Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

LIBERTY MEDICAL, LLC, RECEIVED UNALLOWABLE MEDICARE PAYMENTS FOR INHALATION DRUGS

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

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Office of Inspector General

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Report in Brief
Date: August 2018
Report No. A-09-17-03019

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

Liberty Medical, LLC, Received Unallowable Medicare Payments for Inhalation Drugs

Why OIG Did This Review

For calendar years 2015 and 2016 (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 payments. After analyzing Medicare claim data, we selected three suppliers for review. This report covers one of those suppliers, Liberty Medical, LLC (Liberty), which was among the top 20 suppliers that received the most in Medicare payments during our audit period.

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

How OIG Did This Review

Our review covered 30,861 claim lines for inhalation drugs provided during our audit period, for which Liberty received Medicare payments of $6.6 million. We reviewed a stratified random sample of 100 of these claim lines. For the sampled items, Liberty provided us with supporting documentation, which we reviewed to determine whether the inhalation drugs were properly billed. We did not determine whether the drugs were medically necessary.

What OIG Found

Liberty did not always comply with Medicare requirements when billing for inhalation drugs. Of the 100 sampled claim lines, 94 complied with the requirements; however, the remaining 6 claim lines did not comply with the requirements. Specifically, Liberty did not provide us with medical records for four claim lines and did not have adequate proof-of-delivery documentation for two claim lines. As a result, Liberty received $2,408 in unallowable Medicare payments.

On the basis of our sample results, we estimated that Liberty received at least $47,526 in unallowable Medicare payments for inhalation drugs. These overpayments occurred because Liberty's policies and procedures and its order-processing system were not adequate to ensure that it met Medicare requirements for billing inhalation drugs.

What OIG Recommends and Liberty Comments

We recommend that Liberty (1) refund to the Medicare contractors $47,526 in estimated overpayments for inhalation drugs; (2) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; (3) strengthen its policies and procedures to ensure that it can provide medical records for inhalation drugs when requested; and (4) improve its order-processing system to maintain adequate proof-of-delivery documentation.

Liberty disagreed with our findings and recommendations. For the four sampled claim lines for which it did not provide medical records, Liberty stated that the documentation provided was sufficient to establish medical necessity. In addition, Liberty provided additional proof-of-delivery documentation for six of the eight sampled claim lines we disallowed in our draft report. Although Liberty disagreed with our recommendations, it provided information on actions that it had taken or planned to take to address our second, third, and fourth recommendations.

We did not revise our first finding because the information contained directly in the medical record is the source required to justify payment and must be made available upon request. After reviewing the additional documentation that Liberty provided, we revised our second finding to reflect that there was inadequate proof-of-delivery documentation for two sampled claim lines and adjusted the refund amount in our first recommendation.

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INTRODUCTION

WHY WE DID THIS REVIEW

For calendar years (CYs) 2015 and 2016 (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 payments. After analyzing Medicare claim data, we selected three suppliers for review. This report covers one of those suppliers, Liberty Medical, LLC (Liberty), which was among the top 20 suppliers that received the most in Medicare payments during our audit period.[2]

OBJECTIVE

Our objective was to determine whether Liberty 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 (DME) or to assure its proper functioning.[4] To be paid by Medicare, a service or an item must be reasonable

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

[2] We already issued reports covering our reviews of the other two suppliers: *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.

[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.

and 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 reasonable and necessary. For each inhalation drug, the LCDs also provide the maximum dosage (in milligrams per month) that is reasonable and necessary.[9]

[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, 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.

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, 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 and remains reasonable and necessary for treatment of the beneficiary's condition.[10]

Medicare Requirements for Suppliers To Identify and Return Overpayments

The Office of Inspector General (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).[11]

Liberty Medical, LLC

Liberty is a subsidiary of Liberty Medical Holdings, LLC, which is located in Port St. Lucie, Florida. Liberty is a home delivery supplier of medications, DME, and supplies. The Medicare claim data showed that Liberty billed for the following inhalation drugs: acetylcysteine, albuterol, arformoterol, budesonide, cromolyn sodium, dornase alfa, formoterol, and ipratropium bromide, which are used to treat lung disease. During our audit period, Liberty submitted claims to all four DME MACs: CGS Administrators, LLC; Noridian Healthcare Solutions, LLC; National Heritage Insurance Corp.; and National Government Services, Inc.

