

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**LINCARE PHARMACY SERVICES INC.  
GENERALLY COMPLIED WITH  
MEDICARE REQUIREMENTS WHEN  
BILLING FOR INHALATION DRUGS**

*Inquiries about this report may be addressed to the Office of Public Affairs at  
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Gloria L. Jarmon  
Deputy Inspector General  
for Audit Services

December 2017  
A-09-16-02037

# *Office of Inspector General*

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## Report in Brief

Date: December 2017

Report No. A-09-16-02037

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



### 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 nation-wide. 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, Lincare Pharmacy Services Inc. (Lincare), which received approximately 26 percent of the total Medicare payments for inhalation drugs.

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

### How OIG Did This Review

Our review covered 2.6 million claim lines for inhalation drugs, for which Lincare received Medicare payments of \$338.1 million. We reviewed a random sample of 100 of these claim lines. For the sampled items, we provided copies of the supporting documentation, including beneficiary medical records, to a medical review contractor to determine whether inhalation drugs were properly billed.

## Lincare Pharmacy Services Inc. Generally Complied With Medicare Requirements When Billing for Inhalation Drugs

### What OIG Found

Of the 100 sampled claim lines for inhalation drugs, 97 complied with Medicare requirements. However, the remaining three sampled claim lines did not comply with the requirements. Specifically, the beneficiaries' medical records did not support that the beneficiaries had conditions for which the use of inhalation drugs was considered reasonable and necessary. As a result, Lincare received \$48 in unallowable Medicare payments.

These overpayments occurred because Lincare did not review the beneficiaries' medical records before billing Medicare. However, Lincare informed us that, beginning in May 2016, its practice was to review the medical records for each inhalation drug order to verify that the drug being prescribed was considered reasonable and necessary for the beneficiary's diagnosis. Because the change in Lincare's practice occurred after our audit period, we did not verify that the practice was effectively implemented.

Lincare provided us a copy of its employee training materials, which included general information on reviewing medical records. However, the training materials focused primarily on reviewing medical records for compliance with Medicare requirements for oxygen therapy and did not have information on the specific requirements for inhalation drugs.

### What OIG Recommends and Lincare Comments

We recommend that Lincare ensure that the medical necessity of inhalation drugs is adequately supported in beneficiaries' medical records before billing Medicare. For example, Lincare could update its employee training materials to include the requirement for reviewing medical records to verify that the inhalation drug being prescribed is considered reasonable and necessary for the beneficiary's diagnosis.

Lincare concurred with our recommendation and provided information on actions that it had taken or planned to take to implement our recommendation.

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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<sup>1</sup> 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, Lincare Pharmacy Services Inc. (Lincare), which received 26 percent of the total Medicare payments for inhalation drugs.<sup>2</sup>

### OBJECTIVE

Our objective was to determine whether Lincare 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<sup>3</sup> 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.<sup>4</sup> To be paid by Medicare, a service or an item must be reasonable and

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<sup>1</sup> A nebulizer is a small machine that turns liquid medicine into an inhalable mist.

<sup>2</sup> We already issued a report covering one of the suppliers: *Accredo Health Group, Inc., Properly Billed Medicare for Inhalation Drugs* ([A-09-16-02022](#)), issued August 23, 2017. We plan to issue a separate report on the results of our review of the other supplier.

<sup>3</sup> The Social Security Act (the Act) § 1832(a)(1) and §§ 1861(s)(5), (s)(6), (s)(8), and (s)(9).

<sup>4</sup> 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.<sup>5</sup>

CMS contracted with four durable medical equipment Medicare administrative contractors (DME MACs) to process and pay Medicare Part B claims<sup>6</sup> 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.<sup>7</sup> The DME MACs' local coverage determinations (LCDs)<sup>8</sup> specify clinical circumstances for which the use of inhalation drugs is considered reasonable and necessary. For each inhalation drug, the LCDs also provide the maximum dosage (in milligrams per month) that is reasonable and necessary.<sup>9</sup> CMS guidance states: "For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for

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<sup>5</sup> The Act § 1862(a)(1)(A).

<sup>6</sup> Each claim contains details regarding each provided service or item (called a claim line in this report).

