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INAPPROPRIATE AND QUESTIONABLE MEDICARE BILLING FOR DIABETES TEST STRIPS

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EXECUTIVE SUMMARY: INAPPROPRIATE AND QUESTIONABLE MEDICARE BILLING FOR DIABETES TEST STRIPS
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WHY WE DID THIS STUDY

In 2011, Medicare allowed approximately $1.1 billion to 51,695 suppliers for diabetes test strips (DTS) provided to 4.6 million beneficiaries. Recent investigations and prior Office of Inspector General studies have found that DTS is an area vulnerable to fraud, waste, and abuse. The Centers for Medicare & Medicaid Services (CMS) implemented the Competitive Bidding Program in 2011 to reduce payments for durable medical equipment, prosthetics, orthotics, and supplies and help reduce fraud and abuse. Mail order DTS is included in the Competitive Bidding Program, but non-mail order DTS currently is not.

HOW WE DID THIS STUDY

We analyzed Medicare-allowed 2010 and 2011 DTS claims and inpatient claims from hospitals and skilled nursing facilities for beneficiaries associated with allowed 2010 and 2011 DTS claims. In addition, we identified suppliers that billed amounts that were unusually high—according to at least one of six measures of questionable billing—that were subsequently allowed by Medicare, and we determined the geographic areas for these questionable-billing suppliers. Finally, we determined the extent of questionable billing before and after implementation of the Competitive Bidding Program.

WHAT WE FOUND

In 2011, Medicare inappropriately allowed $6 million for DTS claims billed (1) for beneficiaries without a documented diagnosis code for diabetes, or that inappropriately overlapped with (2) an inpatient hospital stay, or (3) an inpatient Skilled Nursing Facility stay. Further, we found that $425 million in Medicare-allowed claims—made by 10 percent of DTS suppliers—had characteristics of questionable billing. Suppliers in 10 geographic areas nationwide were responsible for 77 percent of questionable billing. However, the Competitive Bidding Program appears to have reduced questionable billing for mail order DTS in Competitive Bidding Areas (CBA). Similar reductions in questionable billing did not occur in non-CBA areas or for non-mail order DTS.

WHAT WE RECOMMEND

CMS partially concurred with two of our recommendations: CMS should enforce existing edits (system processes) to prevent inappropriate DTS claims, and CMS should increase monitoring of DTS suppliers' Medicare billing. CMS concurred with two other recommendations: CMS should provide more education to suppliers and beneficiaries about appropriate DTS billing practices, and CMS should take appropriate action regarding inappropriate Medicare DTS claims and suppliers with questionable DTS billing.

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OBJECTIVES

1. To determine the extent to which diabetes test strip (DTS) suppliers had claims with at least one of three types of errors in 2011: claims without a documented diagnosis code for diabetes, claims that overlapped with an inpatient hospital stay, and claims that overlapped with a Skilled Nursing Facility (SNF) stay.
2. To identify and describe suppliers that exhibited questionable billing for DTS in 2011 and the suppliers' geographic areas.
3. To describe whether the Competitive Bidding Program appears to have reduced questionable billing for mail order DTS in Competitive Bidding Areas (CBA).

BACKGROUND

Diabetes is a chronic disease in which a person has a high blood sugar (i.e., glucose) level because the body either does not produce enough insulin or cells do not respond properly to the insulin that the body does produce.[1] Diabetes may be managed in several ways, including healthy diet, physical activity, and insulin injections.[2] If those with diabetes do not properly manage their glucose levels, medical complications (e.g., hypoglycemia, cardiovascular disease or retinal damage) may occur.

Diabetes disproportionately affects older adults. Approximately 26.9 percent of individuals ages 65 and older—10.9 million people—reported having diabetes in 2010, while only 8.3 percent of individuals of all ages reported having the disease.[3]

Those with diabetes may use small, hand-held meters to test the concentration of glucose in their blood. To test glucose level, the individual inserts a diabetes test strip into the meter. A diabetes test strip is a small, thin, one-time-use piece of plastic on which a sample of blood is placed after pricking the skin. The meter reading provides the individual with information to use in managing his or her diabetes. There are two main types of diabetes, type 1 and type 2. Those with type 1 (i.e., insulin-dependent) diabetes depend on insulin injections to regulate their

[1] National Institutes of Health (NIH), *What are the Types of Diabetes?* Accessed at http://diabetes.niddk.nih.gov/dm/pubs/overview/ on May 15, 2012.
[2] NIH, *Diabetes Overview: How is Diabetes Managed?* Accessed at http://www.diabetes.niddk.nih.gov/dm/pubs/overview/index.htm#managed on May 15, 2012.
[3] National Institute of Diabetes and Digestive and Kidney Diseases, *National Diabetes Statistics, 2011*. Accessed at http://diabetes.niddk.nih.gov/dm/pubs/statistics/DM_Statistics_508.pdf on May 3, 2012.

blood-glucose levels. Generally, type 1 diabetes is diagnosed when individuals are children or young adults. Type 2 (i.e., non-insulin-dependent) diabetes mostly affects adults over age 40. Many individuals with type 2 diabetes can manage the disease with lifestyle changes, such as special diets and exercise, and do not require insulin injections to regulate their blood-glucose levels.[4]

DTS is an area vulnerable to fraud. For example, in response to allegations initially made by a whistleblower, a Tennessee medical supply company agreed to pay the United States Government and the State of Tennessee $18 million to settle claims that the company wrongly solicited Medicare beneficiaries and wrongly billed Medicare for diabetes testing supplies (e.g., blood-glucose monitors, lancets) and other medical products between 2008 and 2010.[5]

Medicare Coverage of Diabetes Test Strips

Medicare covers services and testing supplies to help beneficiaries with diabetes manage the condition. In 2011, Medicare allowed approximately $1.1 billion for DTS.[6]

To be eligible for Medicare coverage of DTS and other diabetes testing supplies, beneficiaries must have diabetes that is being treated by a physician.[7] They also must use the DTS in their homes (i.e., not in a hospital or SNF).[8] To receive Medicare payment, suppliers must document an appropriate diabetes diagnosis code for beneficiaries.[9]

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[4] NIH, *Type 2 Diabetes*. Accessed at http://www.nlm.nih.gov/medlineplus/ency/article/000313.htm on February 27, 2013.

[5] Department of Justice news release, *AmMed Direct, LLC, to Pay $18 Million to Settle False Claims Act Allegations*, April 13, 2012. Accessed at http://www.justice.gov/usao/tnm/pressReleases/2012/4-13-12.html on April 30, 2012.

[6] OIG analysis of Medicare Part B claims data for DTS, 2012. Medicare-allowed amounts are 100 percent of the payment made to a supplier by both Medicare and the beneficiary. Medicare pays 80 percent of allowed charges, and the beneficiary is responsible for the remaining 20 percent.

[7] Medicare Local Coverage Determinations (LCDs) for Glucose Monitors (L11530, L27231, L11520, and L196 for Jurisdictions A, B, C, and D respectively). CMS requires LCDs developed and revised by Durable Medical Equipment Medicare Administrative Contractors (DME MACs) to be identical. CMS, *Medicare Benefit Policy Manual*, Pub. No. 100-08, ch. 13, § 13.1.4.

[8] CMS, *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 15, § 110.1(D).

[9] Medicare LCDs for Glucose Monitors (L11530, L27231, L11520, and L196). Each LCD states that for Medicare coverage of home blood glucose monitors and related accessories and supplies, the patient must have diabetes (International Classification of Diseases 9th Revision (ICD-9) codes 249.00–250.93). In addition, "[t]he ICD-9 diagnosis code describing the condition that necessitates glucose testing must be included on each claim for the monitor, accessories, and supplies."

Suppliers can bill Medicare for DTS for up to 3 months at a time.[10] Each claim must indicate the number of units of DTS and the start and end dates associated with the claim.[11] Medicare covers up to 100 DTS (i.e., two 50-count boxes) per month for insulin-dependent beneficiaries and up to 100 DTS every 3 months for non-insulin-dependent beneficiaries.[12] Medicare allows additional DTS if deemed medically necessary and documented in physician records.[13]

Medicare beneficiaries may purchase their DTS via mail order or non-mail order means. In 2010 and 2011, "mail order" applied to DTS ordered remotely (that is, by telephone, e-mail, Internet, or mail) and delivered by a common carrier such as UPS, FedEx, or the U.S. Postal Service.[14] "Non-mail order" applied to beneficiary storefront pickup and DTS supplier delivery to beneficiaries' homes.[15]

To receive Medicare payment for mail order DTS, suppliers submit claims using the Healthcare Common Procedure Coding System (HCPCS) code A4253 and modifier KL. The KL modifier must be included on each claim to specify that the item was provided via mail order. Claims without the KL modifier indicate that the DTS was provided via non-mail order.[16]

Suppliers may refill an order for mail order or non-mail order DTS only when beneficiaries have nearly exhausted the previous supply and

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[10] Medicare LCDs for Glucose Monitors (L11530, L27231, L11520, and L196).

