Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CGS ADMINISTRATORS, LLC, MADE MEDICARE PAYMENTS FOR DIABETIC TEST STRIPS WHEN BENEFICIARIES HAD NOT NEARLY EXHAUSTED PREVIOUSLY DISPENSED SUPPLIES

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Office of Inspector General

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EXECUTIVE SUMMARY

CGS Administrators, LLC, made Medicare payments for 2012 to suppliers that dispensed diabetic test strips when the beneficiaries had not nearly exhausted test strips previously dispensed by different suppliers, resulting in potential overpayments of an estimated $7.6 million.

WHY WE DID THIS REVIEW

In calendar year (CY) 2012, Medicare allowed payment of approximately $1 billion for home blood-glucose test strips (test strips) dispensed to Medicare beneficiaries nationwide. A previous Office of Inspector General review found that for CY 2007, CGS Administrators, LLC (CGS), a Medicare contractor, made inappropriate payments to multiple suppliers that submitted claims with overlapping service dates for test strips and lancets dispensed to the same beneficiary. These payments were inappropriate because the suppliers dispensed test strips and lancets when the beneficiaries had not nearly exhausted the previously dispensed supplies. In response to one of the recommendations in our report, CGS stated that it had implemented additional system edits to identify and deny such claims. We conducted this followup review to determine whether those system edits had been implemented and were effective in preventing overpayments.

Our objective was to determine whether CGS made payments for CY 2012 to suppliers that dispensed test strips when the beneficiaries had not nearly exhausted test strips previously dispensed by different suppliers.

BACKGROUND

Medicare Part B covers test strips that physicians prescribe for diabetics, whether they are insulin-treated or non-insulin-treated. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a test strip, and inserts the strip into a home blood-glucose monitor to obtain a reading of the blood-sugar level. Medicare covers up to 100 test strips every month for insulin-treated diabetics and every 3 months for non-insulin-treated diabetics (utilization guidelines).

To be reimbursed for a claim for any quantity of test strips, the supplier is required to maintain (1) a physician order containing the items to be dispensed, the specific frequency of testing, and the physician's signature with the date and (2) proof of delivery. There are additional documentation requirements for reimbursement of a claim for a quantity of test strips that exceeds the utilization guidelines. In addition, the supplier may refill an order only when the beneficiary requests that the test strips be dispensed and has nearly exhausted the previous supply, which is no sooner than 10 calendar days before the end of usage for the current product.

Suppliers must submit claims to the durable medical equipment Medicare administrative contractor (contractor) that serves the State or territory in which the Medicare beneficiary permanently resides. The contractor's responsibilities include, but are not limited to, performing edits on these claims to determine whether they are complete and reimbursable, calculating Medicare payment amounts and remitting payments to the appropriate parties, and educating

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

HOW WE CONDUCTED THIS REVIEW

We obtained CY 2012 claim data consisting of 3.2 million line items for test strips for which CGS (the contractor for Jurisdiction C, which covers 15 States and 2 U.S. territories) paid approximately $269 million to suppliers. A line item represented a supply of test strips included on a claim with service beginning and ending dates (e.g., May 22, 2012, through August 21, 2012). We analyzed the claim data and identified 105,933 line items that each had service dates that overlapped service dates of a line item on a prior claim submitted by a different supplier for test strips dispensed to the same beneficiary. CGS paid approximately $10.3 million to suppliers for the 105,933 line items. We reviewed a random sample of 100 of these line items.

We reviewed the claim data and supplier documentation to determine whether each line item of test strips on the prior claim was nearly exhausted when the new supply of test strips was dispensed (i.e., whether the test strips were dispensed sooner than 10 calendar days before the expected end of usage for the current product). We did not review the sampled line items for compliance with other Medicare requirements. Also, because we did not have a medical review contractor review the supplier documentation, the medical necessity of the test strips dispensed to the beneficiaries in our sample was not determined. Therefore, our determination of whether CGS made overpayments for the sampled line items was limited.

