

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE IMPROPERLY PAID
SUPPLIERS AN ESTIMATED
\$92.5 MILLION FOR
INHALATION DRUGS**

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Office of Inspector General

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Report in Brief

Date: October 2019
Report No. A-09-18-03018



Why OIG Did This Review

Since 2010, the Centers for Medicare & Medicaid Services' (CMS's) Comprehensive Error Rate Testing (CERT) program has identified nebulizers and related drugs (i.e., inhalation drugs) among the top 20 supplies with the highest improper Medicare payments. Prior OIG reviews (for calendar years (CYs) 2014 and 2015) found that the top two suppliers of inhalation drugs complied or generally complied with Medicare requirements. However, our review of a third supplier (for CYs 2015 and 2016) found similar billing issues to those identified by the CERT program. These three suppliers received 56 percent of total Medicare payments for inhalation drugs during CY 2017 (audit period). We conducted this nation-wide review to determine whether the issues identified by the CERT program were primarily caused by suppliers that received the remaining 44 percent of payments, which we had not previously reviewed.

Our objective was to determine whether the suppliers covered by our review complied with Medicare requirements when billing for inhalation drugs.

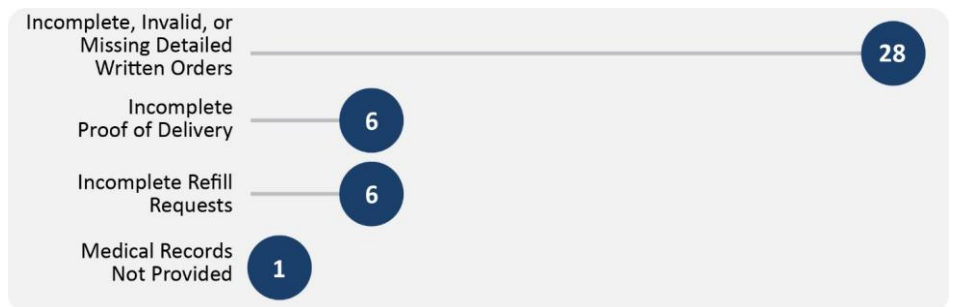
How OIG Did This Review

Our review covered 2.3 million claim lines, totaling \$259.5 million, for inhalation drugs that 7,868 suppliers provided to Medicare beneficiaries during our audit period. We reviewed a stratified random sample of 120 of these claim lines, for which Medicare paid 65 suppliers \$121,185.

Medicare Improperly Paid Suppliers an Estimated \$92.5 Million for Inhalation Drugs

What OIG Found

Not all suppliers complied with Medicare requirements when billing for inhalation drugs. For 81 of the 120 sampled claim lines, suppliers complied with the requirements; however, for the remaining 39 claim lines, 22 suppliers did not comply with documentation requirements (the total below exceeds 39 because 2 claim lines had 2 deficiencies).



On the basis of our sample results, we estimated that \$92.5 million paid to suppliers was unallowable for Medicare reimbursement. Medicare contractor oversight was not sufficient to ensure that suppliers complied with documentation requirements.

What OIG Recommends and CMS Comments

We recommend that CMS instruct the Medicare contractors to recover \$36,825 in overpayments for the 39 unallowable claim lines and notify the 22 suppliers associated with the 39 claim lines with potential overpayments of \$36,825 so that those suppliers can exercise reasonable diligence to investigate and return any identified overpayments. We also made three procedural recommendations to CMS (detailed in the report), including working with the Medicare contractors to expand their review of inhalation drug claims and to provide additional training, which could have saved Medicare an estimated \$92.5 million for CY 2017.

CMS concurred with our recommendations and described actions that it had taken or planned to take to address our recommendations.

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INTRODUCTION

WHY WE DID THIS REVIEW

For calendar year (CY) 2017 (audit period), Medicare paid approximately \$590 million for inhalation drugs provided to Medicare beneficiaries nation-wide. Since 2010, the Centers for Medicare & Medicaid Services' (CMS's) Comprehensive Error Rate Testing (CERT) program, which measures improper Medicare fee-for-service payments annually, has identified nebulizers¹ and related drugs (i.e., inhalation drugs) as among the top 20 durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items with the highest improper payments.² The CERT program found that the DMEPOS suppliers (suppliers) that improperly billed for inhalation drugs did not have complete detailed written orders from prescribing physicians, proof-of-delivery documentation, documented refill requests, or medical records to support the claims billed.

Prior Office of Inspector General (OIG) reviews found that the top two suppliers of inhalation drugs complied or generally complied with Medicare requirements.³ Medicare contractors visited these two suppliers in 2014 and 2015 to provide education on how to properly document claims, which may have contributed to the suppliers' compliance with Medicare requirements. Our review of a third supplier, which received lower payments than the other two suppliers but did not receive onsite Medicare contractor education, found similar billing issues to those identified by the CERT program.⁴ Together, these three suppliers received 56 percent of total Medicare payments for inhalation drugs during our audit period. (See Appendix B for a list of related OIG reports.) We conducted this nation-wide review to determine the extent to which the issues identified by the CERT program were caused by suppliers of inhalation drugs that received the remaining 44 percent of total Medicare payments for our audit period. Therefore, we focused our review on inhalation drug claims submitted by suppliers nation-wide that we had not already reviewed. For our audit period, Medicare Part B paid those suppliers approximately \$261 million for inhalation drugs.

