

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ADVANCED DIABETES SUPPLY
SUBMITTED CLAIMS FOR
DIABETIC TESTING SUPPLIES WITHOUT
THE KL MODIFIER IN ACCORDANCE
WITH MEDICARE BILLING
REQUIREMENTS**

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EXECUTIVE SUMMARY

For calendar year 2011, Advanced Diabetes Supply submitted claims for diabetic testing supplies without the KL modifier in accordance with Medicare billing requirements.

WHY WE DID THIS REVIEW

We performed this review as part of a response to a request from the Senate Special Committee on Aging that we determine whether durable medical equipment suppliers correctly coded Medicare claims for diabetic testing supplies delivered by mail to beneficiaries. Medicare guidance requires suppliers to use the KL modifier on all claims for mail-order diabetic testing supplies, which are reimbursed at a lower amount than supplies provided at local supplier storefronts (walk-in supplier).

Advanced Diabetes Supply (ADS) is one of three suppliers that we selected for review. An analysis of Medicare claim data identified that ADS did not use the KL modifier on claims for diabetic testing supplies provided to beneficiaries who resided more than 30 miles from ADS's business location. Presumably, these claims were for non-mail-order supplies because they did not have the KL modifier, leading us to question how the supplies were delivered to distant beneficiaries if they were not mailed. This report covers ADS, located in Carlsbad, California. Additional reports will cover the two other suppliers that we reviewed.

Our objective was to determine whether ADS submitted claims for diabetic testing supplies without the KL modifier in accordance with Medicare billing requirements.

BACKGROUND

Beneficiaries may obtain diabetic testing supplies from a walk-in supplier or a mail-order supplier, which delivers the supplies through a common carrier (e.g., the U.S. Postal Service or FedEx). However, supplies delivered to a beneficiary without use of a common carrier, such as supplies delivered to a beneficiary's home or to a warehouse store in a company-owned vehicle, are not considered mail-order supplies. The Centers for Medicare & Medicaid Services' (CMS) *Medicare Claims Processing Manual* requires that suppliers use the KL modifier on all claims for mail-order diabetic testing supplies. On November 29, 2010, CMS finalized a rule to revise the definition of "mail order item" in Federal regulations to include "any item ... shipped or delivered to a beneficiary's home, regardless of the method of delivery." The target implementation date for the revised definition is July 1, 2013.

WHAT WE FOUND

For calendar year 2011, ADS submitted claims for diabetic testing supplies without the KL modifier in accordance with Medicare billing requirements. Of 100 sampled line items, 99 were properly submitted without the KL modifier because ADS used company-owned vehicles to deliver diabetic testing supplies to Medicare beneficiaries at their homes (97 line items) or to warehouse stores for beneficiaries to pick up (2 line items). Under Medicare requirements in effect until CMS implements the revised definition of a mail-order item, supplies delivered by

company-owned vehicles are not considered mail-order items. Therefore, claims for these supplies do not require use of the KL modifier. The remaining sampled line item should have been submitted with the KL modifier because ADS had delivered the diabetic testing supplies by mail. ADS discovered this error during our audit and resubmitted the claim with the KL modifier. Consequently, this report has no recommendations.

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INTRODUCTION

WHY WE DID THIS REVIEW

We performed this review as part of a response to a request from the Senate Special Committee on Aging that we determine whether durable medical equipment suppliers correctly coded Medicare claims for diabetic testing supplies delivered by mail to beneficiaries. Medicare guidance requires suppliers to use the KL modifier on all claims for mail-order diabetic testing supplies, which are reimbursed at a lower amount than supplies provided at local supplier storefronts (walk-in supplier).