WHAT WE FOUND

CGS made payments for CY 2012 to suppliers that dispensed test strips when the beneficiaries had not nearly exhausted test strips previously dispensed by different suppliers. Of the 100 line items in our sample, 12 were allowable. We considered an additional 17 line items to be non-errors because the suppliers were no longer in business and the supporting documentation could not be obtained for review. The remaining 71 line items may not have been allowable because the suppliers dispensed test strips before the beneficiaries' existing supplies were nearly exhausted; i.e., sooner than 10 calendar days before the expected end of usage for the current product. For 35, or almost half, of the 71 line items, the suppliers dispensed test strips when there were more than 60 days remaining in the beneficiaries' existing supplies.

On the basis of our sample results, we estimated that $7.6 million, or 74 percent, of the $10.3 million that CGS paid to suppliers may have been unallowable for Medicare reimbursement. (Because a medical review of the sampled line items was not performed, we could not conclusively determine whether the $7.6 million represented overpayments.) These potential overpayments occurred because CGS's system edit was not designed to identify for review claims submitted by multiple suppliers with overlapping service dates for test strips dispensed to the same beneficiary. Rather, the system edit was designed to identify claims with a quantity of test strips that exceeded the utilization guidelines.

WHAT WE RECOMMEND

We recommend that CGS implement a system edit to identify for review claims submitted by multiple suppliers with overlapping service dates for test strips dispensed to the same beneficiary. Implementing this edit could have saved Medicare an estimated $7.6 million for CY 2012.

AUDITEE COMMENTS AND OUR RESPONSE

In written comments on our draft report, CGS did not concur with our findings or recommendation. CGS officials stated that they disagreed with the methodology we used in the development of our data and results. However, the officials stated that they had submitted proposals to CMS for a system edit that would address our recommendation.

After reviewing CGS's comments, we maintain that our findings and recommendation are valid.

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INTRODUCTION

WHY WE DID THIS REVIEW

In calendar year (CY) 2012, Medicare allowed payment of approximately $1 billion for home blood-glucose test strips (test strips) dispensed to Medicare beneficiaries nationwide. A previous Office of Inspector General (OIG) review[1] found that for CY 2007, CGS Administrators, LLC (CGS),[2] a Medicare contractor, made inappropriate payments to multiple suppliers that submitted claims with overlapping service dates for test strips and lancets dispensed to the same beneficiary. These payments were inappropriate because the suppliers dispensed test strips and lancets when the beneficiaries had not nearly exhausted the previously dispensed supplies. In response to one of the recommendations in our report, CGS stated that it had implemented additional system edits[3] to identify and deny such claims. We conducted this followup review to determine whether those system edits had been implemented and were effective in preventing overpayments.

OBJECTIVE

Our objective was to determine whether CGS made payments for CY 2012 to suppliers that dispensed test strips when the beneficiaries had not nearly exhausted test strips previously dispensed by different suppliers.

BACKGROUND

The Medicare Program

The Medicare program provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the program. Medicare Part B provides supplementary medical insurance for medical and other health services.

Medicare Coverage of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Medicare Part B covers durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).[4] 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

[1] *Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C* (A-09-08-00045), issued January 21, 2011. This review included a medical review to determine the allowability of claims for test strips and lancets.

[2] CGS was formerly CIGNA Government Services, LLC. This change was effective June 1, 2011.

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

[4] The Social Security Act (the Act) §§ 1832(a)(1), 1861(s)(6), and 1861(n).

supplies, such as test strips and lancets for patients for whom the glucose monitor is covered. To be paid by Medicare, a service or an item must be reasonable and necessary for the diagnosis or treatment of illness or injury or improve the functioning of a malformed body member (the Act § 1862(a)(1)(A)).

CMS contracted with four durable medical equipment Medicare administrative contractors (contractors) to process and pay Medicare Part B claims for DMEPOS. Each contractor processes claims for one of four jurisdictions, which include specific States and territories. These jurisdictions are known as Jurisdictions A, B, C, and D. Suppliers must submit claims to the contractor that serves the State or territory in which the Medicare beneficiary permanently resides.

The contractors' responsibilities include, but are not limited to, (1) receiving Medicare Part B claims for DMEPOS suppliers and beneficiaries within their jurisdictions, (2) performing edits on these claims to determine whether they are complete and reimbursable, (3) calculating Medicare payment amounts and remitting payments to the appropriate parties, and (4) educating DMEPOS suppliers on Medicare requirements and billing procedures.