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

² The Medicare fee-for-service improper payments reports for 2010 to 2018 indicated that the improper payment rates ranged from 11 to 68 percent. These reports included services provided from July 1, 2008, to June 30, 2017 (www.cms.gov, *CERT Reports*, accessed on Apr. 16, 2019).

³ For these two suppliers, we reviewed claims for inhalation drugs provided to Medicare beneficiaries in CYs 2014 and 2015.

⁴ For this supplier, we reviewed claims for inhalation drugs provided to Medicare beneficiaries in CYs 2015 and 2016. Although this supplier was among the 20 highest paid suppliers of inhalation drugs, it received less than 1 percent of the Medicare payments for inhalation drugs.

OBJECTIVE

Our objective was to determine whether the suppliers covered by our review 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 DMEPOS⁵ 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.⁶ To be paid by Medicare, a service or an item must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (the Act § 1862(a)(1)(A)).

CMS contracted with two durable medical equipment Medicare administrative contractors (DME MACs) to process and pay Medicare Part B claims⁷ for DMEPOS and related supplies, including inhalation drugs. Each DME MAC processes claims for two 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. In addition to processing claims, DME MAC responsibilities include educating suppliers on Medicare requirements and billing procedures and applying system edits to claims to determine whether the claims are complete and should be paid.⁸

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

⁶ CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 15, § 110.3.

⁷ Each claim contains details regarding each provided service or item (called a claim line in this report).

⁸ An edit is programming within the standard claim processing system that selects certain claims; evaluates or compares information on the selected claims or other accessible sources; and, depending on the evaluation, takes action on the claims, such as paying them in full, paying them in part, or suspending them for manual review.

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 individual breathes the medicine in through a mouthpiece connected to the nebulizer, as shown in Figure 1.

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

Figure 1: An Individual Using a Nebulizer



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.⁹ The DME MACs' local coverage determination (LCD) for nebulizers (LCD L33370) specifies clinical circumstances for which the use of inhalation drugs is considered reasonable and necessary.¹⁰ For each inhalation drug, the LCD also provides the maximum dosage (in milligrams per month) that is reasonable and necessary. In addition, the DME MACs' local coverage article (LCA) A55426 includes documentation requirements for all claims submitted to DME MACs.¹¹

For an inhalation drug to be eligible for Medicare reimbursement, the supplier must have a signed, detailed written order from the prescribing physician; proof of delivery; and, for refills of the original order, 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.¹²

⁹ CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 15, §§ 110, 110.1, and 110.3.

¹⁰ This LCD was applicable to all four jurisdictions. 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.

¹¹ *Standard Documentation Requirements for All Claims Submitted to the DME MACs* (LCA A55426), effective date January 1, 2017. An LCA contains coding or other guidelines that complement an LCD.

¹² CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08 (the Manual), chapter 5, §§ 5.2 and 5.7–5.9; LCD L33370; and LCA A55426. The LCA defines timely documentation as a record in the preceding 12 months.

The beneficiary's medical record must contain sufficient documentation of the beneficiary's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use. The supplier should obtain as much documentation from the beneficiary's medical record as needed to assure that the coverage criteria for an item have been met.¹³

Prior Office of Inspector General Reviews

Our prior reviews of the two suppliers that received the highest total amount of Medicare payments for inhalation drugs determined that the suppliers complied or generally complied with Medicare requirements.¹⁴ According to officials from the two DME MACs, they visited these two suppliers in 2014 and 2015 to provide education on how to properly document claims, which may have contributed to the suppliers' compliance with Medicare requirements.

However, our review of a third supplier, which received lower payments than the other two suppliers, found billing issues that were similar to those found by the CERT program.¹⁵ Specifically, this supplier did not provide us with medical records or have adequate proof-of-delivery documentation for some of the sampled claim lines. Officials from the two DME MACs stated that they had not visited this supplier before our review to provide education on how to properly document claims.

Medicare Requirements for Suppliers To Identify and Return Overpayments

OIG believes that this audit report constitutes credible information of potential overpayments. Suppliers that receive notification of these potential overpayments must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule).¹⁶

¹³ The Manual, chapter 5, §§ 5.7 and 5.8, and LCA A55426.

¹⁴ *Accredo Health Group, Inc., Properly Billed Medicare for Inhalation Drugs* ([A-09-16-02022](#)), issued August 23, 2017, and *Lincare Pharmacy Services Inc. Generally Complied with Medicare Requirements When Billing for Inhalation Drugs* ([A-09-16-02037](#)), issued December 14, 2017. For these two suppliers, we reviewed claims for inhalation drugs provided to Medicare beneficiaries in CYs 2014 and 2015. Together, these two suppliers received the highest total amount of Medicare payments for inhalation drugs for CYs 2015, 2016, and 2017.