HOW WE CONDUCTED THIS REVIEW

Liberty received Medicare Part B payments of $6,724,613 for inhalation drugs provided to Medicare beneficiaries during our audit period, representing 36,143 claim lines. (Each claim line represented a supply of an inhalation drug.) After we excluded from our review claim lines with payment amounts of $10 or less and certain claim lines reviewed by the recovery audit contractors (RACs)[12] and other review entities (such as the DME MACs), our review covered

[10] CMS's *Medicare Program Integrity Manual* (the 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.

[11] 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).

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

30,861 claim lines, totaling $6,604,858. We reviewed a stratified random sample of 100 of these claim lines, for which Medicare paid $46,236.

Liberty provided us with supporting documentation for the sampled claim lines. The documentation included medical records that Liberty obtained from the ordering physicians. We reviewed the documentation to determine whether the inhalation drugs were properly billed; however, the documentation was not reviewed by a medical reviewer to determine whether the drugs were medically necessary.[13]

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 B describes our statistical sampling methodology, and Appendix C contains our sample results and estimates.

FINDINGS

Liberty did not always comply with Medicare requirements when billing for inhalation drugs. Of the 100 sampled claim lines, 94 complied with the requirements; however, the remaining 6 claim lines did not comply with the requirements. Specifically, Liberty did not provide us with medical records for four claim lines and did not have adequate proof-of-delivery documentation for two claim lines. As a result, Liberty received $2,408 in unallowable Medicare payments.

On the basis of our sample results, we estimated that Liberty received at least $47,526 in unallowable Medicare payments for inhalation drugs. These overpayments occurred because Liberty's policies and procedures and its order-processing system were not adequate to ensure that it met Medicare requirements for billing inhalation drugs.

LIBERTY DID NOT COMPLY WITH MEDICARE REQUIREMENTS WHEN BILLING FOR INHALATION DRUGS

Medical Records Were Not Provided To Justify Payment for Inhalation Drugs

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

[13] A qualified medical review contractor reviewed the documentation for our reviews of the other two suppliers: Accredo Health Group and Lincare Pharmacy Services.

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. Neither a physician's order nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. The Manual also states 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. 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, Pub. No. 100-08, chapter 5, §§ 5.7 and 5.8).

The LCDs state that information contained directly in the medical record is the source required to justify payment and that the medical record must be available upon request. Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g., letters of medical necessity) are not considered part of the medical record for Medicare payment purposes. A prescription is not considered part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record (LCDs L11499, L27226, L5007, L11488, and L33370).[14]

For 4 of the 100 sampled claim lines, Liberty did not provide us with medical records. For each of these claim lines, Liberty provided a signed, detailed written order from the ordering physician and stated that the order demonstrated the physician's "indication that the beneficiary requires the items ordered from Liberty."

For example, Medicare paid Liberty $760 for providing budesonide, an inhalation drug used to prevent asthma attacks, on November 9, 2015, to a 71-year-old beneficiary. For this sampled claim line, Liberty provided us with a detailed written order signed by the ordering physician certifying that the beneficiary's medical records supported the medical need for the inhalation drug prescribed. However, Liberty did not provide a copy of the beneficiary's medical records.

Liberty did not have policies in place to ensure that it was able to provide medical records for items billed to Medicare when requested. Liberty stated that its practice was to request medical records when processing new orders. However, Liberty did not have procedures in place to verify that it received the medical records it had requested. Effective November 2017, Liberty implemented a policy to verify that it had received medical records from the physician

[14] Effective January 1, 2017, the general documentation requirements for DME were included in CMS's local coverage article A55426, *Standard Documentation Requirements for All Claims Submitted to DME MACs*.

before billing Medicare.[15] Because the change occurred after our audit period, we did not verify that this policy was implemented effectively.

Proof-of-Delivery Documentation Was Not Adequate

Suppliers of DMEPOS items, such as inhalation drugs, are required to maintain proof-of-delivery documentation in their files, and this documentation must be available on request (the Manual, chapter 5, § 5.8).

The LCDs state 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 DMEPOS supplier to the beneficiary. The documentation must also include the date on which the item was delivered (LCDs L11499, L27226, L5007, L11488, and L33370).[16] The Manual and the LCDs state that claims for items that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be recouped.

