

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE CONTRACTORS  
FOR JURISDICTION 15  
OVERPAID PROVIDERS FOR  
SELECTED OUTPATIENT DRUGS**

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March 2014  
A-05-13-00013

# ***Office of Inspector General***

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## EXECUTIVE SUMMARY

*Medicare contractors for Jurisdiction 15 overpaid providers by \$5.1 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 Medicare contractors for Jurisdiction 15 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.

During our audit period (July 1, 2009, through June 30, 2012), National Government Services, Inc. (NGS), began as the Medicare contractor for Jurisdiction 15 (Kentucky and Ohio). Effective October 17, 2011, CGS Administrators, LLC (CGS), became the Medicare contractor for Jurisdiction 15. The Medicare contractors paid providers \$773.6 million for 1.7 million line items for selected outpatient drugs. We reviewed 947 line items with total payments of \$11.6 million that were at risk for overpayment.

Because CGS assumed responsibility for claims formerly paid by NGS for Jurisdiction 15, we have addressed our findings and recommendations to CGS for review and comment.

### WHAT WE FOUND

Payments that the Medicare contractors for Jurisdiction 15 made to providers for 632 of the 947 line items for outpatient drugs we reviewed were not correct. These incorrect payments resulted in overpayments of \$5,094,006 and an underpayment of \$636 that the providers had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, providers

had refunded \$660,203 of overpayments for another 15 line items. The remaining 300 line items were correct.

For the 631 incorrect line items with overpayments of \$5,094,006 that had not been refunded, providers reported incorrect units of service, billed separately for an outpatient drug for which payment was packaged with the primary service, did not provide supporting documentation, reported a combination of incorrect units of service and incorrect HCPCS codes, and used incorrect HCPCS codes. For the one incorrect line item with an underpayment, the provider reported incorrect units of service resulting in an underpayment of \$636. The provider submitted an adjusted claim.

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 overpayments.

### **WHAT WE RECOMMEND**

We recommend that CGS:

- recover the \$5,094,006 in identified overpayments,
- verify the payment of \$636 in the identified underpayment, and
- use the results of this audit in its ongoing provider education activities.

### **CGS's COMMENTS**

In written comments on our draft report, CGS concurred with all of our recommendations and provided information on actions that it had taken or planned to take to address our recommendations.

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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<sup>1</sup>) 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.<sup>2</sup>

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.<sup>3</sup> (See Appendix A for a list of reports related to Jurisdiction 15.)

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 Medicare contractors for Jurisdiction 15 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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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup>

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.

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<sup>4</sup> CMS, *Medicare Financial Management Manual*, Pub. No. 100-06, chapter 7, section 10.

<sup>5</sup> 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.

<sup>6</sup> 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.

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.<sup>7</sup>

## **National Government Services and CGS Administrators**

During our audit period (July 1, 2009, through June 30, 2012), National Government Services, Inc. (NGS), began as the Medicare contractor for Jurisdiction 15 (Kentucky and Ohio). CGS Administrators, LLC (CGS), assumed full responsibility as the Medicare contractor for Jurisdiction 15 effective October 17, 2011. Accordingly, we have addressed our findings and recommendations to CGS for review and comment.

## **HOW WE CONDUCTED THIS REVIEW**

During our audit period, the Medicare contractors for Jurisdiction 15 paid providers \$773.6 million for 1.7 million line items for selected outpatient drugs. We reviewed 947 line items<sup>8</sup> with total payments of \$11.6 million that were at risk for overpayment. These line items were for outpatient drugs with payment status indicator code “G” or “K.”<sup>9</sup> 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.

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<sup>7</sup> 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.