Home Blood-Glucose Test Strips

Medicare Part B covers test strips that physicians prescribe for diabetics, whether they are insulin-treated or non-insulin-treated. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a test strip, and inserts the strip into a home blood-glucose monitor to obtain a reading of the blood-sugar level.

The *Medicare National Coverage Determinations Manual* (the Manual) specifies coverage of test strips for patients who meet certain conditions and use home blood-glucose monitors to better control their glucose levels by frequently checking those levels and contacting their attending physicians for advice and treatment.[5] However, the Manual does not specify utilization guidelines and documentation requirements for test strips.

The Local Coverage Determinations (LCDs) implemented by the contractors establish utilization guidelines and documentation requirements for test strips. These LCDs state that the quantity of test strips that Medicare covers depends on the beneficiary's usual medical needs. The LCDs for the contractors further state that Medicare covers up to 100 test strips every month (i.e., the quantity for a testing frequency of approximately 3 times per day) for insulin-treated diabetics and up to 100 test strips every 3 months (i.e., the quantity for a testing frequency of approximately 1 time per day) for non-insulin-treated diabetics.[6]

[5] The Manual, Pub. No. 100-03, chapter 1, § 40.2, effective June 19, 2006.

[6] For a 1-year period, Medicare covers 1,200 test strips for insulin-treated beneficiaries and 400 test strips for non-insulin-treated beneficiaries.

Medicare Reimbursement Requirements for Test Strips

To be reimbursed for a claim for any quantity of test strips, the supplier is required to maintain (1) a physician order containing the items to be dispensed, the specific frequency of testing, and the physician's signature with the date and (2) proof of delivery. There are additional documentation requirements for reimbursement of a claim for a quantity of test strips that exceeds the utilization guidelines (high-utilization claim).

The supplier must also document a request to refill an order for test strips. The supplier may refill an order only when the beneficiary requests that the supplies be dispensed. The supplier must contact the beneficiary before dispensing the refill to ensure that the test strips remain reasonable and necessary and that existing supplies are nearly exhausted and to confirm any changes to the order. The supplier must dispense the test strips no sooner than 10 calendar days before the end of usage for the current product.

CGS Administrators, LLC

CGS is the contractor for Jurisdiction C. CGS processes and pays DMEPOS claims for Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, U.S. Virgin Islands, Virginia, and West Virginia.

Previous Office of Inspector General Reviews of Diabetic Testing Supplies

OIG has conducted other reviews of Medicare payments for diabetic testing supplies. For example, we reviewed high-utilization claims for test strips and lancets for CY 2007 for all four jurisdictions, which included all 50 States, 5 territories, and the District of Columbia. We estimated that Medicare improperly paid suppliers approximately $209 million for claims that we identified as high-utilization claims. Of this amount, $96.6 million was improperly paid to suppliers for test strips and lancets dispensed to beneficiaries in Jurisdiction C. See Appendix A for related OIG reports on Medicare claims for diabetic testing supplies.

HOW WE CONDUCTED THIS REVIEW

We obtained CY 2012 claim data consisting of 3,214,925 line items for test strips for which CGS paid $268,974,290 to suppliers. A line item represented a supply of test strips included on a claim with service beginning and ending dates (e.g., May 22, 2012, through August 21, 2012). We analyzed the claim data and identified 105,933 line items that each had service dates that overlapped service dates of a line item on a prior claim submitted by a different supplier for test

strips dispensed to the same beneficiary.[7] CGS paid $10,339,648 to suppliers for the 105,933 line items. We reviewed a random sample of 100 of these line items.

We reviewed the claim data and supplier documentation to determine whether each line item of test strips on the prior claim was nearly exhausted when the new supply of test strips was dispensed (i.e., whether the test strips were dispensed sooner than 10 calendar days before the expected end of usage for the current product). We did not review the sampled line items for compliance with other Medicare requirements. Also, because we did not have a medical review contractor review the supplier documentation, the medical necessity of the test strips dispensed to the beneficiaries in our sample was not determined. Therefore, our determination as to whether CGS made overpayments for the sampled line items was limited.

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 contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates.