<sup>7</sup> CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 15, §§ 110, 110.1, and 110.3.

<sup>8</sup> 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.

<sup>9</sup> From January 1, 2014, through September 30, 2015, jurisdictions A through D used LCDs L11499, L27226, L5007, and L11488, respectively. Effective October 1, 2015, all four jurisdictions used LCD L33370.

the type and quantity of items ordered and for the frequency of use . . . .” CMS guidance also states: “If the information in the patient’s medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved . . . .”<sup>10</sup>

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 refill request. The supplier must contact the beneficiary before dispensing a refill to (1) ensure that the refilled item remains reasonable and necessary and that existing supplies are approaching exhaustion and (2) confirm any changes or modifications to the order. 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.<sup>11</sup>

### **Lincare Pharmacy Services Inc.**

Lincare is a wholly owned, indirect subsidiary of Lincare Holdings Inc., which has its headquarters in Clearwater, Florida. Lincare operates three pharmacies that deliver respiratory medications to patients. The Medicare claim data showed that Lincare billed for the following inhalation drugs: acetylcysteine, albuterol, arformoterol, budesonide, formoterol, and ipratropium bromide, which are used to treat lung diseases.

### **HOW WE CONDUCTED THIS REVIEW**

For our audit period, Lincare received Medicare Part B payments of \$339,698,486 for inhalation drugs provided to Medicare beneficiaries, representing 2,816,816 claim lines. (Each claim line represented a supply of an inhalation drug.) After we excluded from our review claim lines with payment amounts of zero and certain claim lines reviewed by the recovery audit contractors (RACs)<sup>12</sup> and other review entities (such as the DME MACs), our review covered 2,637,391 claim lines, totaling \$338,123,134. We reviewed a simple random sample of 100 of these claim lines, for which Medicare paid \$15,144.

Lincare provided us with supporting documentation for the sampled claim lines. The documentation included beneficiary medical records that Lincare 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.

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<sup>10</sup> CMS’s *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 5, §§ 5.7 and 5.8.

<sup>11</sup> 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.

<sup>12</sup> CMS contracts with RACs to identify improper payments of Medicare claims. RACs conduct postpayment reviews to identify improper payments and recoup any overpayments identified.



We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A describes our audit scope and methodology.

## **FINDING**

Lincare generally complied with Medicare requirements when billing for inhalation drugs. Of the 100 sampled claim lines, 97 complied with the requirements. However, the remaining three sampled claim lines did not comply with Medicare requirements. Specifically, the beneficiaries' medical records did not support that the beneficiaries had conditions for which the use of inhalation drugs was considered reasonable and necessary. As a result, Lincare received \$48 in unallowable Medicare payments.

These overpayments occurred because Lincare did not review the beneficiaries' medical records before billing Medicare. According to Lincare, its practice was to obtain a beneficiary's medical records before dispensing an inhalation drug, but it did not review those records to ensure that the medical necessity of the inhalation drug was adequately supported. Lincare informed us that, beginning in May 2016, its practice was to review the medical records for each inhalation drug order to verify that the drug being prescribed was considered reasonable and necessary for the beneficiary's diagnosis in accordance with the applicable LCD. Lincare provided us a copy of the correspondence that it sent to its employees in April 2016 to notify them of the change in its practice for reviewing medical records. Because the change occurred after our audit period, we did not verify that the practice was effectively implemented.

Lincare also provided us a copy of its employee training materials, which included general information on reviewing medical records. According to Lincare, all of its training materials are available on its electronic training portal, which it uses in lieu of a written policy manual. However, the training materials focused primarily on reviewing medical records for compliance with Medicare requirements for oxygen therapy and did not have information on the specific requirements for inhalation drugs.

## **RECOMMENDATION**

We recommend that Lincare ensure that the medical necessity of inhalation drugs is adequately supported in beneficiaries' medical records before billing Medicare. For example, Lincare could update its employee training materials to include the requirement for reviewing medical records to verify that the inhalation drug being prescribed is considered reasonable and necessary for the beneficiary's diagnosis.