<sup>8</sup> In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

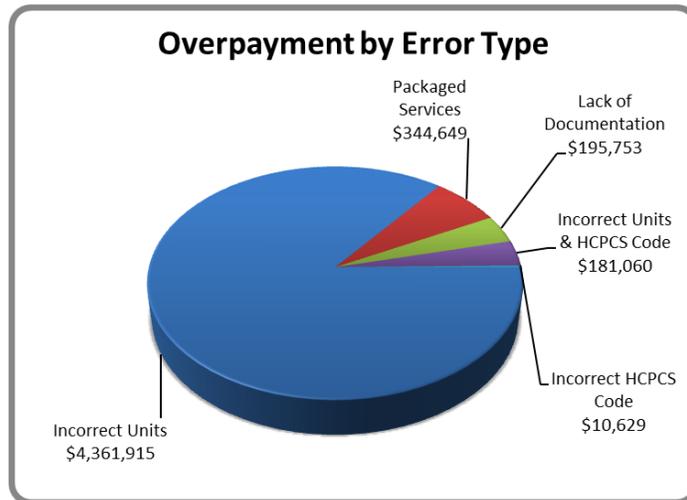
<sup>9</sup> “G” and “K” identify drugs that are separately paid by Medicare. “G” identifies drugs and biologicals paid using the OPPS that include a pass-through payment. (Pass-through payments are additional payments made for a short time to cover the cost for certain innovative medical devices, drugs, 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.

## FINDINGS

Payments that the Medicare contractors for Jurisdiction 15 made to providers for 632 of the 947 line items for outpatient drugs we reviewed were not correct. These incorrect payments resulted in overpayments of \$5,094,006 and an underpayment of \$636 that the providers had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, providers had refunded \$660,203 of overpayments for another 15 line items. The remaining 300 line items were correct.

For the 631 incorrect line items with overpayments of \$5,094,006 that had not been refunded, providers:

- reported incorrect units of service on 421 line items, resulting in overpayments of \$4,361,915;
- billed separately for an outpatient drug for which payment was packaged with the primary service on 92 line items, resulting in overpayments of \$344,649
- did not provide supporting documentation for 34 line items, resulting in overpayments of \$195,753;
- reported a combination of incorrect units of service and incorrect HCPCS codes on 81 line items, resulting in overpayments of \$181,060; and
- used incorrect HCPCS codes on 3 line items, resulting in overpayments of \$10,629.



For the one incorrect line item with an underpayment, the provider reported incorrect units of service resulting in an underpayment of \$636. The provider submitted an adjusted claim.

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.<sup>10</sup>

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

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

### **Incorrect Number of Units of Service**

Providers reported incorrect units of service on 421 line items, resulting in overpayments of \$4,361,915. The incorrect units of service involved 66 different outpatient drugs. The following are examples:

- One provider administered 6 units of rituximab to a patient and billed for 60 units of service. On 21 separate occasions, this type of error occurred, and as a result, the Medicare contractors paid the provider \$811,562 when they should have paid \$67,863, an overpayment of \$743,699.
- Another provider administered 1.1 micrograms of sincalide to a patient and billed for 75 units of service (375 micrograms). Using the HCPCS description of sincalide (injection, sincalide, 5 micrograms), the correct number of units to bill for 1.1 micrograms was 1.<sup>11</sup> On 33 separate occasions, this type of error occurred, and as a result, the Medicare contractors paid the provider \$130,271 when they should have paid \$1,730, an overpayment of \$128,541.

In total, the Medicare contractors paid 86 providers \$5,303,925 when they should have paid \$942,010, an overpayment of \$4,361,915.

### **Billed Separately for Packaged Services**

For selected outpatient drugs that have multiple HCPCS codes, providers billed Medicare on 92 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 \$344,649. 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.

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<sup>10</sup> These requirements are found in the Act, section 1833(e), and the Manual, chapter 17, section 90.2.A.

<sup>11</sup> If the drug dose used in the care of a patient is not a multiple of the dose specified in the HCPCS narrative description, the provider rounds to the next highest unit (the Manual, chapter 17, § 10).

For example, one provider billed Medicare for the lipid formulation of doxorubicin hydrochloride (HCPCS code J9001) rather than the nonlipid formulation of doxorubicin hydrochloride (HCPCS code J9000), the drug actually administered. During the dates of service that the provider administered this drug, Medicare packaged the nonlipid formulation in the payment for related chemotherapy and did not provide for separate reimbursement under the OPPS. On 29 separate occasions, this error occurred; as a result, the Medicare contractors paid the providers \$106,232 when they should have paid \$0, an overpayment of \$106,232.

In total, the Medicare contractors paid five providers \$344,649 for packaged drugs when they should have paid \$0, an overpayment of \$344,649.

### **Lack of Supporting Documentation**

Seventeen providers billed Medicare on 34 line items for which the providers did not provide any documentation to support that a patient had received the amount of the drug service billed. The providers agreed to cancel the claims associated with these line items or file adjusted claims and refund the combined \$195,753 in overpayments that they received.