[11] CMS, *CWF Change for Billing for Glucose Test Strips and Supplies – Follow-up to CR 2156*, Change Request 2363, Transmittal B-03-004 (Jan. 24, 2003). On the claim, the start and end dates are referred to as the "from" and "through" dates, respectively. The "from" date is the date that the DTS is provided directly to the beneficiary or the shipping date, if a delivery/shipping service is used. The "through" date is the date that a beneficiary should exhaust his or her supply of DTS. For example, see *Local Coverage Article for Billing for Glucose Test Strips and Supplies (A143)*.

[12] Medicare LCDs for Glucose Monitors (L11530, L27231, L11520, and L196).

[13] Ibid.

[14] CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 36, §§ 10.2, 20.5.4.1, and 50.6. Accessed at https://www.cms.gov/manuals/downloads/clm104c36.pdf on February 2, 2012. See also CMS, *Mail Order Diabetic Supplies Fact Sheet*. Accessed at https://www.cms.gov/MLNProducts/downloads/DME_Mail_Order_Factsheet_ICN900924.pdf on June 20, 2012.

[15] After Round 1 of the Competitive Bidding Program, the definition of mail order will expand to include DTS delivered by company vehicles and will be any item (e.g., DTS) shipped or delivered to the beneficiary's home regardless of the method of delivery. 75 Fed. Reg. 73170, 73570, and 73623 (Nov. 29, 2010) (revising the definition of "mail order item" in 42 CFR 414.402 and explaining why the new definition will not apply to Round 1).

[16] CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 36, §§ 20.5.4.1 and 50.6.

specifically request additional DTS.[17] Suppliers may not automatically dispense a quantity of DTS on a predetermined basis.[18] Instead, suppliers must contact the beneficiary before dispensing the refill to verify the quantity of DTS that is needed for the next billing period. Suppliers should contact beneficiaries regarding refills no sooner than approximately 7 days before the anticipated delivery/shipping date. The refills should be delivered no sooner than approximately 5 days before the anticipated end of the DTS supply.[19]

The Competitive Bidding Program and Diabetes Test Strips

Before 2011, Medicare reimbursed all DTS suppliers on the basis of established fee schedule amounts, which were updated annually and varied by State. In 2011, Medicare replaced these fee schedule amounts with a Competitive Bidding Program for selected durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in nine CBAs.[20, 21] Mail order DTS was included in the first year of implementation of the Competitive Bidding Program, but non-mail order DTS was not.

CMS used bids submitted by DMEPOS suppliers to determine the competitive bidding payment amounts. CMS evaluated bids on the basis

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[17] CMS, *Medicare Program Integrity Manual.* Pub. 100-08, ch. 4, § 4.26.1 (before Change Request 7410, Transmittal 389). During our review, CMS revised the guidance for timeframes for refills. For claims with dates of services on or after August 2, 2011, CMS revised the contact and delivery timeframes to allow suppliers to (1) contact beneficiaries regarding refills no sooner than 14 days before the delivery/shipping date and (2) deliver refills no sooner than 10 days before the end of usage of the current supply. However, we did not consider this revised guidance in our review. CMS, *Medicare Program Integrity Manual.* Pub. 100-08, ch. 5 § 5.2.6 (added by Change Request 7452, Transmittal 378, effective August 2, 2011) and CMS, *Medicare Program Integrity Manual.* Pub. 100-08, Ch. 4, § 4.26.1 (revised by Change Request 7410, Transmittal 389, effective Oct. 31, 2011).

[18] Ibid.

[19] Ibid.

[20] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 § 302(b)(1), as amended by the Medicare Improvements for Patients and Providers Act of 2008, P.L. 110-275, § 154. Social Security Act § 1847, 42 U.S.C. § 1395w-3.

[21] A CBA is defined by specific ZIP Codes related to Metropolitan Statistical Areas (MSA), which are designated by the Office of Management and Budget that include major cities and the suburban areas surrounding them. The 9 CBAs included in Round 1 of the Competitive Bidding Program were Charlotte (Charlotte–Gastonia–Concord, North Carolina and South Carolina); Cincinnati (Cincinnati–Middletown, Ohio, Kentucky, and Indiana); Cleveland (Cleveland–Elyria–Mentor, Ohio); Dallas (Dallas–Fort Worth–Arlington, Texas); Kansas City (Kansas City, Missouri and Kansas); Miami (Miami–Fort Lauderdale–Miami Beach, Florida); Orlando (Orlando–Kissimmee, Florida); Pittsburgh (Pittsburgh, Pennsylvania); and Riverside (Riverside–San Bernardino–Ontario, California). CMS, *Metropolitan Statistical Areas, Competitive Bidding Areas, and ZIP Codes*. Accessed at http://www.cms.gov/DMEPOSCompetitiveBid/01a_MSAs_and_CBAs.asp#TopOfPage on May 25, 2012.

of suppliers' eligibility, their financial stability, and the bid price.[22] CMS awarded contracts to the suppliers who generally offered lower prices and met applicable quality and financial standards.[23, 24]

Beginning in 2011, beneficiaries residing in CBAs had to obtain mail order DTS through a contract supplier in the Competitive Bidding Program. Non-mail order DTS provided by any Medicare supplier, as well as mail order DTS provided to beneficiaries residing in non-CBA areas, continued to be reimbursed at the fee-schedule amount.[25]

As a result of the Competitive Bidding Program, 2011 payment rates for mail order DTS for beneficiaries residing in CBAs were lower than payment rates for mail order DTS for beneficiaries residing in non-CBA areas. Specifically, the average Medicare payment for mail order DTS provided to beneficiaries in CBAs was $14.62 per 50-count box, less than half of either the national average Medicare payment for mail order DTS of $32.47 or the national average payment for non-mail order DTS of $37.67. The national mail order competition for DTS began on July 1, 2013, for mail order DTS only.[26] After July 1, 2013, beneficiaries may continue to purchase DTS in person at any Medicare-enrolled supplier storefront accredited to furnish these items.[27] The payment rate for non-mail order DTS will be equal to the single payment amount for mail order

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[22] CMS, *Overview of the DMEPOS Competitive Bidding Program.* Accessed at http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home on April 24, 2012.

[23] CMS, *CMS Media Release Database Fact Sheet. Details for: Expansion of Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*. Accessed at http://www.cms.gov/apps/media/press/factsheet.asp?Counter=2812 on April 24, 2012.

[24] The number of winning suppliers in each CBA ranges from 9 to 25. CMS, *Contract Supplier Lists*. Accessed at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Contract-Supplier-Lists.html on June 5, 2012.

[25] CMS educated suppliers about the appropriate billing requirements under the Competitive Bidding Program. For example, CMS produced a Medicare Learning Network (MLN) fact sheet on the diabetes test supplies product category, an MLN article for noncontract suppliers, and an MLN article about the use of modifiers. CMS also led a national supplier call and a contract supplier call about appropriate billing under the Competitive Bidding Program.

[26] The national mail order competition for DTS includes all parts of the United States, including the 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. CMS, *The Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program: Mail-Order Diabetic Supplies*. Accessed at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DME_Mail_Order_Factsheet_ICN900924.pdf on July 31, 2013.

[27] Ibid.

DTS under the Competitive Bidding Program, i.e. $10.41.[28, 29]

CMS estimates that the Competitive Bidding Program will save Medicare Part B $25.7 billion between 2013 and 2022 and will help reduce fraud and abuse.[30] CMS reported that in the first year of implementation, the program saved Medicare approximately $202.1 million.[31] Additionally, expenditures in the nine CBAs for the DMEPOS items included in the program decreased 42 percent in the first year of implementation.[32] CMS also reports that the Competitive Bidding Program has not disrupted beneficiaries' access to DMEPOS items and that no negative health-care consequences have resulted from the program.[33]

Related Office of Inspector General Work

OIG has identified vulnerabilities pertaining to suppliers' claims for DTS.[34] Specifically, OIG found that the documentation associated with some suppliers' claims did not: (1) indicate the medical necessity for DTS quantities in excess of utilization guidelines; (2) support refills of DTS; and (3) contain complete physician orders, and/or contain proof-of-delivery records. OIG also found that DME MACs did not have edits (i.e., system processes) to prevent one supplier from billing for DTS when the beneficiary should still have DTS provided by another supplier.[35, 36]

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[28] CMS, *Round 2 and National Mail Order Single Payment Amounts*. Accessed at http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/DocsCat/Single%20Payment%20Amounts on January 30, 2013.

[29] P.L. 112-240, the American Taxpayer Relief Act of 2012.

[30] According to CMS, the Competitive Bidding Program helps prevent Medicare fraud and abuse because "all suppliers in the program must be licensed, meet strict quality and financial standards, and be accredited by a national accreditation organization." Further, "a reduction in excessive payment amounts makes competitively bid items less attractive targets for fraud and abuse." CMS, *Medicare's DMEPOS Competitive Bidding Program.* Accessed at http://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/PartnerFAQJuly2012.pdf on August 14, 2012.