¹⁵ *Liberty Medical, LLC, Received Unallowable Medicare Payments for Inhalation Drugs* ([A-09-17-03019](#)), issued August 17, 2018. For this supplier, we reviewed claims for inhalation drugs provided to Medicare beneficiaries in CYs 2015 and 2016. This supplier was among the top 20 suppliers that received the highest total amount of Medicare payments for inhalation drugs for CYs 2015, 2016, and 2017.

¹⁶ The Act § 1128J(d); 42 CFR part 401, subpart D; 42 CFR §§ 401.305(a)(2) and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

HOW WE CONDUCTED THIS REVIEW

Our review covered 2.3 million claim lines, totaling \$259.5 million, for inhalation drugs that 7,868 suppliers provided to Medicare beneficiaries in CY 2017. (Each claim line represented a supply of an inhalation drug.) We excluded from our review claim lines submitted by the suppliers that we had already reviewed, claim lines with payment amounts of less than \$5, and claim lines reviewed by the recovery audit contractors (RACs)¹⁷ and other review entities (such as the DME MACs). We reviewed a stratified random sample of 120 claim lines, for which Medicare paid 65 suppliers \$121,185.

Suppliers provided us with supporting documentation, including medical records, for the sampled claim lines. For some sampled claim lines, suppliers were unable to provide the medical records. In those cases, we requested the medical records directly from the prescribing physicians.¹⁸ We reviewed the documentation to determine whether the inhalation drugs were properly billed; however, a medical reviewer did not review the documentation to determine whether the drugs 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.

Appendix A describes our audit scope and methodology, Appendix C describes our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E lists the inhalation drugs covered by our review and their associated Healthcare Common Procedure Coding System (HCPCS)¹⁹ codes.

¹⁷ CMS contracts with RACs to identify improper payments of Medicare claims. RACs conduct postpayment reviews to identify improper payments and recoup any overpayments identified.

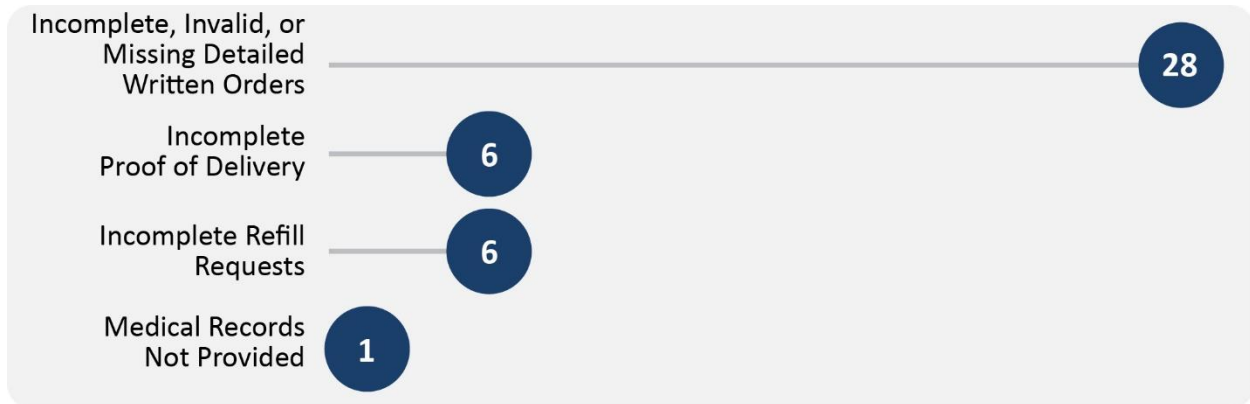
¹⁸ We contacted physicians to request medical records for 27 sampled claim lines and received medical records for 26 of them. For one sampled claim line, the physician's telephone number listed in the supplier's supporting documentation was for a disconnected line. Because we were unable to obtain medical records for this claim line, we considered it to be unallowable. See the section "Medical Records Were Not Provided" on page 10 for more information.

¹⁹ HCPCS codes are a collection of standardized codes that represent medical procedures, supplies, products, and services. These codes are used to facilitate Medicare's processing of health insurance claims.

FINDINGS

Not all suppliers complied with Medicare requirements when billing for inhalation drugs. For 81 of the 120 sampled claim lines, 52 suppliers complied with the requirements; however, for the remaining 39 claim lines, 22 suppliers did not comply with documentation requirements.²⁰ Figure 2 shows the documentation-related deficiencies we found.

Figure 2: Documentation-Related Deficiencies Found in Sampled Claim Lines²¹



As a result, Medicare improperly paid suppliers \$36,825 for the 39 unallowable claim lines. On the basis of our sample results, we estimated that Medicare overpaid suppliers approximately \$92.5 million²² for inhalation drugs. These overpayments occurred because the DME MACs' oversight was not sufficient to ensure that suppliers complied with documentation requirements when billing for inhalation drugs.