### **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 81 line items. These errors resulted in overpayments of \$181,060. For example, 11 providers billed Medicare on 74 line items for 2 to 10 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 neoplasms of the breast. However, the providers should have billed Medicare for 1 to 4 units of service for 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 contractors paid the providers \$181,629 when they should have paid \$37,124, an overpayment of \$144,505.

In total, the Medicare contractors paid 16 providers \$221,496 when they should have paid \$40,436, an overpayment of \$181,060.

### **Incorrect Healthcare Common Procedure Coding System Codes**

Providers used incorrect HCPCS codes on three line items, resulting in overpayments of \$10,629. For example, one provider billed Medicare on 2 line items for 300 units of epoetin alfa, injection (HCPCS code J0885). However, the provider should have billed for 300 units of darbepoetin alfa injection (HCPCS code J0881), the drug actually administered. As a result of these errors, the Medicare contractors paid the provider \$4,704 when they should have paid \$1,522, an overpayment of \$3,182.

In total, the Medicare contractors paid two providers \$12,311 when they should have paid \$1,682, an overpayment of \$10,629.

## **UNDERPAYMENT TO A PROVIDER THAT BILLED INCORRECTLY**

One provider billed Medicare on one line item for an outpatient drug service that included incorrect units of service, resulting in an underpayment of \$636. The provider has submitted an adjusted claim.

## **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<sup>12</sup> errors and other system errors.

The Medicare contractor 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 providers to notify the Medicare contractors of incorrect payments and on beneficiaries to review their *Medicare Summary Notice* and disclose any overpayments.<sup>13</sup>

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 CGS:

- recover the \$5,094,006 in identified overpayments,
- verify the payment of \$636 in the identified underpayment, and
- use the results of this audit in its ongoing provider education activities.

## **CGS's COMMENTS**

In written comments on our draft report, CGS concurred with all of our recommendations and provided information on actions that it had taken or planned to take to address our recommendations. CGS's comments are included in their entirety as Appendix D.

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<sup>12</sup> 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.

<sup>13</sup> 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 15**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Medicare Contractors' Payments in Jurisdiction 15 to Providers for Full Vials of Herceptin Were Often Incorrect</i>	<a href="#"><u>A-05-12-00017</u></a>	12/21/2012
<i>Ashtabula County Medical Center Incorrectly Billed Medicare for Leuprolide Acetate Implants</i>	<a href="#"><u>A-03-12-00010</u></a>	8/3/2012
<i>The Medicare Contractor's Payments in Jurisdictions 6, 8, and 15 to Providers for Full Vials of Herceptin Were Often Incorrect</i>	<a href="#"><u>A-05-10-00091</u></a>	7/10/2012
<i>Review of Medicare Payments Exceeding Charges for Outpatient Services Processed by National Government Services in Jurisdiction 15 for the Period January 1, 2006, Through June 30, 2009</i>	<a href="#"><u>A-05-10-00016</u></a>	10/20/2011
<i>Review of High-Dollar Payments for Medicare Part B Claims Processed by National Government Services for Indiana and Kentucky Providers for the Period January 1, 2004, Through December 31, 2006</i>	<a href="#"><u>A-05-08-00029</u></a>	10/10/2008
<i>Review of High Dollar Payments for Inpatient Services Processed by National Government Services in Illinois, Indiana, Kentucky, and Ohio for Calendar Years 2004 Through 2006 – Hospitals with Less Than 10 High Dollar Payments</i>	<a href="#"><u>A-05-08-00027</u></a>	9/3/2008

## APPENDIX B: AUDIT SCOPE AND METHODOLOGY

### SCOPE

During our audit period (July 1, 2009, through June 30, 2012), the Medicare contractors for Jurisdiction 15 paid providers \$773.6 million for 1.7 million line items for selected outpatient drugs. We reviewed 947 line items, totaling \$11.6 million, that the Medicare contractors paid to 104 providers.<sup>14</sup> 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 OPSS that include a pass-through payment.<sup>15</sup> “K” identifies drugs, biologicals, therapeutic radiopharmaceuticals, brachytherapy sources of radiation, blood, and blood products paid using the OPSS 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 August 2013 and performed fieldwork by contacting CGS in Nashville, Tennessee, and 104 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

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<sup>14</sup> 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.