For 2 of the 100 sampled claim lines, Liberty did not have adequate proof-of-delivery documentation. For each of these claim lines, Liberty provided us with a printout from its computerized order-processing system showing the shipping date; however, neither of these printouts contained a complete record that tracked the item from Liberty to the beneficiary or showed the date on which the inhalation drug was delivered.

For example, Medicare paid Liberty $562 for providing budesonide on December 6, 2016, to a 69-year-old beneficiary. For this sampled claim line, Liberty provided us with a printout of its order-processing system's shipment history screen, which showed that Liberty shipped the budesonide on December 6, 2016. However, this printout did not contain the delivery details showing the complete tracking of the inhalation drug from Liberty to the beneficiary. In addition, the printout did not contain the date on which the drug was delivered.

Liberty stated that its computerized order-processing system automatically connected to the shipping carriers' systems and uploaded the tracking information for each shipment of inhalation drugs. However, Liberty stated that because of intermittent disconnections between the systems, delivery details may not always have been uploaded to its system. Consequently, it could not provide the proof-of-delivery documentation for the two sampled claim lines.

LIBERTY RECEIVED UNALLOWABLE MEDICARE PAYMENTS

Liberty received $2,408 in unallowable Medicare payments for the six sampled claim lines that did not meet Medicare requirements. On the basis of our sample results, we estimated that at

[15] Although Liberty's policy was effective in November 2017, Liberty stated that in June 2017 it implemented the practice of verifying that it had received medical records from the physician before billing Medicare.

[16] See footnote 14.

least $47,526 of the $6,604,858 paid to Liberty for inhalation drugs was unallowable for Medicare reimbursement.

LIBERTY'S POLICIES AND PROCEDURES AND ITS ORDER-PROCESSING SYSTEM WERE NOT ADEQUATE TO ENSURE THAT IT MET MEDICARE REQUIREMENTS

Liberty's policies and procedures and its order-processing system were not adequate to ensure that it met Medicare requirements for billing inhalation drugs. Specifically, Liberty's policies and procedures were not adequate to ensure that Liberty was able to provide medical records for inhalation drugs when requested. In addition, Liberty's order-processing system did not maintain proof-of-delivery documentation for every shipment of inhalation drugs.

RECOMMENDATIONS

We recommend that Liberty:

- refund to the DME MACs $47,526 in estimated overpayments for inhalation drugs (of which $2,408 was overpayments identified in our sample);[17]

- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation;

- strengthen its policies and procedures to ensure that it can provide medical records for inhalation drugs when requested; and

- improve its order-processing system to maintain adequate proof-of-delivery documentation.

[17] OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to Department of Health and Human Services action officials. Action officials at CMS, acting through a MAC or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures. Although the statute allows overpayments to be collected within 5 years of the date a claim is paid, CMS policies specify that a claim must be re-opened within 4 years. If CMS does not re-open one or more sampled claims within this 4-year period, the estimated overpayment will be adjusted accordingly. If a disallowance is taken, a provider has the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a decision by the Office of Medicare Hearings and Appeals. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

LIBERTY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Liberty disagreed with our findings and recommendations. Although Liberty disagreed with our recommendations, it provided information on actions that it had taken or planned to take to address our second, third, and fourth recommendations. Liberty's comments are included as Appendix D. We did not include Liberty's attachments, which contained a copy of the draft report and additional proof-of-delivery documentation that Liberty provided, because they were too voluminous and contained personally identifiable information.

LIBERTY COMMENTS

Liberty's comments on our findings were as follows:

- Regarding our finding that Liberty did not provide medical records for four sampled claim lines, Liberty stated that the documentation provided was sufficient to establish that the claims were "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Liberty stated that it provided detailed written orders that clearly demonstrated the prescribers' indication that the beneficiaries required the items to be ordered from Liberty.

- Regarding our finding that Liberty did not have adequate proof-of-delivery documentation for eight sampled claim lines,[18] Liberty stated that it had provided proof-of-delivery documentation for "all seven [claim lines] identified by OIG in its Preliminary Findings."[19] Liberty stated that for one sampled claim line, it had clearly provided to us sufficient proof-of-delivery documentation. Liberty also stated that for an additional six sampled claim lines, it initially was not able to include proof-of-delivery documentation because of apparent errors that occurred with the systems of the common carriers. Liberty stated, however, that with additional diligence, it was able to obtain proof-of-delivery for these sampled claim lines, which it provided to us.

