Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ACCREDO HEALTH GROUP, INC., PROPERLY BILLED MEDICARE FOR INHALATION DRUGS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Gloria L. Jarmon
Deputy Inspector General
for Audit Services

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Office of Inspector General

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Report in Brief
Date: August 2017
Report No. A-09-16-02022

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

Accredo Health Group, Inc., Properly Billed Medicare for Inhalation Drugs

Why OIG Did This Review

For calendar years 2014 and 2015 (audit period), Medicare paid approximately $1.3 billion for inhalation drugs provided to Medicare beneficiaries nationwide. For the audit period, the Centers for Medicare & Medicaid Services' Comprehensive Error Rate Testing program, which measures improper Medicare fee-for-service payments, found that nebulizers and related drugs (i.e., inhalation drugs) were among the top 20 durable medical equipment, prosthetics, orthotics, and supplies with the highest improper payment rates. After analyzing Medicare claim data for our audit period, we selected three suppliers for review. This report covers one of those suppliers, Accredo Health Group, Inc. (Accredo), which received 26 percent of the total Medicare payments for inhalation drugs.

Our objective was to determine whether Accredo complied with Medicare requirements when billing for inhalation drugs.

How OIG Did This Review

Our review covered 28,718 claim lines for inhalation drugs, for which Accredo received Medicare payments of $306.7 million. We reviewed a random sample of 100 of these claim lines. For each sampled item, we provided copies of the supporting documentation to a medical review contractor to determine whether inhalation drugs were properly billed.

What OIG Found

Accredo complied with Medicare requirements when billing for inhalation drugs. Specifically, all 100 sampled claim lines complied with the requirements.

What OIG Recommends

This report has no recommendations.

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INTRODUCTION

WHY WE DID THIS REVIEW

For calendar years (CYs) 2014 and 2015 (audit period), Medicare paid approximately $1.3 billion for inhalation drugs provided to Medicare beneficiaries nation-wide. For the audit period, the Centers for Medicare & Medicaid Services' (CMS's) Comprehensive Error Rate Testing program, which measures improper Medicare fee-for-service payments, found that nebulizers[1] and related drugs (i.e., inhalation drugs) were among the top 20 durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items with the highest improper payment rates. After analyzing Medicare claim data for our audit period, we selected three suppliers for review. This report covers one of those suppliers, Accredo Health Group, Inc. (Accredo), which received 26 percent of the total Medicare payments for inhalation drugs.[2]

OBJECTIVE

Our objective was to determine whether Accredo complied with Medicare requirements when billing for inhalation drugs.

BACKGROUND

The Medicare Program

The Medicare program provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. CMS administers the program. Medicare Part B provides supplementary medical insurance for medical and other health services.

Medicare Coverage of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Medicare Part B covers DMEPOS[3] and related supplies that are necessary for the effective use of covered DMEPOS items. Related supplies include drugs that must be put directly into the equipment to achieve the therapeutic benefit of the durable medical equipment or to assure its proper functioning.[4] To be paid by Medicare, a service or an item must be reasonable and

[1] A nebulizer is a small machine that turns liquid medicine into an inhalable mist.

[2] We plan to issue separate reports on the results of our review of the other suppliers.

[3] The Social Security Act (the Act) § 1832(a)(1) and §§ 1861(s)(5), (s)(6), (s)(8), and (s)(9).

[4] CMS's *Medicare Benefit Policy Manual,* Pub. No. 100-02, chapter 15, § 110.3.

necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.[5]

CMS contracted with four durable medical equipment Medicare administrative contractors (DME MACs) to process and pay Medicare Part B claims[6] for DMEPOS and related supplies, including inhalation drugs. Each DME MAC processes claims for one of four jurisdictions (A, B, C, and D), which include specific States and territories. Suppliers must submit claims to the DME MAC that serves the State or territory in which a Medicare beneficiary permanently resides.

Nebulizers and Inhalation Drugs

Nebulizers are a type of DMEPOS item that beneficiaries use in home-care settings to administer inhalation drugs. A nebulizer is a small machine that turns liquid medicine into an inhalable mist. The beneficiary breathes the medicine in through a mouthpiece connected to the nebulizer, as shown in the picture.

Physicians typically prescribe inhalation drugs to treat and prevent symptoms associated with lung diseases, such as obstructive pulmonary disease.

Medicare Coverage of Inhalation Drugs

Medicare Part B covers inhalation drugs when it is reasonable and necessary for a beneficiary to administer the drugs through a nebulizer.[7] The DME MACs' local coverage determinations (LCDs)[8] specify clinical circumstances for which the use of inhalation drugs is considered to be reasonable and necessary. For each inhalation drug, the LCDs also provide the maximum dosage (in milligrams per month) that is reasonable and necessary.[9]

For an inhalation drug to be eligible for Medicare reimbursement, the supplier must have a signed, detailed written order from the ordering physician; proof of delivery; and a documented

[5] The Act § 1862(a)(1)(A).

[6] Each claim contains details regarding each provided service or item (called a claim line in this report).