<sup>15</sup> 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 OPSS payment amount.

date of service because these line items were at risk for noncompliance with Medicare billing requirements;

- selected 947 line items at risk of error, totaling \$11,599,097, that the Medicare contractors paid to 104 providers;
- requested that 104 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 claim 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 CGS.

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 in 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: CGS's COMMENTS

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February 12, 2014

Sheri L. Fulcher  
Regional Inspector General for Audit Services  
Office of Audit Services, Region V  
233 North Michigan Avenue, Suite 1360  
Chicago, IL 60601

RE: CGS Response to Final OIG Report entitled *Medicare Contractors for Jurisdiction 15 Overpaid Providers for Selected Outpatient Drugs (A-05-13-00013)*

Dear Ms. Sheri Fulcher,

CGS Administrators, LLC, the Part A/B and Home Health and Hospice Medicare Administrative Contractor for Jurisdiction 15, appreciates the opportunity to comment on the Office of Inspector General's draft report entitled *Medicare Contractors for Jurisdiction 15 Overpaid Providers for Selected Outpatient Drugs (A-05-13-00013)*. In addition to requesting comments on the report, you ask that CGS state concurrence or nonconcurrence with each of the three recommendations in the report.

The OIG makes three (3) recommendations in its report. Those recommendations are:

1. Recover the \$5,094,006 in identified overpayments.
2. Verify the payment of \$636 in the identified underpayment.
3. Use the results of this audit in its ongoing provider education activities.

CGS concurs with the three recommendations in the report. For Recommendation 1, CGS has adjusted or has had the provider adjust the claims identified as overpayments. For Recommendation 2, CGS verified that the payment has been issued to the provider for the identified underpayment. Finally, for Recommendation 3, CGS will continue to use the information from the audit in its supplier educational activities.

As noted in the report, most of these claims were processed by the incumbent contractor National Government Services, Inc. (NGS). Analysis of the adjustment file indicates that only 33 of the 631 claims that were overpaid (5.2%) were processed by CGS. The remaining 94.8% of overpaid claims were processed by NGS.

CGS monitors errors documented by the Comprehensive Error Rate Testing (CERT) Contractor, the Recovery Audit Contractor (RAC), the Office of the Inspector General (OIG) and the Zone Program Integrity Contractors (ZPIC). CGS also uses comparative reports such as the First-look

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CGS Administrators, LLC is a Medicare Part A, B, Home Health and Hospice, and  
DME Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services



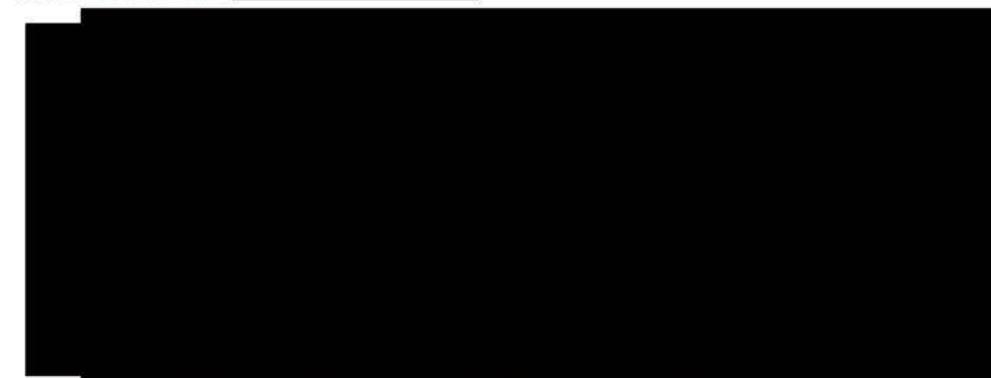
Analysis Tool for Hospital Outlier Monitoring (FATHOM) and internal data including prioritization reports, dollars at risk, feedback from POE, bill type utilization reports and comparative billing reports to assist in identifying areas of risk and vulnerability. This analysis is used to develop a Medical Review Strategy (MRS) that is designed to address improper payments in the Medicare fee-for-service (FFS) program. Outpatient Services, which includes Drugs, is Problem 3 on the J15 Option Year 3 (OY3) Part A MRS; Other Drugs is Problem 5 on the J15 OY3 Part B MRS.

