Charges for Outpatient Services Processed by National Government Services but Transitioned to Palmetto GBA, LLC, in Jurisdiction 11 for the Period January 1, 2006, Through June 30, 2009	A-03-10-00005	11/30/2011
Review of Medicare Payments Exceeding Charges by $500 to $1,000 for Outpatient Services Processed by Palmetto GBA, LLC, in Jurisdiction 11 for the Period January 1, 2006, Through June 30, 2009	A-03-11-00006	10/05/2011
Review of Medicare Payments Exceeding Charges for Outpatient Services Processed by Palmetto GBA, LLC, in Jurisdiction 11 for the Period January 1, 2006, Through June 30, 2009	A-03-10-00006	10/05/2011
Review of High-Dollar Payments for Virginia and West Virginia Outpatient Claims Processed by National Government Services for Calendar Years 2003-2005	A-03-07-00015	10/29/2009
Review of High-Dollar Payments for Virginia Medicare Part B Claims Processed by TrailBlazer Health Enterprises for the Period January 1, 2003, Through December 31, 2005	A-03-07-00020	09/24/2008

Report Title	Report Number	Date Issued
Review of High-Dollar Payments for West Virginia Medicare Part B Claims Processed by Palmetto GBA for the Period January 1, 2003, Through December 31, 2005	A-03-07-00021	09/10/2008

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

During our audit period (July 1, 2009, through June 30, 2012), the Medicare contractors for Jurisdiction 11 paid providers $977.3 million for 1.8 million line items for selected outpatient drugs. We reviewed 2,135 line items totaling $12,733,111 that the Medicare contractors paid to 113 providers.[15] We did not review entire claims; rather, we reviewed specific line items within the claims. These line items included selected outpatient drugs with payment status indicator code "G" or "K." "G" identifies drugs and biologicals paid using the OPPS that include a pass-through payment.[16] "K" identifies drugs, biologicals, therapeutic radiopharmaceuticals, brachytherapy sources of radiation, blood, and blood products paid using the OPPS without a pass-through payment.

We did not review the overall internal control structure of the Medicare contractors or the providers because our objective did not require us to do so. Rather, we limited our review to (1) the Medicare contractors' internal controls to prevent the overpayment of Medicare claims associated with the selected outpatient drugs and (2) providers' internal controls to prevent incorrect billing for outpatient drugs. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History file, but we did not assess the completeness of the file.

We conducted our audit from October 2012 through March 2013 and performed fieldwork by contacting Palmetto GBA in Columbia, South Carolina, and 113 providers that received the selected Medicare payments during our audit period.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- used CMS's National Claims History file to identify outpatient line items for selected outpatient drugs (HCPCS codes with payment status indicator code "G" or "K") for which Medicare payments were made during our audit period;
- used computer matching, data mining, and other analytical techniques to identify payments for outpatient drugs for which the number of units the provider billed was more than the number of units the provider would reasonably administer to a patient on a single date of service because these line items were at risk for noncompliance with Medicare billing requirements;

[15] The audit included a small number of line items for services provided before July 1, 2009, that were paid during our audit period and a small number of line items for services provided before June 30, 2012, that were paid after that date.

[16] Pass-through payments are additional payments made for a short time to cover the cost for certain innovative medical devices, drugs, and biologicals that exceed Medicare's OPPS payment amount.

- selected 2,135 line items at risk of error, totaling $12,733,111, that the Medicare contractors paid to 113 providers;

- requested that the 113 providers furnish documentation to support the services billed, including:

  - the physician's order supporting the outpatient drug and amount ordered,

  - the drug administration record supporting that the outpatient drug was administered in the amount ordered, and

  - relevant financial or administrative notes related to the Medicare claim;

- reviewed the documentation provided to determine whether:

  - the billed information for the selected line items was correct and, if not, why the line item was incorrect,

  - the providers identified and adjusted the claim items before our review, and

  - the claimed units of the outpatient drug were based on dosing instructions provided with the packaging and any limitation on use (such as single-use or multiuse);

- calculated overpayment amounts, including adjustments to the claims due to changes in the allocation of the coinsurance amounts, in accordance with Federal requirements and Medicare payment procedures or used the amount determined by the Medicare contractor; and

- discussed the results of our review with providers and the Medicare contractor.