FINDINGS

CGS made payments for CY 2012 to suppliers that dispensed test strips when the beneficiaries had not nearly exhausted test strips previously dispensed by different suppliers. Of the 100 line items in our sample, 12 were allowable. We considered an additional 17 line items to be non-errors because the suppliers were no longer in business and the supporting documentation could not be obtained for review. The remaining 71 line items may not have been allowable because the suppliers dispensed test strips before the beneficiaries' existing supplies were nearly exhausted; i.e., sooner than 10 calendar days before the expected end of usage for the current product. For 35, or almost half, of the 71 line items, the suppliers dispensed test strips when there were more than 60 days remaining in the beneficiaries' existing supplies.

On the basis of our sample results, we estimated that $7,639,072, or 74 percent, of the $10,339,648 that CGS paid to suppliers may have been unallowable for Medicare reimbursement. (Because a medical review of the sampled line items was not performed, we could not conclusively determine whether the $7,639,072 represented overpayments.) These potential overpayments occurred because CGS's system edit was not designed to identify for review claims submitted by multiple suppliers with overlapping service dates for test strips

[7] We included only the line items for beneficiaries whose use of test strips exceeded the utilization guidelines during CY 2012 (i.e., non-insulin-treated beneficiaries who received more than 400 test strips and insulin-treated beneficiaries who received more than 1,200 test strips). In addition, we included only the line items whose service dates overlapped more than 10 calendar days with a line item on the immediately preceding claim (based on the service beginning dates), which was dispensed by a different supplier, for the same beneficiary. We did not include line items that had been reviewed by CGS or the recovery audit contractors.

dispensed to the same beneficiary. Rather, the system edit was designed to identify claims with a quantity of test strips that exceeded the utilization guidelines.

FEDERAL REQUIREMENTS

The *Medicare Program Integrity Manual* states:

> For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order…. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product.[8]

CGS's LCD L11520[9] states: "Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization." The LCD also states that test strips are covered if the beneficiary has nearly exhausted the supply of test strips that had been previously dispensed; otherwise, the test strips will be denied as not reasonable or necessary.

CGS MADE PAYMENTS TO SUPPLIERS THAT DISPENSED TEST STRIPS BEFORE THE BENEFICIARIES' EXISTING SUPPLIES WERE NEARLY EXHAUSTED

CGS made payments for CY 2012 to suppliers that dispensed test strips when the beneficiaries had not nearly exhausted test strips previously dispensed by different suppliers. For 71 of the 100 line items in our sample, the suppliers dispensed test strips before the beneficiaries' existing supplies were nearly exhausted. Specifically, for each line item, the supply of test strips was dispensed sooner than 10 calendar days before the expected end of usage of the beneficiary's existing supply of test strips.

For example, a physician ordered a testing frequency of once a day for a non-insulin-treated beneficiary. One supplier submitted a claim with service dates from May 22, 2012, through August 21, 2012, for 200 test strips dispensed to this beneficiary.[10] The supplier of the sampled line item dispensed 100 test strips to the same beneficiary on July 14, 2012, when the beneficiary would have used only 53 of the 200 test strips dispensed by the prior supplier, based on a testing frequency of once per day. This indicates that the supplier of the sampled line item dispensed the test strips when the beneficiary should have had a 147-day supply of test strips remaining from a different supplier.