NOT ALL SUPPLIERS COMPLIED WITH DOCUMENTATION REQUIREMENTS WHEN BILLING FOR INHALATION DRUGS

Detailed Written Orders Were Incomplete, Invalid, or Missing

To be paid by Medicare, a service or an item must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (the Act § 1862(a)(1)(A)).

The Manual and the LCD state that a detailed written order must be received by the supplier before a claim is submitted. If the supplier bills for an item without first receiving a completed

²⁰ The total number of suppliers exceeds the 65 associated with our sample because 9 suppliers were associated with both allowable and unallowable claim lines.

²¹ The total exceeds 39 because 2 claim lines had 2 deficiencies.

²² We estimated that for our audit period Medicare overpaid suppliers \$92,471,272.

detailed written order, the claim will be denied as not reasonable and necessary (the Manual, chapter 5, § 5.2.3, and LCD L33370).

The LCA states that the detailed written order must contain the beneficiary's and prescribing physician's names, date of the order, prescribing physician's signature, signature date (if someone other than the prescriber creates the detailed written order), and items to be dispensed. For drugs, the detailed written order must also contain the dosage or concentration and route of administration (e.g., by mouth, injection, or inhalation) (if applicable), frequency of use, quantity to be dispensed, and number of refills (LCA A55426).

For 28 sampled claim lines, suppliers submitted claims when the detailed written orders were incomplete, invalid, or missing.

Incomplete Detailed Written Orders

For 24 sampled claim lines, suppliers provided us with detailed written orders that were missing 1 or more of the required elements. The most prevalent missing elements were the number of refills (22 claim lines) and the quantity to be dispensed (5 claim lines).

For example, Medicare paid a supplier \$493 for providing formoterol, an inhalation drug used to prevent asthma attacks, to a beneficiary on March 8, 2017. The supplier provided a detailed written order that did not contain the frequency of use, quantity to be dispensed, or number of refills.

Invalid Detailed Written Orders

For three sampled claim lines, suppliers provided us with detailed written orders that were invalid because the number of refills had been exceeded or the order did not support the sampled claim line.

For example, Medicare paid a supplier \$6 for providing albuterol, an inhalation drug used to prevent symptoms of chronic obstructive pulmonary disease, and \$5 for providing ipratropium bromide, an inhalation drug used to control and prevent symptoms of lung disease, to a beneficiary on January 27, 2017.²³ The supplier did not have a detailed written order for these two drugs. Rather, it had a detailed written order for a drug combination of albuterol and ipratropium bromide. The supplier provided the beneficiary the two inhalation drugs separately rather than in the form and dosage that the physician prescribed, which could have resulted in improper use of the drugs.²⁴

²³ The claim line for ipratropium bromide was not part of our sample.

²⁴ Improper use of inhalation drugs may cause severe symptoms, such as seizures, difficulty breathing, chest pain, fast and irregular heartbeat, fainting, nausea, dizziness, and headaches (<https://medlineplus.gov/druginformation.html> and <https://www.mayoclinic.org/drugs-supplements>, both accessed on July 3, 2019). We provided information on the sampled claim line to CMS so that it may further investigate this issue.

Missing Detailed Written Order

For one sampled claim line, the supplier submitted a claim when the detailed written order was missing. Medicare paid the supplier \$2,499 for providing dornase alfa, an inhalation drug used to control symptoms of cystic fibrosis, to a beneficiary on June 29, 2017. However, the supplier stated that it did not have a detailed written order to support the sampled claim line that it had billed.

Proof-of-Delivery Documentation Was Incomplete

Federal regulations state that suppliers are responsible for the delivery of Medicare-covered items to beneficiaries and maintaining proof of delivery (42 CFR § 424.57(c)(12)).

The Manual and the LCD state that suppliers are required to maintain proof-of-delivery documentation in their files, and this documentation must be available on request. In addition, claims for items that do not have appropriate proof of delivery from the supplier will be denied (the Manual, chapter 5, § 5.8, and LCD L33370).

The LCA states that for suppliers that deliver directly to the beneficiary, the proof of delivery must be a signed and dated delivery document. Proof-of-delivery documentation must include the beneficiary's name, the delivery address, a description of the item being delivered, the quantity delivered, the date the item was delivered, and the beneficiary's (or designee's) signature (LCA A55426).

In addition, the LCA states that for suppliers that use a shipping service or deliver supplies by mail, the proof-of-delivery documentation must be a complete record tracking the item from the supplier to the beneficiary. The documentation must include the beneficiary's name, the delivery address, the delivery service's package identification number or alternative method that links the supplier's delivery documents with the delivery service's records, a description of the item being delivered, the quantity delivered, the date the item was delivered, and evidence of delivery (LCA A55426).

For six sampled claim lines, suppliers did not provide complete proof-of-delivery documentation. Specifically, the documentation was missing one or more of the required elements.

For example, Medicare paid a supplier \$12,229 for providing treprostinil, an inhalation drug used to treat pulmonary arterial hypertension, to a beneficiary on November 7, 2017. For this sampled claim line, the supplier provided to us a delivery record showing that it had shipped the item to its retail store; however, the supplier did not provide us with the signed and dated delivery document verifying that the inhalation drug was delivered to the beneficiary.