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 C: FEDERAL REQUIREMENTS RELATED TO MEDICARE CONTRACTOR PAYMENT AND PROVIDER BILLING FOR SELECTED OUTPATIENT DRUGS

FEDERAL LAW AND REGULATIONS

The Act, section 1833(e), states: "No payment shall be made to any provider of services … unless there has been furnished such information as may be necessary in order to determine the amounts due such provider … for the period with respect to which the amounts are being paid …."

Further, the Act, sections 1861(s)(2) and 1861(t), define the terms "medical and other health services" and "drugs and biologicals," respectively. These sections identify those drug and biological services that are covered services under the Medicare Part B program and also identify any noncovered or excluded drug and biological services.

Federal regulations provide the methodology that Medicare uses to calculate payment for drugs and biologicals, including the calculation of the coinsurance payment, which is limited to the inpatient deductible amount for each year (42 CFR § 419.41).

CENTERS FOR MEDICARE & MEDICAID SERVICES GUIDANCE

CMS Pub. No. 100-06, *Medicare Financial Management Manual*, chapter 7, section 10, states: "[CMS] contractors shall administer the Medicare program efficiently and economically to achieve the program objectives." Further, the Federal Managers' Financial Integrity Act of 1982 (FMFIA) "establishes internal control requirements that shall be met by CMS. For CMS to meet the requirements of FMFIA, CMS contractors shall demonstrate that they comply with the FMFIA guidelines." Consequently, "the contractor shall establish and maintain efficient and effective internal controls to perform the requirements of the contract…."

The Manual, chapter 1, section 80.3.2.2, states: "In order to be processed correctly and promptly, a bill must be completed accurately."

The Manual, chapter 23, section 20.3, states: "providers must use HCPCS codes … for most outpatient services."

The Manual, chapter 4, section 20.4, states: "The definition of service units … is the number of times the service or procedure [HCPCS code] being reported was performed."

The Manual, chapter 17, section 90.2.A, states: "It is … of great importance that hospitals billing for these products [outpatient drugs] make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient."

The Manual, chapter 17, section 10, states: "If the drug dose used in the care of a patient is not a multiple of the HCPCS code dosage descriptor, the provider rounds to the next highest unit based on the HCPCS long descriptor for the code in order to report the dose provided."

The Manual, chapter 17, section 70, states that, if the provider is billing for an outpatient drug for which an "HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 [milligrams], and 200 [milligrams] are provided, units are shown as 4 …."

The Manual, chapter 17, section 40, states:

> When a physician, hospital or other provider or supplier must discard the remainder of a single use vial or other single use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.

The section further notes: "Multi-use vials are not subject to payment for discarded amounts of drug or biological."

The Manual, chapter 1, section 140.1, states that Medicare contractors must "edit for outpatient and inpatient Part B claims that meet or exceed a reimbursement amount of $50,000." The section further notes that Medicare contractors must "suspend those claims receiving the threshold edit for development and contact providers to resolve billing errors." If the Medicare contractor determines that the reimbursement is excessive and corrections are required, the claim must be returned to the provider. If the billing is accurate and the reimbursement is not excessive, the Medicare contractors will override the edit and process the claim for payment.

CMS Pub. No. 100-02, *Medicare Benefit Policy Manual* (chapter 15, section 50.4.2), states:

> An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.… These decisions are made by the contractor on a case-by-case basis.

APPENDIX D: PALMETTO GBA COMMENTS

PALMETTO GBA
A CELERIAN GROUP COMPANY

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W. JOE JOHNSON
President and Chief Operating Officer

December 30, 2013

Stephen Virbitsky
Office of Inspector General
Office of Audit Services, Region III
150 S. Independence Mall West
Philadelphia, PA 19105-3499

Reference: Draft Report No. A-03-13-00011

Dear Mr. Virbitsky:

This letter is in response to the recent Office of Inspector general (OIG) report entitled "Medicare Contractor Jurisdiction 11 Overpaid Providers for Selected Outpatient Drugs". We appreciate the feedback your review provided and are committed to continuously improving our service to the Medicare beneficiaries and providers we serve.