[31] CMS, *Competitive Bidding Update—One Year Implementation Update, April 17, 2012*. Accessed at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf on April 25, 2012.

[32] Ibid.

[33] Ibid.

[34] OIG, *Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction A* (A-09-08-00043), August 2010.

[35] Ibid.

[36] DME MACs process and pay Medicare Part B claims.

In 2012, OIG issued a fraud alert notifying beneficiaries of common schemes that suppliers use to submit fraudulent Medicare DTS claims.[37] OIG encouraged beneficiaries not to accept DTS from suppliers in exchange for the beneficiaries' Medicare or financial information. This includes not accepting: (1) diabetes supplies in the mail that beneficiaries did not order; (2) "free" diabetes supplies, such as DTS; and (3) other "free" supplies such as heating pads, lift seats, foot orthotics, or joint braces.

In late 2012 and early 2013, OIG issued two reports on DTS. In the first report, OIG found an increase in claims for non-mail order DTS between 2010 and 2011. OIG determined that the increase was partly due to suppliers improperly billing Medicare for the more expensive, non-mail order DTS in 2011, when beneficiaries reported having received the less expensive, mail order DTS.[38] OIG also found that some beneficiaries in CBAs reported inappropriate supplier activities (e.g., routinely waiving copayments or sending unsolicited DTS). As summarized in a 2013 report, OIG reviewed a supplier's 2010 DTS claims and determined that the supplier—in accordance with Medicare billing requirements—had submitted claims for non-mail order diabetic testing supplies without the KL modifier.[39]

METHODOLOGY

We analyzed 2010 and 2011 DTS claims from CMS's Durable Medical Equipment Standard Analytical File. We analyzed approximately 11.2 million DTS claims billed by 51,695 suppliers in 2011 and approximately 11.3 million DTS claims billed by 51,576 suppliers in 2010.[40]

We also used CMS's Inpatient Standard Analytical File and SNF Standard Analytical File to analyze inpatient claims from hospitals and SNFs for beneficiaries associated with DTS claims. We used beneficiaries' Health Insurance Claim Numbers to link these hospital and SNF claims to the DTS claims. Finally, we determined suppliers' geographic areas by using the National Provider Identifier numbers from their claims to look them up

[37] OIG, *Fraud Alert for People with Diabetes.* Accessed at http://www.oig.hhs.gov/newsroom/news-releases/2012/alert20120309.asp on May 25, 2012.

[38] OIG, *Supplier Billing for Diabetes Test Strips and Inappropriate Supplier Activities in Competitive Bidding Areas* (OEI-04-11-00760), November 2012.

[39] OIG, *Neighborhood Diabetes, Inc., Submitted Claims for Diabetic Testing Supplies Without the KL Modifier in Accordance With Medicare Billing Requirements* (A-09-l1-02073), January 2013.

[40] We excluded all claims with a Medicare-allowed amount of zero.

in the National Plan and Provider Enumeration System (NPPES) and find their ZIP Codes.[41]

Identification of Suppliers who Inappropriately Billed for Diabetes Test Strips

We analyzed 2011 DTS claims data from the 18-month update of CMS's Durable Medical Equipment Standard Analytical File to determine the number of claims that (1) were billed for beneficiaries without a documented diagnosis code for diabetes; (2) inappropriately overlapped with an inpatient hospital stay; or (3) inappropriately overlapped with an inpatient SNF stay. We also calculated the total inappropriate Medicare-allowed amounts for these DTS claims and identified suppliers associated with these claims.

DTS claims for beneficiaries without a documented diagnosis code for diabetes. We identified DTS claims with a diagnosis code that did not signify diabetes.[42] ICD-9 codes between 249.00 and 250.93 indicate that a beneficiary has diabetes.[43] Claims for DTS without a diagnosis code in this range do not meet Medicare coverage requirements.

We calculated the number of and Medicare-allowed amounts for DTS claims without a diabetes diagnosis code in 2011. We did not examine supplier documentation to determine whether it indicated a diabetes diagnosis.

Medicare DTS claims for beneficiaries during inpatient hospital stays and SNF stays. Medicare Part B reimburses suppliers for DTS that beneficiaries use in their homes. Part B claims for DTS provided to beneficiaries during inpatient hospital or SNF stays are inappropriate.[44] If a beneficiary is hospitalized or admitted to a SNF, he or she should receive DTS from the facility and not from a separate supplier.

We identified DTS claims that overlapped with an inpatient hospital or SNF stay. Specifically, if the start date on the claim fell between the admission date and discharge date for an inpatient hospital stay or SNF stay covered by Medicare Part A, we determined that the claim was inappropriate.

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[41] The NPPES assigns a National Provider Identifier to all health care providers that enroll in Medicare. It also contains other relevant information for enrollment, such as the provider's physical location, type, and owner. NPPES data are self-reported by suppliers.

[42] To identify beneficiaries' diagnoses, we reviewed the ICD-9 codes listed on DTS claims.

[43] Medicare LCDs for Glucose Monitors (L11530, L27231, L11520, and L196).

[44] *Medicare Claims Processing Manual, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies* (ch. 20, section 01). Accessed at http://www.cms.gov/manuals/downloads/clm104c20.pdf on May 8, 2012.

We calculated the number of and Medicare-allowed amounts for DTS claims that overlapped with a date that the patient was in a hospital or SNF. We also describe how many of the instances of inappropriate billing occurred 1 or 2 days preceding the beneficiary's discharge from the inpatient hospital or SNF.

We excluded appropriate instances of overlap. Appropriate instances of overlap occur when suppliers bill for DTS: (1) on the day a beneficiary is admitted to or discharged from an inpatient hospital or SNF or (2) during a beneficiary's leave of absence from an inpatient hospital or SNF stay.[45]

Identification of Suppliers That Had Questionable DTS Billing

We analyzed 2010 and 2011 DTS claims from the 18-month update of CMS's Durable Medical Equipment Standard Analytical File. We developed six measures of questionable billing on the basis of the results of past OIG analyses and fraud investigations related to DTS suppliers, as well as input from CMS staff. We considered a DTS supplier's billing to be unusually high, or questionable, on each of the six measures if it was greater than the 75th percentile plus 1.5 times the interquartile range (i.e., the Tukey method).[46] Although some of this billing may be legitimate, suppliers that bill for extremely high amounts warrant further scrutiny.

For each questionable-billing characteristic, we identified those suppliers that submitted an unusually high percentage of claims. For each characteristic, we counted as suppliers with questionable billing those for whom Medicare allowed $1,000 or more for each questionable-billing characteristic. Questionable-billing characteristics pertain to supplier claims for both mail order and non-mail order DTS, unless otherwise specified. The six measures of questionable billing we developed were:

Claims for non-mail order DTS provided to beneficiaries residing an unusually long distance from suppliers. We considered suppliers to have questionable billing if they submitted claims for non-mail order DTS (i.e., claims without the KL modifier) provided to beneficiaries residing an unusually long distance from them. Mail order suppliers have an incentive to bill DTS as non-mail order because of the higher payment rates of non-mail order DTS. Suppliers with high percentages of non-mail order DTS claims for beneficiaries that reside an unusually long distance away

[45] *Medicare Claims Processing Manual, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies* (ch. 20, section 01). Accessed at http://www.cms.gov/manuals/downloads/clm104c20.pdf on May 8, 2012.

[46] This is a standard exploratory method for identifying members of a population with unusually high values on a given statistic compared to the rest of the population when no established benchmarks exist. See J.W. Tukey, *Exploratory Data Analysis*, Addison-Wesley, 1977.

are questionable because the suppliers may be inappropriately billing for mail order DTS as non-mail order to receive the higher payment rate. We used the Tukey method to determine the threshold for unusually long distances to be 20 miles.[47, 48] We conducted an additional analysis using a threshold of 50 miles.[49]

DTS claims for beneficiaries in excess of utilization guidelines. We considered suppliers to have questionable billing if they had high percentages of DTS claims for beneficiaries in excess of Medicare utilization guidelines. Medicare covers different amounts of DTS depending on a beneficiary's medical condition. Medicare covers up to 100 DTS (i.e., 2 units) every month for insulin-dependent beneficiaries and every 3 months for non-insulin-dependent beneficiaries.[50] Medicare allows additional DTS if deemed medically necessary and documented in physician records.

Beneficiaries associated with DTS claims at perfectly regular intervals. We considered suppliers to have questionable billing if they had high percentages of beneficiaries who received DTS at perfectly regular intervals. Beneficiaries must specifically request a DTS refill from a supplier before a supplier dispenses it.[51] Suppliers must not refill an order or automatically dispense a quantity of DTS on a predetermined basis. DTS claims that regularly fall on the exact anniversary of the previous claim for the same beneficiary may indicate that a supplier is automatically providing DTS and not seeking the beneficiaries' authorization.