Medicare paid another supplier \$2,356 for providing dornase alfa to a beneficiary on January 11, 2017. For this sampled claim line, the supplier's documentation included a note indicating that the inhalation drug had not been delivered. The supplier's documentation also included the delivery service's package identification number. However, the delivery service's record showed that the package identification number listed in the supplier's documentation "could not be found." Therefore, the supplier was unable to provide the date the item was delivered and evidence of delivery.

Refill Requests Were Incomplete

The Manual states that for DMEPOS products that are supplied as refills to the original order, a supplier must contact the beneficiary before dispensing a refill to (1) ensure that the refilled items remain reasonable and necessary, (2) ensure that existing supplies are approaching exhaustion, and (3) confirm any changes or modifications to the order (the Manual, chapter 5, § 5.2.8).

The LCD states that a supplier is required to have contact with the beneficiary before dispensing a refill of inhalation drugs. The supplier must not deliver a refill without a refill request from the beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary (LCD L33370).

The LCA states that for consumable supplies (i.e., those that are used up), the refill record must include an assessment of the quantity of each item that the beneficiary still has remaining to document that the amount remaining will be nearly exhausted on or about the supply anniversary date (LCA A55426).

For six sampled claim lines, suppliers provided incomplete refill requests. Specifically, suppliers did not document their assessment of the quantity of inhalation drugs that the beneficiaries still had remaining:

- For five sampled claim lines, the refill records documented contact with the beneficiaries and the beneficiaries' requests for refills; however, those records did not show that the suppliers had assessed the quantity of inhalation drugs that the beneficiaries still had remaining or documented that existing supplies were approaching exhaustion.
- For one sampled claim line, the refill request did not show that the supplier had contacted the beneficiary.

For example, Medicare paid a supplier \$2,545 for providing dornase alfa to a beneficiary on July 24, 2017. The supplier provided documentation for a refill request that showed that the supplier had contacted the beneficiary; however, the refill record did not document the supplier's assessment of the quantity of the drug that the beneficiary still had remaining or

document that the amount remaining would have been nearly exhausted on or about the supply anniversary date (i.e., the anticipated refill date).

Medical Records Were Not Provided

Payment must not be made to a provider for an item or a service unless “there has been furnished such information as may be necessary in order to determine the amounts due such provider” (the Act § 1833(e)). To be paid by Medicare, a service or an item must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (the Act § 1862(a)(1)(A)).

The Manual states that a beneficiary’s medical record must contain sufficient documentation of the beneficiary’s medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use (the Manual, chapter 5, § 5.7). The Manual and LCA also state that a supplier should obtain as much documentation from the beneficiary’s medical record as it determines is needed to assure the supplier that the coverage criteria for an item have been met (the Manual, chapter 5, § 5.8, and LCA A555426). If the medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved (the Manual, chapter 5, §§ 5.7 and 5.8, and LCA A55426).

The LCA states that information contained directly in the contemporaneous medical record is the source required to justify payment (LCA A55426). In addition, the LCD states that the medical record must be available upon request (LCD L33370).

For one sampled claim line, neither the supplier nor the prescribing physician provided us with medical records to support the claim line billed. Medicare paid the supplier \$9 for providing albuterol to a beneficiary on July 1, 2017. The supplier stated that the prescribing physician did not respond to the supplier’s request for medical records. We called the physician reported in the claim data and listed in the supplier’s supporting documentation, but the physician’s telephone number was for a disconnected line.

For 27 sampled claim lines, the suppliers did not provide medical records to substantiate the necessity for the type and quantity of drugs ordered and for the frequency of use. These suppliers did not obtain medical records to ensure that the coverage criteria for the sampled claim lines had been met. Most of these suppliers stated that they were unable to acquire the medical records after making multiple requests to the prescribing physicians. However, we contacted the prescribing physicians and obtained medical records for 26 sampled claim lines. As a result, we did not consider these claim lines to be unallowable.

MEDICARE IMPROPERLY PAID SUPPLIERS AN ESTIMATED \$92.5 MILLION FOR INHALATION DRUGS

Medicare improperly paid 22 suppliers for 39 unallowable claim lines, totaling \$36,825. On the basis of our sample results, we estimated that \$92.5 million of the \$259.5 million paid to suppliers for inhalation drugs was unallowable for Medicare reimbursement.

MEDICARE CONTRACTOR OVERSIGHT WAS NOT SUFFICIENT TO ENSURE THAT SUPPLIERS COMPLIED WITH DOCUMENTATION REQUIREMENTS

DME MAC oversight was not sufficient to ensure that suppliers complied with documentation requirements when billing for inhalation drugs. The DME MACs stated that in 2017, they focused their medical reviews on claims for inhalation drugs that they considered at high risk of being billed incorrectly. However, we found that 29 of the 39 unallowable claim lines in our sample (74 percent) were for inhalation drugs that the DME MACs had focused their medical reviews on, indicating that these reviews were not sufficient to prevent improper payments. In addition, the DME MACs did not review claims for the inhalation drugs with the highest reimbursement rates, which accounted for the remaining 10 unallowable claim lines in our sample (26 percent).