Utilizing the above noted sources we implemented multiple interventions in our medical review strategy, including the creation and refinement of Local Coverage Determinations (LCDs). CGS has two active LCDs that include the majority of codes listed on the reports. In addition procedure-to-diagnosis editing is established based on these LCDs.

The LCDs and drugs included in those LCDs are as follows:

- LCD L31836 – Chemotherapy and Biologicals
  - J9355 - Herceptin
  - J9310 - Rituximab
  - J9000/J9001/J9002 - Doxorubicin
  - J9217/J1950 - Leuprolide Acetate
- LCD L31867 - Erythropoiesis Stimulating Agents (ESAs)
  - J0881 Darbepoetin Alpha /J0885 Epoetin Alpha

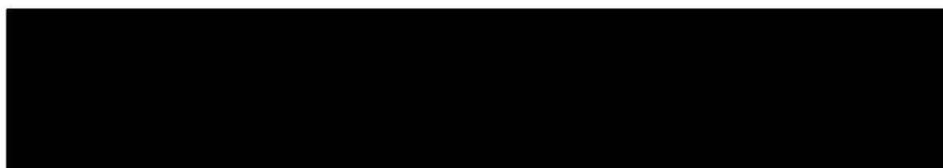
Additionally, CMS released Medically Unlikely Edits (MUEs) associated with these codes that established maximum [REDACTED]



In addition to the MUEs, the CGS Contractor Medical Director (CMD) is creating a list of Clinically Unbelievable Edits (CUEs). Similar to MUEs, CUEs are used by Medicare Contractors to reduce the paid claim error rate. Claims for supplies/services that exceed clinically unbelievable parameters are automatically denied as not reasonable and necessary. Unlike MUE values, all CUE values are kept confidential.

Office of Inspector General Note—The deleted text has been redacted to protect proprietary information.

CGS MR also conducted multiple probes after the J15 transition to review claims for aberrant use of Herceptin, Infliximab, and Rituximab.

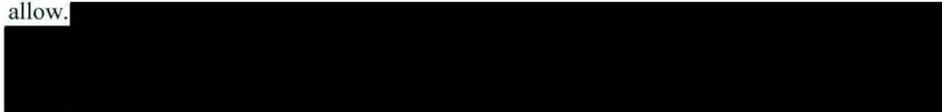


Errors consist mostly of problems related to orders and failure to provide medical records. There have been significant reversals due to providers submitting signed orders upon appeal.

CGS Provider Outreach and Education (POE) has used MR results, OIG findings, and CMS guidance to provide ongoing education to providers and facilities. Web articles and monthly bulletins pertaining to Medical Review findings and CMS guidance on medications and appropriate dosing are posted frequently to alert and educate the provider community. Representative samples of these articles are noted below:

- [https://www.cgsmedicare.com/kyb/pubs/mb\\_J15/2013/03\\_2013/PDFs/OH\\_2013\\_03.pdf](https://www.cgsmedicare.com/kyb/pubs/mb_J15/2013/03_2013/PDFs/OH_2013_03.pdf)
- <http://www.cgsmedicare.com/parta/pubs/news/2013/1013/COPE23550H.html>
- [http://www.cgsmedicare.com/ohb/pubs/mb\\_J15/2012/07\\_2012/index.html](http://www.cgsmedicare.com/ohb/pubs/mb_J15/2012/07_2012/index.html)
- <https://www.cgsmedicare.com/parta/pubs/news/2013/0813/cope22853.html>
- <https://www.cgsmedicare.com/ohb/pubs/news/2013/0113/cope21012.html>
- <http://www.cgsmedicare.com/parta/pubs/news/2012/1112/730.html>

CGS has taken appropriate measures regarding reviews and edits as our strategy and funding allow.

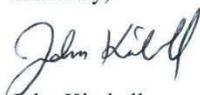


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[REDACTED] CGS uses our MRS to identify and prioritize potential aberrancies and implement interventions to avoid overpayments within the scope of our contracts, authorization, and experience.

In summary, CGS Administrators, LLC is fully aware of the vulnerabilities outlined in draft report A-05-13-00013 and, as demonstrated above, has taken aggressive and extensive steps to address those vulnerabilities. Should you have any additional questions, please feel to contact Larry Kennedy at 615.782.4607 or [Larry.Kennedy@cgsadmin.com](mailto:Larry.Kennedy@cgsadmin.com).

Sincerely,



John Kimball  
Vice President, Operations

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DME Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services

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