Beneficiaries associated with multiple DTS claims submitted by the same supplier during overlapping time periods. We considered suppliers to have questionable billing if they had high percentages of beneficiaries for whom they had submitted multiple DTS claims during overlapping time

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[47] We calculated distance by determining the number of miles between the center of the ZIP code of the supplier's physical location and the center of the ZIP Code for the corresponding beneficiary. Therefore, a distance of 0 miles indicates that the beneficiary and supplier were in the same ZIP Code. The median distance between ZIP Codes was 2 miles and the mean distance was 34.2 miles. Distances ranged between 0 and 8,230 miles. For example, one beneficiary's permanent residence was in Guam, but he or she had claims for non-mail order DTS from a supplier in Florida.

[48] Beneficiaries at a temporary residence (e.g., on vacation) may obtain non-mail order DTS from a local supplier. For beneficiaries in CBAs, suppliers must submit claims with the KT modifier for non-mail order DTS furnished to beneficiaries who have traveled outside the CBA in which they reside. In 2011, there were 6,251 DTS claims with the KT modifier. We removed these claims from our analysis.

[49] We judgmentally selected 50 miles to remove suppliers that may have used supplier vehicles to deliver the DTS and were properly billing for non-mail order DTS.

[50] Medicare LCDs for Glucose Monitors (L11530, L27231, L11520, and L196).

[51] CMS, *Medicare Program Integrity Manual*. Pub. 100-04, ch. 5 § 2.6.

periods. Suppliers may refill an order for DTS only when beneficiaries have nearly exhausted the previous supply and specifically request that the DTS be dispensed.[52] Suppliers may provide DTS refills on or after the anniversary of the prior DTS order/shipping date (i.e., the start date). Previous OIG work found that many suppliers submit claims for the same beneficiary for DTS during overlapping time periods.[53]

DTS claims for a given beneficiary in 2010 but not in 2011. We considered suppliers to have questionable billing if they had high percentages of DTS claims for beneficiaries who received DTS in 2010 but did not receive DTS in 2011.[54] Diabetes is a chronic disease that requires regular medical attention. Beneficiaries who needed DTS in 2010 would likely still need DTS in 2011, provided that they are still Medicare beneficiaries.[55]

Beneficiaries with DTS claims from any supplier in 2010 but not in 2011 may have received DTS in 2010 from suppliers who provided excess DTS before the start of the Competitive Bidding Program. In addition, some beneficiaries may not have received DTS from the supplier; the supplier may have been fraudulently billing on behalf of the beneficiary in 2010.

Beneficiaries associated with overlapping DTS claims from more than one supplier. We considered suppliers to have questionable billing if they had high percentages of beneficiaries with overlapping DTS claims from more than one supplier. When multiple suppliers submit DTS claims for the same beneficiary during overlapping time periods, the beneficiary may receive excess DTS (1) not authorized by the attending physician, and/or (2) in excess of Medicare utilization guidelines. Previous OIG work found that DME MACs allowed DTS claims from multiple suppliers for one beneficiary during overlapping time periods.

Analysis of Geographic Areas of DTS Suppliers With Questionable Billing

We determined the geographic areas of DTS suppliers with questionable billing in 2011. To do this, we obtained each supplier's physical location ZIP Code from NPPES and identified suppliers' Core Based Statistical

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[52] CMS, *Medicare Program Integrity Manual.* Pub. 100-04, ch. 5 § 2.6.

[53] OIG, *Blood Glucose Test Strips: Inappropriate Medicare Payments,* OEI-03-98-00230, June 2000.

[54] This category of beneficiaries includes only those who did not receive DTS in 2011 from *any* supplier. It does not include beneficiaries who switched suppliers—i.e., those who received DTS in 2010 from one supplier and in 2011 from a different supplier.

[55] We used the Medicare Enrollment Database to identify and remove from our analysis beneficiaries who (1) were associated with DTS in 2010 but not in 2011 and (2) had dates of death in either 2010 or 2011.

Areas (CBSA).[56, 57] Four hundred twenty-eight suppliers (9 percent) were in rural areas (i.e., not in a CBSA).

In geographic areas with the highest totals of questionable Medicare-allowed amounts, we calculated the number of DTS suppliers with questionable billing out of the total number of DTS suppliers, and the number of claims associated with the questionable-billing suppliers. In addition, we identified the geographic areas of suppliers with four or more questionable-billing characteristics.

Analysis to Determine Medicare-Allowed Amounts in Questionable Billing for Suppliers in CBAs Before and After Implementation of the Competitive Bidding Program

We examined the extent to which Medicare-allowed amounts for mail order DTS questionable billing in CBAs decreased after the Competitive Bidding Program was implemented. To do this, we identified beneficiaries who (1) received mail order DTS in 2010 in the areas that became CBAs in 2011 and (2) received mail order DTS in 2011 in CBAs. (We refer to these beneficiaries as "beneficiaries in CBAs").

For these beneficiaries, we calculated the amount that Medicare allowed in questionable billing for mail order DTS and the number of suppliers with questionable billing. We calculated the percentage change in the amount that Medicare allowed in questionable billing for mail order DTS and the number of suppliers with questionable billing between 2010 and 2011.

For context and to establish a baseline, we also conducted this same analysis for beneficiaries who were not affected by the Competitive Bidding Program. These beneficiaries (1) lived in non-CBA areas in 2011 and areas that match non-CBA areas in 2010 (we refer to these beneficiaries as "beneficiaries in non-CBA areas") and/or (2) received non-mail order DTS in 2011 and 2010.

We did not include two questionable-billing characteristics in our analysis of suppliers' questionable billing in CBAs before and after implementation of the Competitive Bidding Program. First, we did not include the characteristic of suppliers' having claims for non-mail order DTS provided

[56] A CBSA is a region around an urban center that has at least 10,000 people. We used DTS suppliers' ZIP Codes to determine their CBSAs. CBSAs may be categorized as metropolitan or micropolitan. A metropolitan area is defined as a core urban area with a population of 50,000 people or more. A micropolitan area is defined as an urban cluster of at least 10,000 and fewer than 50,000 people. U.S. Census Bureau, *Metropolitan and Micropolitan Definition Files*. Accessed at http://www.census.gov/population/metro/data/def.html on May 18, 2012.

[57] We used the NPPES active NPI file as of August 2011 to identify the supplier ZIP Codes for the geographic areas analysis. NPPES data are self-reported by suppliers.

to beneficiaries residing an unusually long distance from them. We did not include this characteristic because it provides information only about non-mail order DTS, and the Competitive Bidding Program includes only mail order DTS. Second, we did not include the characteristic of suppliers' having DTS claims for beneficiaries in 2010 but not in 2011. We did not include this characteristic because it specifies a comparison between 2010 and 2011 and identifies suppliers active in 2010, and the Competitive Bidding Program was not in place at that time.

Limitations

The six questionable-billing characteristics included in our analysis are not intended to be a comprehensive set of characteristics for identifying questionable billing for DTS under Medicare. Additionally, although the presence of these characteristics raises questions about the appropriateness of the DTS claims submitted by suppliers, we did not conduct a medical record review to determine whether the claims that suppliers submitted for DTS were inappropriate or potentially fraudulent.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

In 2011, Medicare inappropriately allowed $6 million for DTS claims with three types of errors

Medicare coverage policies prohibit payment for DTS claims without an appropriate documented diagnosis code for diabetes and with dates of services that overlap with an inpatient hospital or SNF stay.[58] In addition, CMS has implemented claims-processing edits to prevent these payments. However, Medicare inappropriately allowed $6 million for DTS suppliers that had at least one of these three types of errors in 2011.

These inappropriate claims represent less than 1 percent of the $1.1 billion allowed for DTS in 2011, but they still pose a program vulnerability. The DTS suppliers with these inappropriate claims represented 11 percent of all DTS suppliers in 2011. On average, these suppliers inappropriately received $999 from Medicare in 2011 for DTS. One supplier inappropriately received $692,036 for DTS, the highest amount for any one supplier in 2011.

In 2011, 5,803 suppliers had claims with at least one of the three types of errors we analyzed. A total of 5,045 DTS suppliers exhibited one type of error, 667 suppliers exhibited two types of errors, and 91 exhibited all three.[59] Table 1 shows the inappropriate Medicare-allowed amount, number of claims, and number of suppliers by the three types of errors we analyzed.

[58] Medicare LCDs for Glucose Monitors (L11530, L27231, L11520, and L196). CMS, *Medicare Program Integrity Manual.* Pub. 100-04, ch. 20 § 10.2.

[59] OIG analysis of Part B DTS claims, 2012.

Table 1: Inappropriate Medicare-Allowed Claims for Diabetes Test Strips, 2011

Error Type	Inappropriate Medicare-Allowed Amount	Number of Claims	Number of Suppliers*
DTS claims for beneficiaries without a documented diagnosis code for diabetes	$2,315,584	23,778	2,211
DTS claims that inappropriately overlapped with a hospital stay	$3,382,550	25,589	4,115
DTS claims that inappropriately overlapped with an SNF stay	$112,787	908	326
Total	**$5,798,689**	**50,170**	**5,803**

*Sum of column exceeds total because some suppliers had multiple types of errors.
Source: OIG analysis of Part B DTS claims, 2012.