- Regarding our statistical estimate of unallowable payments, Liberty stated that it does not believe that there are sufficient grounds for OIG to recommend denial of any of the sampled claim lines. With respect to the four sampled claim lines for which Liberty did not provide medical records, Liberty stated: "A four percent error rate (reflecting four out of 100 sampled claims) is inherently unreasonable to extrapolate, since the error rate is smaller than the confidence levels of the sample . . . ." With respect to the eight sampled claim lines for which Liberty did not have adequate proof-of-delivery documentation, Liberty stated that it has clearly provided the responsive information

[18] In our draft report, we found that Liberty did not have adequate proof-of-delivery documentation for eight sampled claim lines.

[19] On September 21, 2017, we provided Liberty a list of the eight sampled claim lines that were missing proof-of-delivery documentation (not seven as indicated in Liberty's response).

and, if OIG upholds its draft findings, "it can only be because Liberty was unable to timely furnish the responsive information." Liberty stated that "it would be completely inappropriate for OIG to recommend extrapolation of those eight [claim lines] against any claims universe." In its conclusion at the end of its comments, Liberty stated that "any findings made by OIG in its final report are isolated and statistically minimal, therefore, not reasonable to extrapolation."

Liberty's comments on our recommendations were as follows:

- Regarding our first recommendation, Liberty stated that it strongly objected to refunding $240,715[20] to the DME MAC for the reasons stated in its comments on our findings.

- Regarding our second recommendation, Liberty strongly disagreed that any overpayments had been made and, therefore, it did not believe additional similar overpayments would be identified in accordance with the 60-day rule. Liberty stated that it maintains a compliance program and policies and procedures to ensure that any overpayments are repaid in accordance with the 60-day rule.

- Regarding our third recommendation,[21] Liberty disagreed with the recommendation but stated that it has "implemented policies and procedures that go above and beyond the Medicare requirements to acquire and maintain medical records for inhalation drugs upon request."

- Regarding our fourth recommendation,[22] although Liberty disagreed that improvement to its order-processing system was necessary, it stated that it has developed and implemented reporting that identifies any instance in which (1) proof-of-delivery information from a common carrier is missing from its system or (2) a package containing medications billed to Medicare Part B was not delivered. In these instances, Liberty stated that it will contact the common carrier to obtain the missing information or the beneficiary to determine whether the package was delivered and to obtain a written attestation from the beneficiary.

OFFICE OF INSPECTOR GENERAL RESPONSE

Regarding Liberty's comments on our finding related to medical records, we did not revise our finding or the part of our recommended refund amount related to this finding because Medicare guidance states that a detailed written order is not considered part of the medical

[20] In our draft report, this was our recommended refund amount.

[21] In our draft report, this was our fourth recommendation.

[22] In our draft report, this was our third recommendation.

record; rather, the information contained directly in the medical record is the source required to justify payment and must be made available upon request. Further, if the medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved.[23]

Regarding Liberty's comments on our finding related to proof-of-delivery documentation, Liberty indicated that it had provided sufficient documentation for one sampled claim line. However, our audit did not identify this claim line as unallowable (i.e., it was not listed in the summary of findings that we provided to Liberty on September 21, 2017). After reviewing the proof-of-delivery documentation that Liberty provided for six sampled claim lines, we revised our finding to reflect that these claim lines were allowable and revised the estimated overpayment and the refund amount in our first recommendation. Liberty did not provide proof-of-delivery documentation for the remaining two sampled claim lines that we identified in the summary of findings that we provided to Liberty; therefore, those two sampled claim lines remain unallowable.

Regarding Liberty's comments on our statistical estimate, we disallowed claim lines because they did not meet Medicare requirements, not because Liberty was unable to provide the documentation in a timely manner. Moreover, the confidence level represents the expected percent of the time that the confidence interval will contain the actual overpayment amount. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. This approach results in an estimate that is lower than the actual overpayment amount 95 percent of the time, and thus it generally favors the provider. In addition, the requirement that a determination of a sustained or high level of payment error must be made before extrapolation applies only to Medicare contractors. (See the Act § 1893(f)(3) and the Manual, Pub. No. 100-08, chapter 8, § 8.4.1.4.) Further, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.[24]

We maintain that our findings and recommendations, as revised, are valid.