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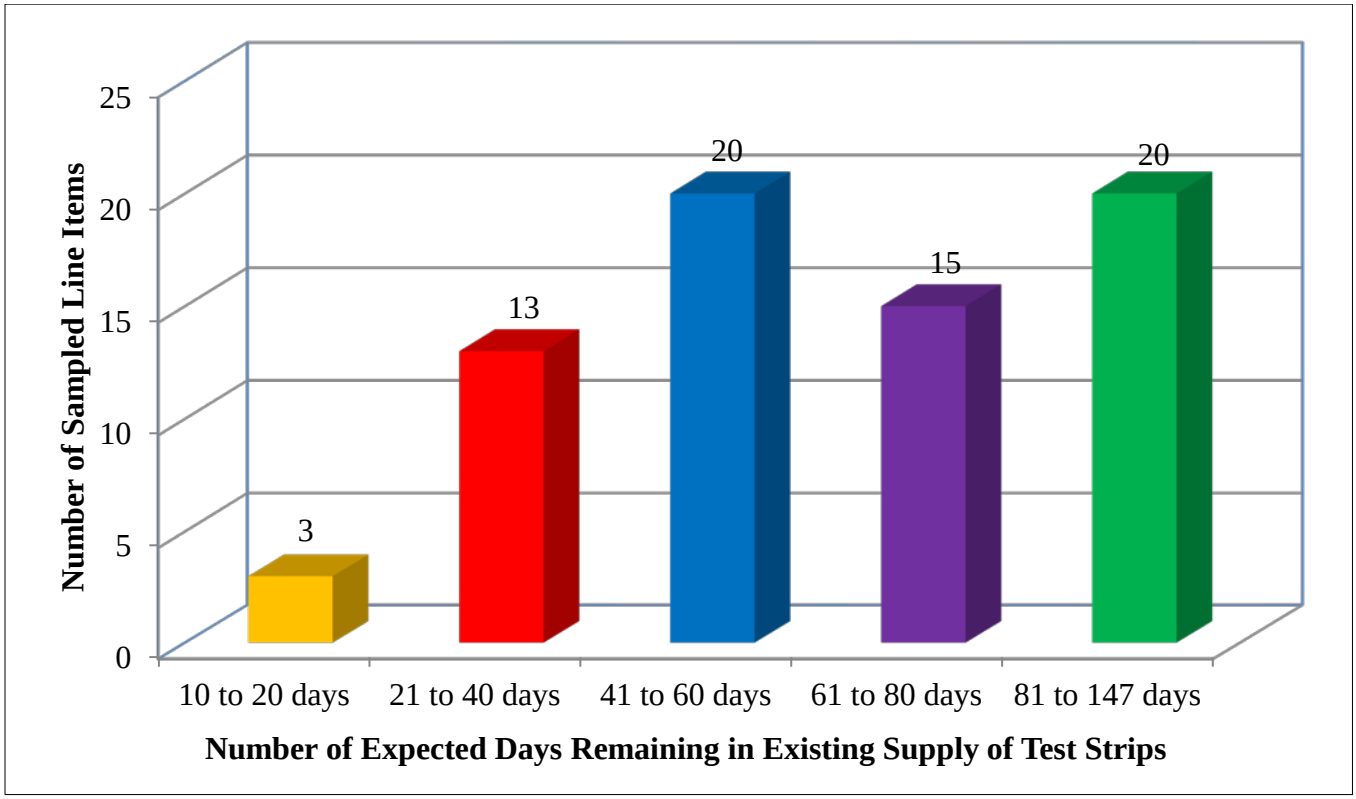
[8] Pub. No. 100-08, chapter 5, § 5.2.6.

[9] LCD L11520 was revised during our audit period. However, the requirements listed were applicable throughout our audit period.

[10] On the basis of the testing frequency shown on the physician's order, the supplier should have dispensed only 100 test strips to the beneficiary. Although this line item was not in our sample, we notified CGS of this potential error.

For 35, or almost half, of the 71 sampled line items, the suppliers dispensed test strips when there should have been more than 60 days remaining in the beneficiaries' existing supplies. The figure below shows the number of sampled line items associated with different ranges of days that should have been remaining in the beneficiaries' existing supplies of test strips when the suppliers dispensed test strips for the 71 sampled line items.

Figure: Number of Sampled Line Items Associated With Different Ranges of Expected Days Remaining in the Beneficiaries' Existing Supplies of Test Strips



For the 71 line items in our sample, CGS made $7,211 in Medicare payments to suppliers that dispensed test strips when the beneficiaries had not nearly exhausted test strips previously dispensed by different suppliers. On the basis of our sample results, we estimated that $7,639,072, or 74 percent, of the $10,339,648 that CGS paid to suppliers may have been unallowable for Medicare reimbursement. Because a medical review of the sampled line items was not performed, we could not conclusively determine whether the $7,639,072 represented overpayments.

CGS'S SYSTEM EDITS WERE NOT DESIGNED TO IDENTIFY TEST STRIP CLAIMS WITH OVERLAPPING SERVICE DATES

In response to a recommendation in our previous report, CGS stated that it had implemented additional edits "to identify and deny claims from multiple suppliers with overlapping dates of service for the same beneficiary."