Medicare inappropriately allowed $2.3 million in 2011 for DTS claims for beneficiaries without a documented diagnosis code for diabetes

In 2011, Medicare allowed $2.3 million for DTS claims with a diagnosis code that did not signify diabetes. The top five diagnoses associated with these inappropriate claims were: chronic airway obstruction, long-term use of insulin, urinary incontinence, osteoarthrosis, and obstructive sleep apnea.[60]

Medicare inappropriately allowed $3.5 million in 2011 for DTS claims that overlapped with a stay in an inpatient hospital or a SNF

Specifically, overlap between DTS claims and an inpatient hospital stay accounted for $3.4 million in inappropriate Medicare claims in 2011. Nationwide, Medicare allowed 25,589 claims from 4,115 DTS suppliers when DTS claims and an inpatient hospital stay inappropriately overlapped. Of these inappropriate claims, 5,022 claims (20 percent) occurred 1 day before the discharge date from the inpatient hospital, and an additional 3,852 claims (15 percent) occurred 2 days before the discharge date.

Overlap between DTS claims and a SNF stay accounted for an additional $112,787. In 2011, Medicare allowed 908 claims from 326 DTS suppliers when DTS claims and an SNF stay inappropriately overlapped. Of these

[60] The ICD-9 code for long-term use of insulin is V58.67. This does not fall within the range of ICD-9 codes required for DTS billing (i.e., 249.00–250.93). In 2011, Medicare allowed $162,406 for DTS for beneficiaries with the V58.67 diagnosis code.

inappropriate claims, 99 claims (11 percent) occurred 1 day before the discharge date from the SNF, and 73 claims (8 percent) occurred 2 days before the discharge date.

Medicare allowed $425 million in questionable billing to 10 percent of DTS suppliers

In 2011, 10 percent (4,959 of 51,695) of DTS suppliers exceeded the threshold that indicated unusually high billing for at least one of our six questionable-billing measures.[61]

One percent (758) of the DTS suppliers exceeded the thresholds for two or more measures. Table 2 shows the number and percentage of DTS suppliers by the number of measures of questionable billing for which DTS suppliers exceeded thresholds.

Table 2: Number and Percentage of DTS Suppliers by Number of Questionable-Billing Measures for Which Suppliers Exceeded Thresholds That Indicate Unusually High Billing, 2011

Number of Measures of Questionable Billing for Which DTS Suppliers Exceeded Thresholds	Number of DTS Suppliers	Percentage of DTS Suppliers*
0	46,736	90%
1	4,201	8%
2	634	1%
3	111	0%
4	13	0%
5 or more	0	0%
Total	**51,695**	**100%**

Source: OIG analysis of Part B DTS claims, 2012.
*The percentages do not sum to 100 percent because of rounding.

For each measure of questionable billing, Table 3 shows the median among all DTS suppliers, the threshold that indicated unusually high billing, the range of unusually high billing, the Medicare-allowed amounts for claims associated with questionable billing, and the number of DTS suppliers with unusually high billing.

[61] Of these, 1,640 DTS suppliers with questionable billing also had at least one inappropriately allowed claim in 2011.

Table 3: DTS Suppliers with Unusually High Billing by Measure of Questionable Billing, 2011

Measure of Questionable Billing	Median Among All DTS Suppliers*	DTS Suppliers With Unusually High Billing**			
		Threshold	Range	Medicare-Allowed Amounts for Claims with Questionable Billing	Number of Suppliers
Average percentage of suppliers' non-mail order DTS claims for beneficiaries that resided an unusually long distance away	5%	25%	25% to 100%	$55 million	1,689
Average percentage of suppliers' DTS claims in excess of Medicare utilization guidelines	7%	26%	26% to 100%	$242 million	1,378
Average percentage of suppliers' beneficiaries that were associated with DTS at perfectly regular intervals	3%	11%	11% to 100%	$67 million	851
Average percentage of suppliers that had an unusually high percentage of beneficiaries associated with overlapping DTS claims submitted by the same supplier	15%	38%	38% to 100%	$10 million	745
Average percentage of suppliers' DTS claims for beneficiaries in 2010 but not in 2011	15%	40%	40% to 100%	$2 million***	683
Average percentage of suppliers' beneficiaries associated with overlapping DTS claims from more than one supplier	10%	26%	26% to 100%	$102 million	508
Total**				**$425 million**	**4,959**

*The median (i.e., the 50th percentile) indicates that half of all DTS suppliers fell below this value.
**We considered a DTS supplier's billing to be unusually high if it was greater than the 75th percentile plus 1.5 times the interquartile range.
***This questionable-billing characteristic identifies 2010 Medicare-allowed amounts.
****Sum of column exceeds total because some suppliers had multiple questionable-billing characteristics.
Source: OIG analysis of Part B data for DTS, 2012.

In 2011, 1,689 suppliers had an unusually high percentage of non-mail order DTS claims for beneficiaries residing an unusually long distance from suppliers

In 2011, Medicare allowed $55 million in questionable billing to 1,689 DTS suppliers for beneficiaries who resided an unusually long distance away (i.e., over 20 miles) from suppliers.[62] Further, Medicare allowed a total of $4.2 million to 78 suppliers for which 100 percent of

[62] Some suppliers in this analysis may have delivered the DTS to beneficiaries in supplier-owned vehicles and, therefore, appropriately billed the DTS as non-mail order.

their non-mail order DTS claims were for beneficiaries residing over 20 miles away. Additionally, Medicare allowed 46 suppliers over $100,000 each for non-mail order DTS associated with beneficiaries residing over 20 miles from suppliers' locations.

For one supplier in Fort Lauderdale, FL, Medicare allowed $2.3 million for 14,741 non-mail order claims for beneficiaries who resided over 20 miles away. Medicare allowed over $1 million to each of two additional suppliers in Woburn, MA, and Fort Worth, TX.[63]

When we used 50 miles as the distance threshold, we found that Medicare allowed over $19 million to 994 DTS suppliers for beneficiaries that resided more than 50 miles away from suppliers. Further, Medicare allowed $4.1 million to suppliers for which 100 percent of their non-mail order DTS claims were for beneficiaries residing over 50 miles away from the supplier.

In 2011, 1,378 suppliers had an unusually high percentage of DTS claims in excess of utilization guidelines

Medicare allowed $242 million in questionable billing to 1,378 suppliers that had high percentages of DTS claims in excess of utilization guidelines in 2011. For 12 suppliers, 100 percent of their DTS claims exceeded utilization guidelines. For 245 suppliers, 50 percent or more of their DTS claims exceeded utilization guidelines. Twenty-five suppliers had over $1 million each in DTS claims that exceeded utilization guidelines.

In 2011, 851 suppliers had an unusually high percentage of beneficiaries associated with DTS at perfectly regular intervals

Medicare allowed $67 million in questionable billing to 851 DTS suppliers that had high percentages of beneficiaries associated with DTS at perfectly regular intervals. For one supplier, 100 percent of its beneficiaries were associated with DTS on the exact anniversary of the previous claim. For 12 suppliers, Medicare allowed over $1 million each in DTS claims for beneficiaries at perfectly regular intervals.

In 2011, 745 suppliers had an unusually high percentage of beneficiaries associated with overlapping DTS claims submitted by the same supplier

Medicare allowed $10 million in questionable billing to 745 DTS suppliers that had high percentages of beneficiaries with multiple DTS claims submitted by the same supplier during overlapping time periods. For three suppliers, 100 percent of their beneficiaries were associated with

[63] There are 676 and 909 suppliers, respectively, in the Boston, MA, CBSA (which includes Woburn, MA) and the Dallas-Fort Worth, TX, CBSA.

multiple DTS claims from the same supplier during the same time period. For two suppliers, Medicare allowed over $1 million each for beneficiaries with multiple DTS claims from the same supplier during the same time period. For 198 suppliers, 50 percent or more of their beneficiaries were associated with multiple DTS claims from the same supplier during the same time period.

In 2011, 683 DTS suppliers had an unusually high percentage of DTS claims for beneficiaries associated with DTS from any supplier in 2010 but not in 2011

In 2010, Medicare allowed $2 million in questionable billing to 683 DTS suppliers that had high percentages of Medicare DTS claims for beneficiaries in 2010 but not in 2011. These beneficiaries did not receive DTS from any other supplier in 2011. For 33 suppliers, over 75 percent of their allowed claims were for beneficiaries associated with DTS in 2010 but not in 2011.

In 2011, 508 suppliers had an unusually high percentage of beneficiaries associated with overlapping DTS claims from more than one supplier

Medicare allowed $102 million in questionable billing to 508 DTS suppliers that had high percentages of beneficiaries with DTS from at least one other supplier during overlapping time periods. For 77 suppliers, at least 50 of their beneficiaries had claims from at least one additional supplier during overlapping time periods in 2011. For one supplier, 100 percent of its beneficiaries had DTS claims from at least one other supplier during overlapping time periods in 2011.