During the audit period (July 1, 2009 through June 30, 2012), Palmetto GBA, LLC (Palmetto) was the Medicare contractor for North Carolina and South Carolina. From July 1, 2009 through May 15, 2011, National Government Services (NGS) was the Medicare contractor for Virginia and West Virginia. Effective May 16, 2011, Palmetto became the Medicare contractor for Jurisdiction 11 (North Carolina, South Carolina, Virginia, and West Virginia) and assumed responsibility for claims formerly paid by NGS.

During the audit period 2,135 line items were selected in which:

(1) 672 lines were refunded by providers before fieldwork;

(2) 563 lines were correct;

(3) 862 incorrect line items with overpayments of $2,169,751 were not refunded by providers; and

(4) 38 incorrect line items with underpayments of $16,437 were not adjusted.

Providers attributed the incorrect billings to clerical errors and to provider billing systems that could not prevent or detect the incorrect billing of outpatient drug services. The Medicare contractors overpaid these providers because neither the CWF nor the FISS had sufficient edits in place prevent or detected the overpayments. The following was recommended by your office:

- **Recover the $2,169,751 identified overpayments.**
  Palmetto GBA Response:

  Palmetto GBA will establish overpayments as claims are adjusted and recover overpayment via CMS-directed debt collection guidelines.

- **Verify the payment of $17,437 in identified underpayments.**
  Palmetto GBA Response:

  Palmetto GBA will verify underpayments identified and assist providers adjusting claims as needed, if they choose to do so.

- **Use the results of this audit in its on-going provider education activities.**
  Palmetto GBA Response:

  Palmetto GBA has continuously published and/or conducted educational efforts as it pertains to the correct billing of drugs as listed below:

  - **General Articles:**
    - Chemotherapy and Biologicals: Medicare Guidance

  - **Drug related Articles:**
    - Infusion, Injection and Hydration Services
    - Golimumab, Simponi Aria Coding Guideleines
    - Kyprolis (Carfilzomib) Coding and Billing Guidelines and Indications
    - Testopel (Testosterone) Pellets: Coding Reminder
    - Aflibercept (Eylea) Coding and Billing Guidelines
    - Provenge (sipuleucel-T)

  - **Medically Unlikely Edits:**
    - Part A Ask the Contractor Teleconference – April and October, 2013
    - Provider Outreach and Education Advisory Group Teleconference – July, 2013

  - **Drug Billing:**
    - FAQ – Can I Bill for Drug Wastage from a Multi-Dose/Multiuse Vial or package of Drug or Biological?

  - **HCPCS Codes:**
    - ***Neupogen (J1440), J2505 (Neulasta) and J1745 (Remicade)***
      - **FAQ** – How Should I Submit Part A Biological Response Modifiers (BRM)/Monoclonal Antibodies Administration?
    - ***Herceptin (J9355)***
      - **Article** – Herceptin (Trastuzumab): Coverage and Billing

- **Article** – Completion of Prepayment Service-Specific Targeted Medical Review of HCPCS Code J9355 Trastuzumab (Herceptin)
- **FAQ** – If our pharmacy incorrectly reconstituted Herceptin (Trastuzumab) using sterile water instead of bacteriostatic water, and we are unable to store and use the rest of the vial, can our facility bill for the wasted drug and the administered amount?

  - ***Rituximab (J9310) and Bevacizumab (J9035)***
    - **Article** – Incorrect Number of Units Billed for Rituximab (HCPCS J9310) and Bevacizumab (HCPCS C9257 and J9035) – Dose versus Units Billed

  - **Face to Face education and Tours which covered Drugs and Biologicals, Lack of Supporting Documentation, Packaged Services, Incorrect units of Service, Non-covered Use of Drugs**

    - Face to face seminar Health Insurance Institute – Greensboro NC – Oct 2012
    - Part A 2012 Fall Tour
    - Part A 2013 Fall Tour

In closing, Palmetto GBA understands the importance of correct coding, billing and payment activities.

Thank you for providing Palmetto GBA with the opportunity to offer feedback regarding your review. If you have any questions, please do not hesitate to contact me.

Sincerely

cc: Any Drake, COR, CMS
Sandra Brown, CMS
Carol Sutton, Palmetto GBA
Ed Sanchez, Palmetto GBA