[23] The Manual, Pub. No. 100-08, chapter 5, §§ 5.7 and 5.8; LCDs L11499, L27226, L5007, L11488, and L33370.

[24] *See Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), *adopted by* 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Liberty received Medicare Part B payments of $6,724,613 for inhalation drugs provided to Medicare beneficiaries in CYs 2015 and 2016, representing 36,143 claim lines. (Each claim line represented a supply of an inhalation drug.) We excluded from our review 4,929 claim lines, totaling $33,361, with payment amounts of $10 or less. We also excluded from our review 353 claim lines, totaling $86,394, reviewed by the RACs and other review entities.[25] Our review covered the remaining 30,861 claim lines, totaling $6,604,858. We reviewed a stratified random sample of 100 of these claim lines, for which Medicare paid $46,236.

Liberty provided us with supporting documentation for the sampled claim lines. The documentation included medical records that Liberty obtained from the ordering physicians. We reviewed the documentation to determine whether the inhalation drugs were properly billed; however, the documentation was not reviewed by a medical reviewer to determine whether the drugs were medically necessary.

We did not review Liberty'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 May to September 2017, which included fieldwork performed at Liberty's office located in Port St. Lucie, Florida.

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

[25] 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, OIG, and law enforcement entities.

- obtained from CMS's National Claims History (NCH) file the paid Medicare Part B claims for inhalation drugs that Liberty provided to Medicare beneficiaries for our audit period;[26]

- created a sampling frame of 30,861 claim lines for inhalation drugs and randomly selected a sample of 100 claim lines (Appendix B);

- 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 Liberty 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 Liberty (Appendix C); and

- shared the results of our review with Liberty 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.

[26] 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.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The target population consisted of Medicare Part B claim lines for inhalation drugs that Liberty provided in CYs 2015 and 2016, for which Liberty received Medicare payments.

SAMPLING FRAME

We obtained claim data from CMS's NCH file, representing 36,143 claim lines totaling $6,724,613. We excluded from our review 4,929 claim lines, totaling $33,361, with payment amounts of $10 or less. We also excluded from our review 353 claim lines, totaling $86,394, reviewed by the RACs and other review entities. As a result, the sampling frame consisted of 30,861 claim lines for inhalation drugs provided in CYs 2015 and 2016, for which Liberty received Medicare payments of $6,604,858.

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 two strata (Table 1).

Table 1: Strata in Sampling Frame

Stratum	Description	No. of Claim Lines in Stratum	Total Payments for Claim Lines in Stratum
1	Includes payment amounts greater than $10 and less than or equal to $400	25,107	$1,861,333
2	Includes payment amounts greater than $400	5,754	4,743,525
Total		**30,861**	**$6,604,858**

SAMPLE SIZE

We selected a total of 100 claim lines, consisting of 50 claim lines from each stratum.

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 25,107 and the claim lines in stratum 2 from 1 to 5,754. After generating 50 random numbers for each stratum, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the amount of unallowable payments for inhalation drugs. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner will be less than the actual overpayment total at least 95 percent of the time.

APPENDIX C: 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	25,107	$1,861,333	50	$4,449	3	$75
2	5,754	4,743,525	50	41,787	3	2,333
Total	**30,861**	**$6,604,858**	**100**	**$46,236**	**6**	**$2,408**

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

Point estimate	$306,145
Lower limit	47,526
Upper limit	564,764

APPENDIX D: LIBERTY COMMENTS

LIBERTY MEDICAL, LLC FIRST REVISED RESPONSE TO OIG DRAFT REPORT
Report Number A-09-17-03019

Liberty Medical, LLC d/b/a Liberty Medical Supply ("Liberty") appreciates the opportunity to provide this response to the Office of Inspector General for the Department of Health and Human Services (the "OIG") draft report entitled *Liberty Medical, LLC, Received Unallowable Medicare Payments for Inhalation Drugs* (the "Draft Report"). The Draft Report is available as Attachment 1.

Liberty strongly objects to both the findings and recommendations of the Draft Report. Specifically, the Draft Report finds that, of a sample of 100 items furnished by Liberty, 12 items did not have adequate or sufficient documentation to meet Medicare billing requirements. From this draft finding, OIG calculated $4,344 in unallowable Medicare payments for the 12 items, which were then extrapolated to suggest a finding that Liberty received at least $240,715 in unallowable Medicare payments for inhalation drugs. Liberty disagrees with these findings and recommendations, and submits this timely response by the OIG-issued deadline of May 3, 2018 to contest such findings.