Seventy-seven percent of questionable billing was associated with suppliers in 10 geographic areas

In 2011, 77 percent of questionable billing ($329 million of the total $425 million) was associated with suppliers in 10 geographic areas nationwide.[64] These 10 geographic areas housed 20 percent (999 of 4,959) of DTS suppliers with questionable billing. Overall, the 4,959 DTS suppliers with questionable billing were in 651 CBSAs and 428 rural ZIP Codes.[65] Eighty-six geographic areas had more than 8 suppliers with questionable DTS billing in 2011; 301 geographic areas did not have any suppliers with questionable DTS billing in 2011.[66]

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[64] Nine of the top 10 geographic areas were CBSAs. Amory, MS, is a rural area.

[65] There are 955 CBSAs in the United States. There were 4,464 suppliers in CBSAs and 428 suppliers in rural ZIP Codes with at least one questionable billing characteristic. The ZIP Codes of 67 suppliers were not listed in NPPES; therefore, we cannot determine whether these suppliers were in rural locations or CBSAs.

[66] The average number of questionable billing suppliers per geographic area was seven.

Table 4 lists these geographic areas, the number of suppliers with questionable billing, the total number of suppliers, the percentage of suppliers with questionable billing, and the Medicare-allowed amount for suppliers with questionable billing.

Table 4: Geographic Areas With the Highest Number of Suppliers With DTS Questionable Billing, 2011

Geographic Area	Questionable Medicare-Allowed Amount	Number of DTS Suppliers With Questionable Billing	Total Number of DTS Suppliers	DTS Suppliers With Questionable Billing out of Total DTS Suppliers
Port St. Lucie, FL	$114,963,257	11	79	14%
Miami-Fort Lauderdale-Pompano Beach, FL	$113,196,111	222	1125	20%
Nashville-Davidson-Murfreesboro-Franklin, TN	$34,698,435	33	330	10%
New York-Northern New Jersey-Long Island, NY-NJ-PA	$15,497,578	358	3647	10%
Tampa-St. Petersburg-Clearwater, FL	$14,208,167	61	571	11%
Amory, MS	$9,399,811	4	8	50%
Phoenix-Mesa-Glendale, AZ	$7,325,878	63	579	11%
Kansas City, MO-KS	$7,256,647	30	307	10%
Boston-Cambridge-Quincy, MA-NH	$6,481,774	25	676	4%
Los Angeles-Long Beach-Santa Ana, CA	$5,844,420	192	1628	12%
National	$424,905,138	4,959	51,695	10%

Source: OIG analysis of Part B data for DTS, 2012.

In addition, 13 suppliers with questionable billing had 4 or more questionable billing characteristics. These 13 suppliers were in 11 CBSAs. Three suppliers with four or more questionable-billing characteristics had over $1 million in allowed DTS claims. These suppliers were in Miami, FL ($13.9 million), Atlanta, GA ($3.7 million), and Cleveland, OH ($1.6 million).

Appendix A lists the geographic areas of DTS suppliers with four or more measures of questionable billing in 2011. Appendix B lists the geographic areas of the top 10 questionable-billing DTS suppliers in 2011.

The Competitive Bidding Program appears to have reduced questionable billing for mail order DTS in CBAs

The amount Medicare allowed for mail order DTS in CBAs for suppliers exhibiting questionable billing decreased by 87 percent ($28.9 million) between 2010 and 2011. This corresponds to when the Competitive Bidding Program went into effect. Questionable billing in non-CBA areas did not have a similar decrease.

As shown in Table 5, the amount Medicare allowed for mail order DTS for suppliers exhibiting questionable billing in CBAs decreased from $33.2 million to $4.3 million between 2010 and 2011. We did not find this trend in areas that were not affected by the Competitive Bidding Program. That is, there was only a small decrease in the amount Medicare allowed for suppliers with questionable billing for mail order DTS for beneficiaries in non-CBA areas (i.e., beneficiaries not affected by the Competitive Bidding Program) between 2010 and 2011.

Table 5: Medicare-Allowed Amounts for Suppliers With Questionable Billing for Mail Order DTS in CBAs and Non-CBA Areas in 2010 and 2011

Medicare-Allowed Amount	2010	2011	Change Between 2010 and 2011
Beneficiaries in CBAs	$33,232,992	$4,291,370	-87%
Beneficiaries in Non-CBA Areas	$395,286,785	$382,894,324	-3%

Source: OIG analysis of Part B data for DTS, 2012.

Additionally, as shown in Table 6, the number of suppliers with questionable billing that provided mail order DTS to beneficiaries in CBAs decreased by 36 percent from 2010 to 2011. We did not find this trend in areas that were not affected by the Competitive Bidding Program. That is, the number of suppliers with questionable billing for mail order DTS associated with beneficiaries in non-CBA areas increased by 6 percent between 2010 and 2011.

Table 6: Number of Suppliers With Questionable Billing for Mail Order DTS in CBAs and Non-CBA Areas in 2010 and 2011

Number of Suppliers	2010	2011	Change Between 2010 and 2011
Beneficiaries in CBAs	303	194	-36%
Beneficiaries in Non-CBA areas	660	697	6%

Source: OIG analysis of Part B data for DTS, 2012.

Based on our analysis of 2010 and 2011 data, these data suggest that the Competitive Bidding Program was successful in reducing the amount

Medicare allowed in questionable billing, and the number of suppliers with questionable billing, for mail order DTS.

See Appendix C for the Medicare-allowed amounts for suppliers with questionable billing, and the number of suppliers with questionable billing, for mail order DTS in CBAs and non-CBA areas. Appendix C also contains these data for non-mail order DTS.

CONCLUSION AND RECOMMENDATIONS

In 2011, Medicare allowed approximately $1.1 billion to 51,695 suppliers for DTS provided to 4.6 million beneficiaries. Recent investigations and prior OIG studies have found that DTS is vulnerable to fraud, waste, and abuse. This report found continued vulnerabilities in Medicare payments for DTS claims.

Specifically, we found that Medicare inappropriately allowed $6 million for DTS claims with three types of errors. Further, we found that in 2011, Medicare allowed $425 million in questionable billing to 10 percent of DTS suppliers. Additionally, 77 percent of suppliers with questionable billing were in 10 geographic areas nationwide. However, based on our data from 2010 and 2011, the Competitive Bidding Program appears to have reduced questionable billing for mail order DTS in CBAs. Similar reductions in questionable billing did not occur in non-CBA areas or for non-mail order DTS.

We recommend that CMS:

Enforce existing edits to prevent inappropriate DTS claims

CMS should enforce claims-processing edits to prevent inappropriate claims that do not include an appropriate diabetes diagnosis code. Additionally, these edits should identify DTS claims that overlap with an inpatient hospital stay or a SNF stay, and flag them for further review to ensure the overlap is appropriate (i.e., on the day of discharge or during a leave of absence).

Increase monitoring of DTS suppliers' Medicare billing

CMS should instruct DME MACs and Medicare Zone Program Integrity Contractors (ZPIC) to increase monitoring of suppliers' DTS claims by using measures of questionable billing similar to those in this report.[67] CMS should develop additional thresholds and new edits for these measures and instruct its contractors to conduct additional review of DTS suppliers that exceed the thresholds. CMS should also consider including these measures of questionable billing in its predictive analytic work.

On July 1, 2013, the national mail order (NMO) Competitive Bidding Program for diabetic testing supplies began. CMS believes the NMO Competitive Bidding Program will reduce the number of mail order DTS suppliers. We encourage CMS to closely monitor suppliers that are

[67] ZPICs perform Medicare integrity work for Medicare Parts A and B. This includes conducting audits, interviewing beneficiaries and providers, and initiating administrative sanctions (including suspending payments, determining overpayments, and referring providers for exclusion from Medicare).

awarded an NMO contract. CMS should also monitor non-NMO suppliers that did not win contracts.

Provide more education to suppliers and beneficiaries about appropriate DTS billing practices

- CMS should educate suppliers about appropriate DTS billing practices. CMS should continue to implement supplier training that addresses the unique requirements of billing Medicare for DTS.
- CMS should educate beneficiaries about how to identify potential fraud, waste, or abuse in DTS by more closely examining their benefits statements and/or better understanding Medicare's payment policies for DTS.

Take appropriate action regarding inappropriate Medicare DTS claims and suppliers with questionable DTS billing

In a separate memorandum, we will refer to CMS for appropriate action a list of suppliers with the inappropriate-billing characteristics that we identified. We will also forward for further analysis the 4,959 DTS suppliers with questionable billing.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS partially concurred with two of our four recommendations and concurred with the remaining two recommendations. CMS acknowledged the high billing rate of DTS and described the steps being taken to address it. These include implementation of the NMO Competitive Bidding Program, which will reduce the cost of mail-order diabetes testing supplies by an average of 72 percent. Further, the payment amounts for non-mail order diabetes testing supplies were reduced to the NMO Competitive Bidding Program amounts on July 1, 2013. CMS noted that implementing market-based payment amounts will make diabetes testing supplies a less-tempting target for fraudulent suppliers.