## **LINCARE COMMENTS**

In written comments on our draft report, Lincare concurred with our recommendation and provided information on actions that it had taken or planned to take to implement our recommendation. Lincare's comments are included in their entirety as Appendix B.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

For CYs 2014 and 2015, Lincare received Medicare Part B payments of \$339,698,486 for inhalation drugs provided to Medicare beneficiaries, representing 2,816,816 claim lines. (Each claim line represented a supply of an inhalation drug.) We excluded from our review 166,700 claim lines with payment amounts of zero; 298 claim lines, totaling \$39,730, reviewed by the RACs; and 12,427 claim lines, totaling \$1,535,622, reviewed by other review entities.<sup>13</sup> Therefore, our review covered the remaining 2,637,391 claim lines, totaling \$338,123,134. We reviewed a simple random sample of 100 of these claim lines, for which Medicare paid \$15,144.

Lincare provided us with supporting documentation for the sampled claim lines. The documentation included beneficiary medical records that Lincare 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 Lincare'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 July 2016 to March 2017, which included fieldwork performed at one of Lincare's pharmacies located in Carlsbad, California, and a customer service center located in Los Alamitos, California.

### 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 Lincare officials to obtain an understanding of Lincare's procedures for (1) providing inhalation drugs to beneficiaries, (2) maintaining documentation for inhalation drugs, and (3) billing Medicare for inhalation drugs;

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<sup>13</sup> 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 Lincare provided to Medicare beneficiaries for our audit period;<sup>14</sup>
- created a sampling frame of 2,637,391 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 had been canceled or adjusted;
- obtained documentation from Lincare as support for the sampled claim lines and provided the documentation to the medical review contractor, which 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 Lincare 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.

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<sup>14</sup> Our review enabled 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.

## APPENDIX B: LINCARE COMMENTS



December 6, 2017

### VIA U.S. AND ELECTRONIC MAIL

HHS Office of Inspector General  
Office of Audit Services, Region IX  
90 – 7<sup>th</sup> Street, Suite 3-650  
San Francisco, California 94103

Attention: Lori A. Ahlstrand, Regional Inspector General  
for Audit Services

**Re: Your letter to Lincare Pharmacy Services Inc. dated November 7, 2017 (the “Letter”), enclosing an OIG draft report entitled “Lincare Pharmacy Services Inc. Generally Complied With Medicare Requirements When Billing for Inhalation Drugs” (the “Draft Report”)**

**Report Number: A-09-16-02037**

Dear Ms. Ahlstrand:

Lincare Pharmacy Services Inc. (hereafter “LPS”), a wholly-owned, indirect subsidiary of Lincare Holdings Inc. and Medicare-enrolled supplier of respiratory medications, is in receipt of the Letter and Draft Report and appreciates the opportunity to provide the following comments:

In its Report in Brief and on page 4 of the Draft Report, the OIG recommends that “Lincare ensure that the medical necessity of inhalation drugs is adequately supported in the beneficiaries’ medical records before billing Medicare.” LPS concurs with this recommendation. Moreover, prior to the OIG’s having furnished the draft for comment, LPS had already taken steps to further improve and correct its internal processes and procedures in a manner consistent with the OIG’s recommendation.

Specifically, while as a matter of past policy LPS may not have obtained records from the treating physician in support of medical necessity prior to billing, as noted in the Draft Report, in and around May 2016, Lincare changed its policy and began obtaining the supporting records prior to dispensing and billing.

Additionally, LPS has been in the process of updating its training offerings to now specifically include policies and procedures related to employees’ obtaining records supporting the medical necessity of dispensing respiratory medications prior to dispensing and billing. LPS intends to finalize this training in February 2018.

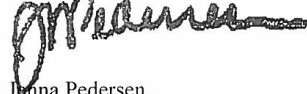
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Jennifer L. Pedersen (Corporate Compliance Officer)

LPS takes seriously its obligation to appropriately bill for drugs it dispenses under the Medicare Program and trusts the above-described actions already in progress address concerns the OIG has raised. LPS is available to discuss the OIG's concerns.

Thank you for your attention to this matter. Should you have any questions regarding the content of this letter, please do not hesitate to contact me at 727-530-7700.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jenna Pedersen', written in a cursive style.

Jenna Pedersen,  
Corporate Compliance Officer