Liberty is a nationally accredited pharmacy that furnishes medically necessary medications for patients with certain chronic conditions. Liberty strives to operate its business and furnish Medicare-covered items in compliance with all Federal, State, and local laws and regulations, including Medicare billing requirements. Compliance with all regulatory requirements and customer satisfaction are of the utmost importance to Liberty, and Liberty has a robust compliance program in place for this purpose. As always, Liberty is committed to working with OIG to address and, if necessary, correct any issues identified.

1. **Liberty Maintains Appropriate Proof of Delivery Documentation to Support Its Claims for Payment for Inhalation Drugs**

Liberty disagrees with OIG's Preliminary Findings document, which alleged that eight of the sample claims do not have sufficient documentation because they do not contain proof of delivery information required by the LCD, L33370, and the Medicare Program Integrity Manual.

As a preliminary matter, Liberty notes that the Draft Report states that Liberty lacked proof of delivery documentation on *eight* claims in the sample; however, only seven claims were identified in the Preliminary Findings - S1-07, S1-11, S1-14, S1-31, S2-07, S2-10, and S2-30. Based on the data provided by OIG, Liberty believes that there were in fact only the identified seven claims subject to this allegation and that the statement relating to an undisclosed eighth claim was an error in the OIG Draft Report. We, therefore, focus our response on only those seven claims that were identified with specificity. Section 5.8(B) of the Medicare Program Integrity Manual requires suppliers to "maintain proof of delivery documentation in their files." The LCD also states that "DMEPOS suppliers are required to maintain POD documentation in their files" and the proof of delivery "must be made available…upon request." Liberty adequately maintains this information. It is the policy of Liberty

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to comply with all Medicare billing requirements, including the proof of delivery requirement, and Liberty has policies and procedure in place to prevent any deviation from these requirements.

Liberty delivers covered items to Medicare beneficiaries via mail order using widely recognized common carriers to provide shipping services, including the United States Postal Service and United Parcel Service. Medicare Policy Article A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs (Revised 12/21/2017) - suggests that for suppliers reliant on delivery via shipping or delivery service directly to a beneficiary, the proof of delivery should include: the beneficiary's name; delivery address; delivery service's package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records; sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description); quantity delivered; date delivered; and evidence of delivery.

Specifically, for sample item S1-31, Liberty clearly provided sufficient proof of delivery documentation. In fact, the Proof of Delivery Shipment History Screen shows, within the beneficiary's system record, the delivery address, the order number (which links to the detailed description of the items delivered and quantity delivered), the tracking number from the shipping carrier, and the delivery details taken from the shipping carrier's website at the time of delivery (which include date delivered and evidence of delivery, showing that the order was "DELIVERED FRONT DOOR/PORCH") (*See* page 10 of S1-31 packet). This documentation emphatically establishes a "complete record tracking the item(s) from the DMEPOS supplier to the beneficiary" in accordance with the Policy Article.

For sample items S1-07, S1-11, S1-14, S2-07, S2-10, and S2-30, Liberty was not able to include the proof of delivery documentation in response to the Preliminary Findings due to apparent errors that occurred with the systems of the common carriers; however, because these items were in fact appropriately delivered to the beneficiaries in question, with additional diligence, Liberty was able to obtain proof of delivery for all these claims and submits such proofs of delivery as Attachment 2. Liberty submits that, with respect to the items shipped via the United States Postal Service, no additional proof should even have been required beyond demonstrating that the items were placed in the custody of the common carrier. The United States Postal Service is itself a government agency and it assures delivery one hundred percent of the time. For OIG to challenge that items placed in the custody of the United States Postal Service were somehow not delivered to the stated recipient is an unfair and inappropriate indictment of our national postal system, which should inherently be trusted. That said, using back-up systems and mining for data that is ordinarily not pulled for its standard efforts to establish proof of delivery, Liberty nonetheless has been able to locate copies or print-outs of all materials that are needed to comport with the requirements of the Policy Article. These attached documents unequivocally demonstrate compliance with respect to proof of delivery for sample items S1-07, S1-11, S1-14, S2-07, S2-10, and S2-30. The carrier issued tracking number recorded in the patient record as well as the date of service (the date the order was dispensed and transferred to the carrier for delivery) matches the tracking number (Label ID DESC) and the "ACCEPT OR PICKUP "date in the Postal Service Document as does the zip code and city and state match the demographics in the patient account.