CMS partially concurred with our first recommendation to enforce existing edits to prevent inappropriate DTS claims. CMS stated that it is already enforcing billing procedures for claims where the beneficiary does not have a diabetes diagnosis. Further, CMS stated that it will implement billing procedures that deny unpaid DME claims that have a service date greater than 2 days before a Part A discharge date or a Part A discharge status that was not to home. CMS should ensure that these edits apply to both inpatient hospital stays and SNF stays.

CMS partially concurred with our second recommendation to increase monitoring of DTS suppliers' Medicare billing. CMS noted that it plans to develop a revised DTS medical review strategy after the NMO Competitive Bidding Program for diabetes test supplies is implemented. While CMS will consider additional automated edits, it cannot commit to implementing edits that require only more medical review, because of resource limitations. CMS also stated that it will closely monitor suppliers in the NMO Competitive Bidding Program and non-mail order DTS suppliers. Additionally, CMS noted that it launched a model in the Fraud Prevention System in January 2013 related to DTS.

CMS concurred with our third recommendation that it provide more education to suppliers and beneficiaries about appropriate DTS billing practices. CMS stated that it has provided extensive education on the definition of "mail order" and the requirements for submitting mail order and non-mail order DTS claims. Additionally, CMS noted that it provides educational materials to beneficiaries, including a handbook mailed to beneficiaries annually about DTS coverage, as well as public service announcements and a letter mailed to beneficiaries about the NMO Competitive Bidding Program.

CMS also concurred with the fourth recommendation that it take appropriate action regarding inappropriate Medicare DTS claims and suppliers with questionable DTS billing. CMS stated that it will forward the list of questionable suppliers to the RACs and DME MACs and will instruct them to consider information in this report when prioritizing their medical review strategies or other interventions.

CMS also provided technical comments. In response, we made revisions to the report, where appropriate. For the full text of CMS's comments, see Appendix D.

APPENDIX A

Geographic Areas of Diabetes Test Strips Suppliers With Four or More Measures of Questionable Billing, 2011

Geographic Area	Medicare-Allowed Amount	Number of Suppliers	Diabetes Test Strips (DTS) Suppliers out of Total DTS Suppliers With Four or More Measures of Questionable Billing *
Miami–Fort Lauderdale–Pompano Beach, FL	$15,480,748.14	2	15%
Atlanta-Sandy Springs-Marietta, GA	$4,360,452.40	2	15%
Cleveland-Elyria-Mentor, OH	$1,970,246.89	1	8%
New York-Northern New Jersey-Long Island, NY-NJ-PA	$591,296.94	1	8%
Dayton, OH	$195,321.57	1	8%
Dallas-Fort Worth-Arlington, TX	$81,481.08	1	8%
El Dorado, AR	$63,749.18	1	8%
Indianapolis-Carmel, IN	$55,894.71	1	8%
San Antonio-New Braunfels, TX	$54,596.44	1	8%
Fairmont, WV	$43,091.05	1	8%
San Juan-Caguas-Guaynabo, PR	$2,757.24	1	8%
National	$22,899,635.64	13	100%

*The percentages do not sum to 100 percent because of rounding.
Source: Office of Inspector General analysis of Part B data for DTS, 2012.

APPENDIX B

Geographic Areas of Top 10 Questionable-Billing Diabetes Test Strips Suppliers, 2011

Supplier Number	Geographic Area	Questionable Medicare-Allowed Amount
Supplier 1	Port St. Lucie-Sebastian-Vero Beach, FL	$114,748,373
Supplier 2	Miami-Fort Lauderdale-Pompano Beach, FL	$19,943,999
Supplier 3	Nashville-Davidson--Murfreesboro--Columbia, TN	$17,932,498
Supplier 4	Nashville-Davidson--Murfreesboro--Columbia, TN	$16,330,932
Supplier 5	Miami-Fort Lauderdale-Pompano Beach, FL	$13,913,613
Supplier 6	Miami-Fort Lauderdale-Pompano Beach, FL	$11,442,097
Supplier 7	Miami-Fort Lauderdale-Pompano Beach, FL	$10,688,470
Supplier 8	Tampa-St. Petersburg-Clearwater, FL	$10,401,737
Supplier 9	New York-Newark-Bridgeport, NY-NJ-CT-PA	$7,763,993
Supplier 10	Miami-Fort Lauderdale-Pompano Beach, FL	$6,722,770

Source: Office of Inspector General analysis of Part B data for diabetes test strips, 2012.

APPENDIX C

Medicare-Allowed Amounts for and Number of Suppliers With Questionable Billing for Mail Order and Non-Mail Order Diabetes Test Strips[1] in Competitive Bidding Areas[2] and Non-Competitive Bidding Areas[3] in 2010 and 2011

Table C-1: Medicare-Allowed Amounts for and Number of Suppliers With Questionable Billing for Mail Order DTS in CBAs in 2010 and 2011

Measure of Questionable Billing	2010	2011	Change From 2010 to 2011
Beneficiaries associated with multiple DTS claims submitted by the same supplier during overlapping time periods:			
Medicare-allowed amount	$772,156	$6,024	-99%
Number of suppliers	24	8	-67%
Beneficiaries associated with DTS claims at perfectly regular intervals:			
Medicare-allowed amount	$5,130,164	$1,040,701	-80%
Number of suppliers	133	52	-61%
Beneficiaries associated with overlapping DTS claims from more than one supplier:			
Medicare-allowed amount	$5,188,186	$397,390	-92%
Number of suppliers	108	73	-32%
DTS claims for beneficiaries in excess of utilization guidelines:			
Medicare-allowed amount	$22,143,612	$2,847,988	-87%
Number of suppliers	178	113	-37%
Total Medicare-allowed amount	**$33,232,992**	**$4,291,370**	**-87%**
Total number of suppliers	**303**	**194**	**-36%**

Source: Office of Inspector General (OIG) analysis of Part B data for DTS, 2012.
[1] DTS.
[2] CBAs.
[3] Non-CBA areas.

Table C-2: Medicare-Allowed Amounts for and Number of Suppliers With Questionable Billing for Mail Order DTS in Non-CBA Areas in 2010 and 2011

Measure of Questionable Billing	2010	2011	Change From 2010 to 2011
Beneficiaries associated with multiple DTS claims submitted by the same supplier during overlapping time periods:			
Medicare-allowed amount	$7,652,322	$5,972,260	-22%
Number of suppliers	46	54	17%
Beneficiaries associated with DTS claims at perfectly regular intervals:			
Medicare-allowed amount	$53,218,904	$58,709,687	10%
Number of suppliers	319	352	10%
Beneficiaries associated with overlapping DTS claims from more than one supplier:			
Medicare-allowed amount	$72,763,498	$98,380,726	35%
Number of suppliers	164	185	13%
DTS claims for beneficiaries in excess of utilization guidelines:			
Medicare-allowed amount	$261,691,402	$219,911,302	-16%
Number of suppliers	355	313	-12%
Total Medicare-allowed amount	**$395,286,785**	**$382,894,324**	**-3%**
Total number of suppliers	**660**	**697**	**6%**

Source: OIG analysis of Part B data for DTS, 2012.

Table C-3: Medicare-Allowed Amounts for and Number of Suppliers With Questionable Billing for Non-Mail Order DTS in CBAs in 2010 and 2011[68]

Measure of Questionable Billing	2010	2011	Change From 2010 to 2011
Beneficiaries associated with multiple DTS claims submitted by the same supplier during overlapping time periods:			
Medicare-allowed amount	$457,293	$361,111	-21%
Number of suppliers	86	113	31%
Beneficiaries associated with DTS claims at perfectly regular intervals:			
Medicare-allowed amount	$797,742	$1,880,789	136%
Number of suppliers	123	145	18%
Beneficiaries associated with overlapping DTS claims from more than one supplier:			
Medicare-allowed amount	$310,141	$323,994	4%
Number of suppliers	116	85	-27%
DTS claims for beneficiaries in excess of utilization guidelines:			
Medicare-allowed amount	$1,986,617	$4,556,094	129%
Number of suppliers	260	273	5%
Total Medicare-allowed amount	**$3,550,236**	**$7,121,368**	**101%**
Total number of suppliers	**519**	**544**	**5%**

Source: OIG analysis of Part B data for DTS, 2012.

[68] As shown in Table C-3, there was a 101 percent increase in the amount Medicare allowed in questionable billing for non-mail order DTS in CBAs between 2010 and 2011. Prior OIG work has determined that this was in part due to suppliers' improperly billing mail order DTS as non-mail order. OIG, *Supplier Billing for Diabetes Test Strips and Inappropriate Supplier Activities in Competitive Bidding Areas* (OEI-04-11-00760), November 2012.