The DME MACs have tried to reduce improper payments by providing educational materials and webinars on Medicare requirements for inhalation drugs. (Webinars are seminars conducted over the internet.) Since 2015, the DME MACs have provided educational materials on their websites, conducted webinars on general coverage requirements, and held individualized education when requested by suppliers or to address the reasons for unallowable payments identified during the DME MACs' review of suppliers' claims. The webinars included general guidance on detailed written orders, refill requests, proof of delivery, and medical record documentation. However, the DME MACs stated that not all suppliers have taken advantage of these educational opportunities, and some suppliers continue to submit claims for inhalation drugs that do not comply with documentation requirements.

CONCLUSION

Adequate documentation is essential for proper oversight of suppliers billing for inhalation drugs. Both CMS and the DME MACs rely on supplier documentation to determine whether inhalation drugs were properly billed to Medicare. Proof-of-delivery documentation helps the DME MACs to determine whether drugs were actually provided to beneficiaries, while medical records, detailed written orders, and the beneficiaries' refill request records help the DME MACs to determine whether the drugs were reasonable and necessary for the treatment of beneficiaries' illnesses. Adequate documentation, especially properly completed detailed written orders, also helps to ensure that beneficiaries receive the correct medications in the dosages prescribed by their physicians. Effective DME MAC oversight of suppliers is essential for reducing improper payments for inhalation drug claims and for ensuring beneficiaries' quality of care.

Our review showed that detailed written orders were particularly problematic. We found that suppliers dispensed inhalation drugs when they did not have detailed written orders or when the orders were missing required elements, such as the frequency of use, quantity to be dispensed, and number of refills. For one sampled item, we found that the supplier dispensed and billed for two separate drugs when the detailed written order prescribed the combined form of these drugs.

Effective oversight of suppliers billing for inhalation drugs includes educating suppliers on Medicare requirements and monitoring their billing. The DME MACs have taken actions to educate the top two suppliers on Medicare requirements for inhalation drugs and provided various educational materials and webinars on Medicare requirements for inhalation drugs. However, this nation-wide review shows that suppliers other than the top two suppliers are still not adequately documenting the support for their claims and were responsible for an estimated \$92.5 million in improper payments for inhalation drugs in CY 2017. The DME MACs continued their educational efforts in 2017; however, not all suppliers have taken advantage of the educational opportunities available to them. In addition, DME MACs have continually monitored supplier billing by reviewing inhalation drug claims that they considered at high risk of being billed incorrectly; however, this review demonstrates that they also need to review claims for other inhalation drugs (e.g., the drugs with the highest reimbursement rates).

Additional steps must be taken to help reduce improper payments for inhalation drugs. If CMS had advised the DME MACs to expand their review of claims to include the inhalation drugs with the highest reimbursement rates and to provide additional training to suppliers on documentation requirements, Medicare could have saved an estimated \$92.5 million for CY 2017.

Incomplete Detailed Written Orders May Adversely Affect Beneficiaries

Beneficiaries' quality of care may be compromised when physicians exclude required elements from the detailed written orders because suppliers may dispense inhalation drugs in an improper form, dosage, or quantity, which may result in improper use of these drugs. Improper use may cause severe symptoms, such as seizures, difficulty breathing, chest pain, fast and irregular heartbeat, fainting, nausea, dizziness, and headaches (<https://medlineplus.gov/druginformation.html> and <https://www.mayoclinic.org/drugs-supplements>, both accessed on July 3, 2019). Suppliers may also dispense and bill for unneeded inhalation drugs, which may have a financial impact on beneficiaries because they pay more in coinsurance.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services instruct the durable medical equipment Medicare administrative contractors to:

- recover \$36,825 in overpayments for the 39 unallowable claim lines and
- notify the 22 suppliers associated with the 39 claim lines with potential overpayments of \$36,825 so that those suppliers can exercise reasonable diligence to investigate and return any identified overpayments, in accordance with the 60-day rule, and identify and track any returned overpayments as having been made in accordance with this recommendation.

We also recommend that the Centers for Medicare & Medicaid Services work with the durable medical equipment Medicare administrative contractors to do the following, which could have saved Medicare an estimated \$92,471,272 for CY 2017:

- expand their review of suppliers' claims to include additional inhalation drugs (e.g., those with the highest reimbursement rates);
- provide additional training to suppliers on Medicare documentation requirements for inhalation drugs; and
- identify suppliers that consistently bill for inhalation drugs that do not comply with Medicare documentation requirements, perform reviews of those suppliers, collect the amount overpaid for unallowable claims, and educate them on Medicare requirements for inhalation drugs.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and described actions that it had taken or planned to take to address our recommendations. CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix F.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered 2,266,433 claim lines, totaling \$259,454,219, for inhalation drugs that 7,868 suppliers provided to Medicare beneficiaries in CY 2017. (Each claim line represented a supply of an inhalation drug.) We excluded from our review claim lines submitted by the suppliers that we had already reviewed, claim lines with payment amounts of less than \$5, and claim lines reviewed by the RACs and other review entities (such as the DME MACs). We reviewed a stratified random sample of 120 claim lines, for which Medicare paid 65 suppliers \$121,185.