Advanced Diabetes Supply (ADS) is one of three suppliers that we selected for review. An analysis of Medicare claim data identified that ADS did not use the KL modifier on claims for diabetic testing supplies provided to beneficiaries who resided more than 30 miles from ADS's business location. Presumably, these claims were for non-mail-order supplies because they did not have the KL modifier, leading us to question how the supplies were delivered to distant beneficiaries if they were not mailed. This report covers ADS, located in Carlsbad, California. Additional reports will cover the two other suppliers that we reviewed.¹

OBJECTIVE

Our objective was to determine whether ADS submitted claims for diabetic testing supplies without the KL modifier in accordance with Medicare billing requirements.

BACKGROUND

Diabetic Testing Supplies

According to sections 1832(a)(1), 1861(s)(6), and 1861(n) of the Social Security Act, Medicare Part B covers durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). DMEPOS includes blood glucose monitors that physicians prescribe for diabetics, whether they are insulin-treated or non-insulin-treated. Part B also covers diabetic testing supplies, such as blood-testing strips (test strips), lancets, glucose control solutions, and spring-powered lancet devices for patients for whom the glucose monitor is covered.

To obtain a reading of the blood-glucose level, the patient uses a disposable sterile lancet to draw a drop of blood, places it on a test strip, and inserts the test strip into a home blood-glucose monitor. These monitors enable certain patients to better control their blood-sugar levels by frequently checking those levels and appropriately contacting a physician for advice and treatment.

¹ Reports A-09-11-02073 (issued in January 2013) and A-09-12-02053 (not yet issued) cover the two other suppliers.

Medicare Reimbursement of Diabetic Testing Supplies

Medicare's fee schedule for DMEPOS establishes the maximum amounts reimbursed to suppliers for diabetic testing supplies. The amount allowed by Medicare for payment for an individual item, such as a box of test strips, is equal to the lesser of the fee schedule amount or the amount charged by a supplier. Medicare pays the beneficiary or the supplier the amount allowed for payment, less the beneficiary share (i.e., deductibles and coinsurance). For a supplier to be reimbursed by Medicare for a claim for any quantity of diabetic testing supplies, the supplier is required to maintain supporting documentation, including but not limited to a physician order and proof of delivery.

Walk-In and Mail-Order Suppliers

Beneficiaries may obtain diabetic testing supplies from a walk-in supplier or a mail-order supplier. A walk-in supplier has a physical location where beneficiaries or their caregivers can pick up diabetic testing supplies. A mail-order supplier receives requests for supplies from beneficiaries remotely (e.g., by mail, phone, or email or through a Web site) and delivers the supplies through a common carrier (e.g., the U.S. Postal Service or FedEx). Supplies delivered to a beneficiary without use of a common carrier, such as supplies delivered to a beneficiary's home or to a warehouse store in a company-owned vehicle, are not considered mail-order supplies.²

Required Use of KL Modifier for Mail-Order Diabetic Testing Supplies

The Centers for Medicare & Medicaid Services' (CMS) *Medicare Claims Processing Manual* (Pub. No. 100-04) requires that suppliers use the KL modifier³ on all claims for diabetic testing supplies delivered by mail to Medicare beneficiaries (chapter 36, section 20.5.4.1). When the KL modifier was introduced on July 1, 2007, it was used only as an informational modifier to identify mail-order supplies, with no impact on the Medicare reimbursement amount. However, the Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275, required a 9.5-percent reduction in the fee schedule amounts for certain items, including diabetic testing supplies delivered by mail on or after January 1, 2009, in any geographical area (section 154(a)(2)). Effective January 1, 2009, the KL modifier became a pricing modifier, reducing the reimbursement for diabetic testing supplies delivered by mail.

² *Facts about the DMEPOS Competitive Bidding Program Round 1 Rebid: Mail-Order Diabetic Supplies*. Issued September 25, 2009, by Palmetto GBA, Competitive Bidding Implementation Contractor.

³ A modifier is either alphanumeric or two letters reported with a Healthcare Common Procedure Coding System (HCPCS) code and is designed to give Medicare and commercial payers additional information needed to process a claim. (HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.) Medicare requires use of the KL modifier for only the following mail-order diabetic testing supplies: test strips, glucose control solutions, lancet devices, lancets, and replacement batteries for blood glucose monitors.