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Because Liberty is able to produce, and has now provided, proof of delivery documentation for all seven claims identified by OIG in its Preliminary Findings, Liberty disagrees with the Draft Report allegation that our proof of delivery documentation was not adequate. These findings must be overturned and the Draft Report must be revised.

2. The Medical Record Documentation Furnished by Liberty is Sufficient to Determine Coverage

Liberty also disagrees with OIG's Preliminary Findings document, which alleged that four of the 100 sampled items did not have sufficient documentation because they did not contain medical records. Specifically, OIG determined sample items S1-18, S1-37, S2-11, and S2-23 lacked medical record documentation. Liberty believes that the documentation furnished with respect to these four sample items is sufficient to establish that the claims were "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" 42 U.S.C. § 1395y(a), which is the sole statutory basis for coverage.

In arguing that these claims should not be covered, OIG instead points to "Section 1833(e) of the Social Security Act [which] precludes payment 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.'" OIG further relies on the LCD, which has no force of law or regulation to state that "[i]t is expected that the beneficiary's medical records will reflect the need for the care provided" and that such "documentation must be available upon request." Finally, OIG suggests that the LCD, L33370, requires that the beneficiary's medical records reflect the need for care.

It is the policy of Liberty to comply with all Medicare billing requirements, including the requirement to reflect medical necessity in the medical records, and Liberty has policies and procedure in place to prevent any deviation from these requirements. The documentation provided by Liberty in support of these four sample claims demonstrates that the items furnished to Medicare beneficiaries were reasonable and necessary because they were (1) furnished to a Medicare beneficiary who was clearly diagnosed with diabetes; (2) ordered by a licensed physician in specified quantities deemed necessary by the physician to address the beneficiary's specific condition; (3) confirmed to be needed by the beneficiary by telephone or written communication from the beneficiary received prior to furnishing the items; (4) furnished in the quantities ordered and confirmed by the beneficiary; and (5) supported by the medical record. While Liberty makes every attempt to obtain supporting medical records from prescribing physicians, it is sometimes unable to do so because the physician refuses to provide the records. Nonetheless, in prescribing the inhalation medications from Liberty, these physicians have certified to Liberty that they maintain supporting documentation. Further, Liberty is not a physician or licensed medical provider. Liberty is unable to second-guess the prescribing decisions of a treating physician and must rely on the records provided to it. Such records should be sufficient in these situations to meet the statutory requirement for reasonable and necessary. To the extent that there may be small variations in documentation or nomenclature between the supporting evidence of medical necessity furnished by Liberty and the LCD or program guidance, the clear evidence of a beneficiary's medical need and a physician's clinical decision to order must trump any technicalities of a guidance document. See Willowood of Great Barrington, Inc. v. Sebelius, 638 F. Supp. 2d 98, 106 (D. Mass. 2009) (citing 42 C.F.R. § 405.1062(a)); U.S. ex rel. Ryan v. Lederman, No. 04-CV-

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2483, 2014 WL 1910096, at *4 (E.D.N.Y. May 13, 2014) ("An LCD is not binding on a contractor in another area of the country or on an ALJ who decides cases at higher stages of the appeal process.").

Accordingly, we disagree that the records provided for samples S1-18, S1-37, S2-11, and S2-23 do not reflect the need for the care furnished by Liberty. To the contrary, the detailed written orders for these samples clearly demonstrate the prescriber's indication that the beneficiary requires the items ordered from Liberty. In addition, for samples S1-18, S1-37, and S2-23, the prescriber expressly certifies in the detailed written order that the prescriber's medical records support the medical need for the items prescribed. To the extent that OIG nonetheless determines that these four items were not reasonable and necessary, the documentation provided clearly shows that Liberty could not reasonably have known that the claims would be denied. Liberty reasonably relied in good faith on the prescribing physician's prescription and clinical decision-making, as well as the physician's own certification that he/she maintained sufficient supporting documentation. Therefore, the items must nonetheless be paid pursuant to the Medicare limitation of liability provisions set forth in 42 U.S.C. §§ 1395pp. Under the limitation of liability provisions, payment to a supplier must still be made in the case where it is ultimately determined that the items in question were not reasonable and necessary, but where the supplier of those items did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services. *See id.*

Accordingly, Liberty asserts that the claims for sample items S1-18, S1-37, S2-11, and S2-23 should be covered as reasonable and necessary based on the documentation available, or in the alternative, must be deemed covered based on the statutory limitation of liability provisions set forth in 42 U.S.C. §§ 1395pp.