Suppliers provided us with supporting documentation, including medical records, for the sampled claim lines. For some sampled claim lines, suppliers were unable to provide the requested medical records. In those cases, we requested the medical records directly from the prescribing physicians.²⁵ We reviewed the documentation to determine whether the inhalation drugs were properly billed; however, a medical reviewer did not review the documentation to determine whether the drugs were medically necessary.²⁶

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

We conducted our audit from May 2018 to March 2019.

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;

²⁵ We contacted physicians to request medical records for 27 sampled claim lines and received medical records for 26 of them. For one sampled claim line, the physician's telephone number listed in the supplier's supporting documentation was for a disconnected line. Because we were unable to obtain medical records for this claim line, we considered it to be unallowable.

²⁶ A qualified medical review contractor reviewed the documentation for our prior reviews of two suppliers: Accredo Health Group and Lincare Pharmacy Services.

- obtained from CMS’s National Claims History (NCH) file the paid Medicare Part B claims for inhalation drugs that suppliers provided to Medicare beneficiaries for our audit period;²⁷
- created a sampling frame of 2,266,433 claim lines for inhalation drugs²⁸ and selected a stratified random sample of 120 claim lines (Appendix C);
- 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 suppliers and physicians as support for the sampled claim lines and determined whether each claim line was allowable in accordance with Medicare requirements;
- estimated the amount of the unallowable payments for inhalation drugs provided by suppliers (Appendix D); and
- discussed the results of our review with CMS 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.

²⁷ Our review enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS’s NCH file, but we did not assess the completeness of the file.

²⁸ See Appendix E for a list of inhalation drugs and their associated HCPCS codes for the claim lines in our frame.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Liberty Medical, LLC, Received Unallowable Medicare Payments for Inhalation Drugs</i>	<u>A-09-17-03019</u>	8/17/2018
<i>Lincare Pharmacy Services Inc. Generally Complied With Medicare Requirements When Billing for Inhalation Drugs</i>	<u>A-09-16-02037</u>	12/14/2017
<i>Accredo Health Group, Inc., Properly Billed Medicare for Inhalation Drugs</i>	<u>A-09-16-02022</u>	8/23/2017
<i>Questionable Billing for Brand-Name Inhalation Drugs in South Florida</i>	<u>OEI-03-09-00530</u>	12/21/2010
<i>Review of Payments for Inhalation Drugs Made by Region C Durable Medical Equipment Regional Carrier</i>	<u>A-06-00-00053</u>	10/4/2001

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

The target population consisted of CY 2017 Medicare Part B paid claim lines for inhalation drugs billed by suppliers nation-wide, excluding paid claim lines for inhalation drugs billed by three suppliers that we reviewed in prior audits.²⁹

We obtained claim data for the target population from CMS's NCH file, consisting of 2,703,382 claim lines, totaling \$261,435,500, with paid amounts greater than zero. We excluded from our review 435,799 claim lines, totaling \$1,329,820, with payment amounts less than \$5. We also excluded from our review 1,150 claim lines, totaling \$651,461, reviewed by the RACs and other review entities. As a result, the sampling frame consisted of 2,266,433 claim lines for inhalation drugs provided in CY 2017, for which suppliers received Medicare payments of \$259,454,219.

SAMPLE UNIT

The sample unit was a claim line for a supply of an inhalation drug.

SAMPLE DESIGN

We used a stratified random sample. To accomplish this, we separated the sampling frame into four strata (Table 1).

Table 1: Strata in Sampling Frame

Stratum	Payment Range of Claim Lines	No. of Claim Lines	Total Payments for Claim Lines
1	Equal to or greater than \$5 but less than \$50	1,568,180	\$18,960,111
2	Equal to or greater than \$50 but less than \$400	440,692	64,823,255
3	Equal to or greater than \$400 but less than \$1,000	235,451	108,469,434
4	Equal to or greater than \$1,000	22,110	67,201,419
Total		2,266,433	\$259,454,219

SAMPLE SIZE

We selected a total of 120 claim lines, consisting of 30 claim lines from each stratum.

²⁹ In prior audits, we reviewed inhalation drugs billed by Accredo Health Group ([A-09-16-02022](#)), Lincare Pharmacy Services ([A-09-16-02037](#)), and Liberty Medical ([A-09-17-03019](#)).