Change in Federal Definition of “Mail-Order Item”

On July 13, 2010, CMS issued a notice of proposed rulemaking in the Federal Register to revise the definition of “mail order item.” The proposed rule states that CMS “discovered that suppliers ... tried to adopt certain approaches to circumvent the mail order definition. ... For example, some mail order suppliers considered purchasing a fleet of cars to deliver [diabetic testing supplies] to the beneficiary’s home so as not to be considered a mail order supplier” (75 Fed. Reg. 40040, 40214). These suppliers would be able to increase their level of reimbursement because they would be paid the same amount as walk-in suppliers.

CMS finalized the rule on November 29, 2010, to include the following definition of a mail-order item at 42 CFR § 414.402: “ ... any item (for example, diabetic testing supplies) shipped or delivered to the beneficiary’s home, regardless of the method of delivery” (75 Fed. Reg. 73170, 73623). This definition will be effective when CMS implements the national mail-order competition of the DMEPOS Competitive Bidding Program (competitive bidding program) for diabetic testing supplies, whose target implementation date is July 1, 2013.

Competitive Bidding Program for Mail-Order Diabetic Testing Supplies

On January 1, 2011, CMS launched the first phase of the competitive bidding program, in which DMEPOS suppliers competed to become Medicare-contracted suppliers by submitting bids to furnish certain items in competitive bidding areas (CBA).⁴ CMS awarded contracts to some suppliers to provide certain DMEPOS items in CBAs. Beneficiaries who permanently resided in a CBA could choose to obtain diabetic testing supplies from either a Medicare-contracted mail-order supplier or a walk-in supplier. Medicare does not cover mail-order diabetic testing supplies delivered by noncontracted suppliers to Medicare beneficiaries residing in a CBA.

CMS plans to implement the second phase and the national mail-order competition of the competitive bidding program at the same time (July 1, 2013). The national mail-order competition includes only mail-order diabetic testing supplies and will not be limited to certain CBAs. For this competition, CMS will award supplier contracts for delivery of diabetic testing supplies across the Nation to beneficiaries who elect to have these supplies delivered to them. Medicare will reimburse only contracted suppliers for mail-order diabetic testing supplies.

Advanced Diabetes Supply

ADS, a division of North Coast Medical Supply Inc., is a DMEPOS supplier that specializes in the sale of diabetes equipment and supplies. ADS is based in Carlsbad, California, and delivers diabetic testing supplies to customers nationwide. ADS is not a contracted supplier for the first phase of the competitive bidding program.

ADS mails diabetic testing supplies to customers who do not reside in a CBA and uses company-owned vehicles to deliver these supplies to customers who reside in the Riverside CBA

⁴ CBAs are defined by specific zip codes related to Metropolitan Statistical Areas, which include major cities and the surrounding suburbs.

in California.⁵ ADS's home delivery program was established in December 2010 to prepare for home delivery services beginning in January 2011, when the first phase of the competitive bidding program was implemented.

In September 2009, ADS entered into a contract with a membership warehouse club to deliver diabetic testing supplies to its stores for pickup by customers. ADS pays a fixed fee to the membership warehouse club for its general and administrative expenses related to providing ADS's diabetic testing supplies to customers.

HOW WE CONDUCTED THIS REVIEW

For calendar year (CY) 2011, ADS received Medicare Part B payments of \$635,440 for 11,292 line items without the KL modifier for test strips, glucose control solutions, lancet devices, and lancets provided to Medicare beneficiaries. A line item represented an individual type of diabetic testing supply included on a claim. We reviewed a random sample of 100 of these line items; 98 of these line items were for beneficiaries residing in a CBA.

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 contains the details of our audit scope and methodology. Appendix B contains a list of related Office of Inspector General reports on Medicare claims for diabetic testing supplies.