Table C-4: Medicare-Allowed Amounts for and Number of Suppliers With Questionable Billing for Non-Mail Order DTS in Non-CBA Areas in 2010 and 2011			
Measure of Questionable Billing	**2010**	**2011**	**Change From 2010 to 2011**
Beneficiaries associated with multiple DTS claims submitted by the same supplier during overlapping time periods:			
Medicare-allowed amount	$4,662,777	$4,041,784	-13%
Number of suppliers	649	676	4%
Beneficiaries associated with DTS claims at perfectly regular intervals:			
Medicare-allowed amount	$4,434,763	$5,556,782	25%
Number of suppliers	682	711	4%
Beneficiaries associated with overlapping DTS claims from more than one supplier:			
Medicare-allowed amount	$2,602,851	$3,204,223	23%
Number of suppliers	389	422	8%
DTS claims for beneficiaries in excess of utilization guidelines:			
Medicare-allowed amount	$15,590,781	$14,483,191	-7%
Number of suppliers	1,269	1,188	-6%
Total Medicare-allowed amount	**$27,266,702**	**$27,243,881**	**0%**
Total number of suppliers	**2,708**	**2,711**	**0%**

Source: OIG analysis of Part B data for DTS, 2012.

APPENDIX D

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: APR 3 0 2013

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: *Inappropriate and Questionable Medicare Billing for Diabetes Test Strips* (OEI-04-11-00330)

Thank you for the opportunity to review and comment on the OIG draft report titled, "Inappropriate and Questionable Medicare Billing for Diabetes Test Strips, (OEI-04-11-00330)." The Centers for Medicare & Medicaid Services (CMS) appreciates the time and resources OIG has invested to review this issue. OIG's audit focused on Medicare-allowed 2010 and 2011 claims for diabetes test strips (DTS). OIG also examined instances of allowed claims that overlapped with dates for which a patient was in a hospital or skilled nursing facility.

The CMS is aware of, and acknowledges, the high Medicare billing rate of DTS and is proactively taking steps to address it. This July, CMS will update its claims processing procedures to ensure that Medicare does not pay for durable medical equipment (DME) while a beneficiary is in an inpatient hospital. Also in July, CMS will implement the National Mail Order Program under competitive bidding for diabetic supplies. This program will reduce the cost of mail-order diabetic testing supplies by an average of 72 percent. Under the American Taxpayer Relief Act of 2012, the fee schedule amounts for retail diabetic testing supplies will be reduced to the National Mail Order Program amounts starting on July 1. Implementing market-based payment amounts will make diabetic testing supplies a less tempting target for fraudulent suppliers.

We have reviewed the report and responded to your recommendations below.

OIG Recommendation 1

Enforce existing edits to prevent inappropriate DTS claims. CMS should enforce claims-processing edits to prevent inappropriate claims that do not include an appropriate diabetes diagnosis code. Additionally, these edits should identify DTS claims that overlap with an inpatient hospital stay or a skilled nursing facility stay and flag them for further review to ensure the overlap is appropriate (i.e., on the day of discharge or during a leave of absence).

CMS Response

The CMS partially concurs with this recommendation. CMS is already enforcing claims-processing procedures to prevent payments for claims where the beneficiary does not have a diabetes diagnosis. CMS will work to ensure that these processes are working appropriately and update them if necessary.

In July, CMS will implement billing procedures that will ensure DME claims (e.g., diabetic test strips) with a date of service greater than 2 days prior to a Part A discharge date or a Part A discharge status that was not to home will deny the DME claim (if it hasn't been paid yet), or prompt the payment contractor to collect the overpayment related to the DME claim (if the claim was paid already).[1] The corrective action will be monitored for progress made and results achieved.

OIG Recommendation 2

Increase monitoring of DTS suppliers' Medicare billing. CMS should instruct Durable Medical Equipment Medicare Administrative Contractors (DME MACs) and Medicare Zone Program Integrity Contractors (ZPICs) to increase monitoring of suppliers' DTS claims by using measures of questionable billing similar to those in this report. CMS should develop additional thresholds and new edits for these measures and instruct its contractors to conduct additional review of DTS suppliers that exceed the thresholds. CMS should also consider including these measures of questionable billing in its predictive analytic work.

On July 1, 2013, the national mail order (NMO) Competitive Bidding Program for diabetic testing supplies will begin. CMS believes the NMO Competitive Bidding Program will drastically reduce the number of mail order DTS suppliers. We encourage CMS to closely monitor suppliers that are awarded an NMO contract under the NMO program. CMS should also monitor non-NMO suppliers that did not win contracts.

CMS Response

The CMS partially concurs with this recommendation. CMS is currently working with our contractors to address DTS issues. The DME MACs work collaboratively to decrease improper payments for DTS. In 2010, they implemented a Documentation Compliance Review project to focus on the critical issue of submitting proper supporting documentation. The DME MACs actively educate the supplier community by targeting the top billing error categories and reviewing DTS claims to reduce overpayments and refine educational efforts.

The CMS plans to develop a revised DTS medical review strategy after the NMO Competitive Bidding Program for diabetic testing supplies is implemented in July 2013. While CMS might consider additional automated edits, CMS cannot commit to implementing edits that only require more medical review, due to resource limitations.

[1] Change Request (CR) 8172 titled, "Revision to CWF and VMS: Reject or Informational Unsolicited Response (IUR) Edit for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Provided During an Inpatient Stay" will be implemented in July 2013.

The Competitive Bidding Program only contracts with qualified, accredited suppliers that meet financial standards. Contract suppliers were carefully screened and selected based on a variety of qualifications. Medicare requires that all suppliers in the program meet strict quality and business standards and be accredited by a national accreditation organization. In addition to stringent standards of participation, CMS closely monitors DMEPOS competitive bidding program contract suppliers using a variety of methods. This monitoring will continue for the NMO program, CMS will also be closely monitoring non-mail order DTS.

In addition, CMS launched a model in the Fraud Prevention System in January 2013 related to Diabetic Testing Supplies. CMS will consider the recommendations of this report for continued refinement and testing of the model.

OIG Recommendation 3

Provide more education to suppliers and beneficiaries about appropriate DTS billing practices.

- CMS should educate suppliers about appropriate DTS billing practices. CMS should continue to implement supplier training that addresses the unique requirements of billing Medicare for DTS.

- CMS should educate beneficiaries about how to identify potential fraud, waste, or abuse in DTS by more closely examining their benefits statements and/or better understanding Medicare's reimbursement policies for DTS.

CMS Response

The CMS concurs. CMS has provided extensive education on the definition of mail-order and the requirements for submitting mail order and non-mail-order claims. CMS will continue to educate suppliers leading up to the implementation of the NMO program.

To educate beneficiaries, CMS issues the Medicare & You Handbook which includes information about coverage of diabetes testing supplies and reminds beneficiaries to check their benefit statements for fraud. The handbook is mailed annually to each beneficiary household. CMS recently re-designed Medicare.gov to highlight Medicare benefits on the home page. CMS is also creating a number of beneficiary-oriented drop-in articles and public service announcements (PSAs) about the NMO program. In addition, CMS is mailing a letter to beneficiaries about the national mail-order program for diabetic testing supplies that will clearly explain what Medicare pays for testing supplies.

OIG Recommendation 4

Take appropriate action regarding inappropriate Medicare DTS claims and suppliers with questionable DTS billing. In a separate memorandum, we will provide CMS with information about the inappropriate claims we identified so that it may take appropriate action. We will also forward for further analysis the 7,684 DTS suppliers with questionable billing.

CMS Response

The CMS concurs with this recommendation. CMS requests that OIG furnish the necessary data (Medicare contractor numbers, provider number, claims information including the paid date, claim number, Health Care Common Procedure Code number and Health Insurance Claim numbers, etc.) to follow up on the claims referenced in the memorandum mentioned above. In addition, CMS requests that Medicare contractor-specific data be written to separate CD-ROMs or sent to a secure portal to better facilitate the transfer of information to the appropriate contractors.

Upon receipt of the files from OIG, CMS will take appropriate action on the erroneously allowed claims identified in the sample. CMS will forward the listing of questionable claims to the Recovery Auditors and Medicare Administrative Contractors (MACs). The Recovery Auditors review Medicare claims on a post-payment basis and are tasked with identifying inappropriate payments. While CMS does not mandate areas for Recovery Audit review, we will share this information with them. We will instruct the MACs to consider this issue when prioritizing their medical review strategies or other interventions.

The CMS will also take appropriate administrative action as it relates to the work of the Zone Program Integrity Contractors (ZPICs), our anti-fraud contractors.

The CMS appreciates OIG's efforts and insight on this report. CMS looks forward to continually working with OIG on issues related to waste, fraud and abuse in the Medicare program.

Attachment

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This report was prepared under the direction of Dwayne Grant, Regional Inspector General for Evaluation and Inspections in the Atlanta regional office, and Jaime Durley, Deputy Regional Inspector General.

Starr Kidda served as the lead analyst for this study. Other principal Office of Evaluation and Inspections staff from the Atlanta regional office who conducted the study include Rachel Daiber. Central office staff who provided support include Berivan Demir Neubert, Scott Horning, Scott Manley, and Christine Moritz.

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