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the claim lines in stratum 1 from 1 to 1,568,180, the claim lines in stratum 2 from 1 to 440,692, the claim lines in stratum 3 from 1 to 235,451, and the claim lines in stratum 4 from 1 to 22,110. After generating 30 random numbers for each stratum, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the amount overpaid by Medicare to suppliers that did not comply with Medicare requirements when billing for inhalation drugs.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results

Stratum	No. of Claim Lines in Sampling Frame	Value of Frame	Sample Size	Value of Sample	No. of Unallowable Claim Lines	Value of Unallowable Claim Lines
1	1,568,180	\$18,960,111	30	\$336	8	\$89
2	440,692	64,823,255	30	3,897	8	819
3	235,451	108,469,434	30	13,793	15	6,932
4	22,110	67,201,419	30	103,159	8	28,985
Total	2,266,433	\$259,454,219	120	\$121,185	39	\$36,825

**Table 3: Estimated Value of Unallowable Payments
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$92,471,272
Lower limit	68,514,320
Upper limit	116,428,225

**APPENDIX E: INHALATION DRUGS REVIEWED AND ASSOCIATED
HEALTHCARE COMMON PROCEDURE CODING SYSTEM CODES**

Inhalation Drug	HCPCS Code
Pentamidine	J2545
Arformoterol	J7605
Formoterol	J7606
Acetylcysteine	J7608
Albuterol	J7611 and J7613
Levalbuterol	J7612
Levalbuterol (concentrated)	J7614
Albuterol/ipratropium bromide combination	J7620
Budesonide	J7626
Cromolyn sodium	J7631
Dornase alfa	J7639
Ipratropium bromide	J7644
Metaproterenol	J7669
Tobramycin	J7682
Treprostinil	J7686
Iloprost	Q4074

APPENDIX F: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: September 25, 2019

TO: Gloria Jarmon
Deputy Inspector General for Audit Services
Office of Inspector General

FROM: Seema Verma
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Improperly Paid Suppliers an Estimated \$92.5 Million for Inhalation Drugs (A-09-18-03018)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS recognizes the importance of providing Medicare beneficiaries with access to medically necessary services and, at the same time, protecting the Medicare Trust Funds from improper payments. CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system and prepayment and postpayment medical reviews. As part of this strategy, CMS recovers identified improper payments in accordance with relevant law and agency policies and procedures.

Additionally, CMS has taken action to prevent improper Medicare payments by educating health care providers on proper billing for inhalation drugs. As noted by OIG, in 2014 and 2015, Medicare contractors visited the top two suppliers of inhalation drugs to provide education on how to properly document claims. Subsequently, OIG reviewed these suppliers and found they generally complied with Medicare requirements. CMS continues to educate suppliers and health care providers on appropriate Medicare billing through various channels including the Medicare Learning Network, weekly electronic newsletters, and quarterly compliance newsletters. For example, a fact sheet of provider compliance tips for nebulizers and related drugs was published in April 2019¹.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services instruct the durable medical equipment Medicare administrative contractors to recover \$36,825 in overpayments for the 39 unallowable claim lines.

CMS Response

CMS concurs with this recommendation. CMS will instruct its durable medical equipment Medicare Administrative Contractors to recover the identified overpayments consistent with relevant law and the agency's policies and procedures.

¹ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ProviderComplianceTipsforNebulizersandRelatedDrugs-ICN909469.pdf>

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services instruct the durable medical equipment Medicare administrative contractors to notify the 22 suppliers associated with the 39 claim lines with potential overpayments of \$36,825 so that those suppliers can exercise reasonable diligence to investigate and return any identified overpayments, in accordance with the 60-day rule, and identify and track any returned overpayments as having been made in accordance with this recommendation.

CMS Response

CMS concurs with this recommendation. CMS will instruct its durable medical equipment Medicare Administrative Contractors to notify the identified suppliers of OIG's audit and the potential overpayment and track any returned overpayments made in accordance with this recommendation and the 60-day rule.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services work with the durable medical equipment Medicare administrative contractors to expand their reviews of suppliers' claims to include additional inhalation drugs (e.g., those with the highest reimbursement rates).

CMS Response

CMS concurs with this recommendation. CMS will direct its Medicare contractors to consider expanding their reviews of suppliers' claims to include additional inhalation drugs, such as those with the highest payment rates.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services work with the durable medical equipment Medicare administrative contractors to provide additional training to suppliers on Medicare documentation requirements for inhalation drugs.

CMS Response

CMS concurs with this recommendation. As stated above, CMS published and marketed a fact sheet of provider compliance tips for nebulizers and related drugs in April 2019. CMS will continue to educate suppliers on properly billing for inhalation drugs, including the documentation requirements for inhalation drugs.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services work with the durable medical equipment Medicare administrative contractors to identify suppliers that consistently bill for inhalation drugs that do not comply with Medicare documentation requirements, perform reviews of those suppliers, collect the amount overpaid for unallowable claims, and educate them on Medicare requirements for inhalation drugs.

CMS Response

CMS concurs with this recommendation. CMS will work with its Medicare contractors to identify suppliers that consistently bill for inhalation drugs that do not comply with Medicare documentation requirements and instruct them to perform reviews of those suppliers and collect any identified overpayments consistent with relevant law and the agency's policies and procedures, as well as provide education regarding the Medicare requirements as appropriate.