RESULTS OF REVIEW

For CY 2011, ADS submitted claims for diabetic testing supplies without the KL modifier in accordance with Medicare billing requirements. Of 100 sampled line items, 99 were properly submitted without the KL modifier because ADS used company-owned vehicles to deliver diabetic testing supplies to Medicare beneficiaries at their homes (97 line items) or to warehouse stores for beneficiaries to pick up (2 line items). Under Medicare requirements in effect until CMS implements the revised definition of a mail-order item, targeted for July 2013, supplies delivered by company-owned vehicles are not considered mail-order items. Therefore, claims for these supplies do not require use of the KL modifier. The remaining sampled line item should have been submitted with the KL modifier because ADS had delivered the diabetic testing supplies by mail. ADS discovered this error during our audit and resubmitted the claim with the KL modifier. Consequently, this report has no recommendations.

⁵ The Riverside (Riverside–San Bernardino–Ontario, California) CBA is located in southern California.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

For CY 2011, ADS received Medicare Part B payments of \$635,440 for 11,292 line items without the KL modifier for test strips, glucose control solutions, lancet devices, and lancets provided to Medicare beneficiaries. A line item represented an individual type of diabetic testing supply included on a claim. We reviewed a random sample of 100 of these line items; 98 of these line items were for beneficiaries residing in a CBA. We limited our review of the sampled line items to determining ADS's compliance with Medicare billing requirements for use of the KL modifier. We did not review compliance with other requirements, such as presence of a physician order.

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

We conducted our audit from March to November 2012 and performed fieldwork at ADS's office in Carlsbad, California.

METHODOLOGY

To accomplish our audit objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed ADS's policies and procedures for (1) receiving and processing orders for diabetic testing supplies, (2) maintaining supporting documentation, and (3) processing Medicare claims;
- interviewed ADS officials to obtain an understanding of ADS's procedures for (1) receiving and processing orders for diabetic testing supplies, (2) maintaining supporting documentation, (3) ensuring that the KL modifier was used on Medicare claims for mail-order supplies, and (4) processing Medicare claims;
- analyzed CY 2011 Medicare paid claim data to identify line items that ADS submitted without the KL modifier for test strips, glucose control solutions, lancet devices, and lancets;
- created a sampling frame of 11,292 line items for test strips, glucose control solutions, lancet devices, and lancets without the KL modifier and randomly selected a sample of 100 line items;
- obtained supporting documentation from ADS for each sampled line item and reviewed it to determine whether ADS should have used the KL modifier when it submitted claims for diabetic testing supplies delivered by mail; and

- shared the results of our review with ADS.

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 B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

| Report Title | Report Number | Date Issued |
|---|--|--------------------|
| <i>Neighborhood Diabetes, Inc., Submitted Claims for Diabetic Testing Supplies Without the KL Modifier in Accordance With Medicare Billing Requirements</i> | <u>A-09-11-02073</u> | 01/16/13 |
| <i>Supplier Billing for Diabetes Test Strips and Inappropriate Supplier Activities in Competitive Bidding Areas</i> | <u>OEI-04-11-00760</u> | 11/07/12 |
| <i>Medicare Contractors Lacked Controls To Prevent Millions in Improper Payments for High Utilization Claims for Home Blood-Glucose Test Strips and Lancets</i> | <u>A-09-11-02027</u> | 06/13/12 |
| <i>Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets – Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction B</i> | <u>A-09-08-00044</u> | 02/17/11 |
| <i>Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets – Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction D</i> | <u>A-09-08-00046</u> | 02/04/11 |
| <i>Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets – Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C</i> | <u>A-09-08-00045</u> | 01/21/11 |
| <i>Medicare Market Shares of Mail Order Diabetic Testing Strips</i> | <u>OEI-04-10-00130</u> | 12/02/10 |
| <i>Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets – Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction A</i> | <u>A-09-08-00043</u> | 08/30/10 |