3. Extrapolation of Denied Sample Claims Is Improper in This Review

As explained above, Liberty does not believe that there are sufficient grounds for OIG to recommend denial on any of the 100 claims included in the sample. Liberty expressly disputes OIG's findings with respect to all twelve claims cited as claims errors in the Draft Report. Even if OIG disagrees with our defenses set forth herein, we do not believe that any recommendation for an extrapolation of findings is appropriate in this matter.

Specifically, with respect to the eight claims identified as allegedly lacking proof of delivery information, Liberty has clearly provided the responsive information attached to this response. To the extent that OIG nonetheless upholds its draft findings, it can only be because Liberty was unable to timely furnish the responsive information and not because there is a finding that the information has not been furnished. In such case, it would be completely inappropriate for OIG to recommend extrapolation of those eight claims against any claims universe. Since Liberty has furnished documentation for the eight claims in question, it stands to reason that similar documentation can be provided for all other claims. Any attempt to extrapolate would simply apply a technical response error in the timing of the response to claims for which documentation was never requested. This would be an inherently unfair result and not supported by due process. Therefore, extrapolation cannot stand.

Further, if OIG nonetheless upholds its recommendations with regard to the four claims where additional supporting medical record documentation was unable to be obtained from the prescribing

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physicians, there would be only four total claims at issue that could be subject to extrapolation. OIG's own sampling methodology is based on a confidence level of plus or minus ten percent. A four percent error rate (reflecting four out of 100 sampled claims) is inherently unreasonable to extrapolate, since the error rate is smaller than the confidence levels of the sample in the first place. Simply put, there could be no reasonable confidence that a four percent error rate is representative across the universe of claims. The error rate is simply too small.

Accordingly, Liberty reserves the right to challenge any attempt to extrapolate the findings in the draft report, after considering the additional information furnished in conjunction with this response, based upon OIG's final recommendations in any final report.

4. Liberty's Response to OIG Recommendations

a. Refund

Liberty strongly objects to refunding to the DME MAC the amount of $240,715 for the reasons set forth above.

b. Additional Similar Overpayments

For the reasons set forth above, Liberty strongly disagrees that any overpayments have been made. Therefore, we do not believe "additional similar overpayments" would be identified. Liberty maintains a compliance program as well as policies and procedures to ensure that any identified overpayments are repaid in accordance with the 60-day rule.

c. Proof of Delivery

Liberty was able to obtain proof of delivery for all claims reviewed by OIG. Although the proof of delivery was not initially available at the time of audit, because the documentation was ultimately submitted, we disagree that any improvement to the order-processing system is necessary. Nonetheless, Liberty has developed and implemented reporting to identify any instance where (a) delivery information from a common carrier is missing in our system or (b) a package containing medications billed to Medicare Part B was not delivered. In scenario (a), Liberty will perform a systems check and contact the common carrier to secure the missing information. In scenario (b), Liberty will contact the beneficiary to determine if the package was delivered and to obtain a written attestation from the beneficiary. If the beneficiary has not received the items ordered, Liberty will ship a replacement order to the beneficiary.

d. Medical Records

Liberty disagrees with the recommendation that it should strengthen its policies and procedures to ensure that it can provide medical records for the reasons stated above. However, Liberty has implemented policies and procedures that go above and beyond the Medicare requirements to acquire and maintain medical records for inhalation drugs upon request.

Conclusion

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In conclusion, Liberty strongly disagrees with the draft findings in the OIG Draft Report. We are committed to working with OIG to ensure that any concerns with Liberty's inhalation drug documentation are fully addressed. We believe that all of our claims are for reasonable and necessary services and that our documentation adequately substantiates our assertions. We further believe that any findings made by OIG in its final report are isolated and statistically minimal, therefore, not reasonable to extrapolation. Should you have any questions or require additional information, please feel free to contact us at 772-398-5810 (desk) or 772-485-4632 (cell).

Sincerely,

Phillip Monaco, R.Ph.
Vice President of Operations and
Chief Pharmacist

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