[7] CMS's *Medicare Benefit Policy Manual,* Pub. No. 100-02, chapter 15, §§ 110, 110.1, and 110.3.

[8] An LCD is a decision by a Medicare contractor, such as a DME MAC, whether to cover a particular item or service on a contractor-wide basis in accordance with section 1862(a)(1)(A) of the Act.

[9] From January 1, 2014, through September 30, 2015, jurisdictions A through D used LCDs L11499, L27226, L5007, and L11488, respectively. From October 1 through December 31, 2015, all four jurisdictions used LCD L33370.

refill request. The supplier must also maintain timely documentation to support that the inhalation drug continues to be used by the beneficiary and remains reasonable and necessary for treatment of the beneficiary's condition.[10]

Accredo Health Group, Inc.

Accredo is a wholly owned subsidiary of Express Scripts Holding Company and has its headquarters in Memphis, Tennessee. Accredo is a specialty pharmacy corporation that is focused on dispensing injectable, infused, oral, and inhaled drugs. During our audit period, Accredo had 29 pharmacies throughout the United States.

The Medicare claim data showed that Accredo billed for the following inhalation drugs: dornase alfa, tobramycin, treprostinil, and iloprost. Dornase alfa and tobramycin are used to treat cystic fibrosis. Treprostinil and iloprost are used to treat pulmonary arterial hypertension.

HOW WE CONDUCTED THIS REVIEW

For our audit period, Accredo received Medicare Part B payments of $318,761,039 for inhalation drugs provided to Medicare beneficiaries, representing 29,813 claim lines. (A claim line represented a supply of an inhalation drug.) After we excluded from our review certain claim lines reviewed by the recovery audit contractors (RACs) and other review entities (such as the DME MACs), our review covered 28,718 claim lines, totaling $306,720,090. We reviewed a simple random sample of 100 of these claim lines, for which Medicare paid $1,084,252.

Accredo provided us with supporting documentation for the sampled claim lines. The documentation included medical records that Accredo obtained from the ordering physicians. We provided copies of the documentation to a medical review contractor to determine whether the inhalation drugs were properly billed.

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.

The Appendix describes our audit scope and methodology.

[10] CMS's *Medicare Program Integrity Manual,* Pub. No. 100-08, chapter 5, §§ 5.2 and 5.7–5.9, and LCDs L11499, L27226, L5007, L11488, and L33370. The LCDs define timely documentation as a record (e.g., a medical record or supplier documentation) in the 12 months preceding the date that the drug was dispensed.

RESULTS OF REVIEW

Accredo complied with Medicare requirements when billing for inhalation drugs. Specifically, all 100 sampled claim lines complied with the requirements. Consequently, this report has no recommendations.

APPENDIX: AUDIT SCOPE AND METHODOLOGY

SCOPE

For CYs 2014 and 2015, Accredo received Medicare Part B payments of $318,761,039 for inhalation drugs provided to Medicare beneficiaries, representing 29,813 claim lines. (Each claim line represented a supply of an inhalation drug.) We excluded from our review 94 claim lines, totaling $978,373, reviewed by the RACs and 1,001 claim lines, totaling $11,062,576, reviewed by other review entities.[11] Therefore, our review covered the remaining 28,718 claim lines, totaling $306,720,090. We reviewed a simple random sample of 100 of these claim lines, for which Medicare paid $1,084,252.

Accredo provided us with supporting documentation for the sampled claim lines. The documentation included medical records that Accredo obtained from the ordering physicians. We provided copies of the documentation to a medical review contractor to determine whether the inhalation drugs were properly billed.

We did not review Accredo's overall internal control structure. Rather, we limited our review of internal controls to those that were significant to our objective.

We conducted our audit from March 2016 to February 2017, which included fieldwork performed at Accredo's main dispensing center in Warrendale, Pennsylvania.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed DME MAC officials to obtain an understanding of Medicare reimbursement requirements for inhalation drugs;
- interviewed Accredo officials to obtain an understanding of Accredo's procedures for (1) providing inhalation drugs to beneficiaries, (2) maintaining documentation for inhalation drugs, and (3) billing Medicare for inhalation drugs;

[11] CMS created a RAC data warehouse to track information about claims reviewed by the RACs. Other review entities used this data warehouse to identify claims they had previously reviewed so that these claims could be excluded from RAC review. DMEPOS review entities include DME MACs, the Office of Inspector General, and law enforcement entities.

- obtained from CMS's National Claims History file the paid Medicare Part B claims for inhalation drugs that Accredo provided to Medicare beneficiaries for our audit period;[12]

- created a sampling frame of 28,718 claim lines for inhalation drugs and randomly selected a sample of 100 claim lines;

- reviewed data from CMS's Common Working File and other available data for the sampled claim lines to determine whether claims has been canceled or adjusted;

- obtained documentation from Accredo as support for the sampled claim lines and provided the documentation to the medical review contractor, who determined whether each claim line was allowable in accordance with Medicare requirements;

- reviewed the medical review contractor's results; and

- shared the results of our review with Accredo 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.

[12] 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.