In July 2009, CGS implemented a system edit that was designed to target high-utilization claims submitted by multiple suppliers. When a supplier submits a claim for test strips for a beneficiary, the edit looks back 80 days from the beginning date of service on the claim to determine whether a different supplier dispensed test strips to the same beneficiary. If so, the system determines whether the total number of test strips dispensed for the 80-day period exceeds a predefined number of test strips.[11] If CGS paid for more than the predefined number of test strips during that 80-day period, the system generates a letter to the supplier requesting documentation to support the claim. The documentation provided by the supplier is then reviewed by CGS's medical review staff, who determine whether the claim is allowable.[12]

According to CGS officials, this system edit would also detect claims with overlapping service dates. However, the edit was not specifically designed to identify for review claims submitted by multiple suppliers with overlapping service dates for test strips dispensed to the same beneficiary. Rather, the edit was designed to identify claims with a quantity of test strips that exceeded the utilization guidelines. Because the edit does not specifically target claims with overlapping service dates, unallowable claims with overlapping service dates may bypass the edit if the quantity of test strips dispensed to the beneficiary does not exceed the edit's threshold.

CGS could have saved Medicare an estimated $7,639,072 for CY 2012 if its system edit had been designed to identify for review test strip claims submitted by multiple suppliers with overlapping service dates.

RECOMMENDATION

We recommend that CGS implement a system edit to identify for review claims submitted by multiple suppliers with overlapping service dates for test strips dispensed to the same beneficiary. Implementing this edit could have saved Medicare an estimated $7,639,072 for CY 2012.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CGS did not concur with our findings or recommendation. CGS officials stated that they disagreed with the methodology we used in the development of our data and results. Although CGS did not concur with our recommendation, it stated that it had submitted proposals to CMS that advocated for a multisupplier automated editing solution and that this solution would satisfy our recommendation. In addition, CGS stated that it continued to seek additional strategies to address the overutilization of testing supplies and provided information on specific actions taken. CGS's comments are included in their entirety as Appendix E.[13]

[11] In CY 2012, the system edit's threshold exceeded the utilization guidelines and varied depending on CGS's workload.

[12] According to CGS, as a result of this edit, in CY 2012 it reviewed 18,655 test strip claims totaling $7,089,586 and denied 18,446 of these claims totaling $6,975,505.

[13] We redacted confidential information that was included in CGS's comments.

After reviewing CGS's comments, we maintain that our findings and recommendation are valid.

MEDICAL REVIEW WAS NOT CONDUCTED

Auditee Comments

CGS stated that conducting medical review on claims is the only way to definitively establish the medical necessity of additional testing supplies and that these claims should be paid. It also stated that the overpayment amount in our report may have been overestimated because we did not conduct medical review. Further, CGS stated that the utilization guidelines included in our report give the impression that payment coverage terminates at 100 test strips per month for insulin-treated diabetics and 100 test strips per 3-month period for non-insulin-treated diabetics. CGS stated that the LCD defines this as average usage and that testing more frequently may be warranted if medical necessity requires it. CGS commented that one of the key issues with our report is that we did not consider medical necessity when determining whether payment should have been made but drew "a hard line" at the point of average usage and considered any additional test strips unnecessary.

Office of Inspector General Response

We acknowledge that conducting medical review is the only way to definitively establish the allowability of the sampled line items. For that reason, we state in our report that because we did not conduct such a review, we could not conclusively determine whether the $7.6 million represented overpayments. We also state in our report that Medicare may cover a quantity of test strips that exceeds the utilization guidelines if additional documentation requirements are met. In addition, we did not disallow line items simply because they exceeded the LCD's utilization guidelines. We explain in our report that the calculation of the expected number of test strips that the beneficiary would have had on hand when the sampled item was dispensed was based on the testing frequency shown on the physician's order (even if it exceeded the utilization guidelines).

CGS'S SYSTEM EDIT WAS DESCRIBED INCORRECTLY

Auditee Comments

CGS disagreed with our statement that potential overpayments occurred because CGS's system edit was not designed to identify for review claims submitted by multiple suppliers with overlapping service dates for test strips dispensed to the same beneficiary. CGS said that our statement that the edit was designed to identify claims with a quantity of test strips that exceeded the utilization guidelines was incorrect. CGS stated that although its edits were not designed "the way the OIG thought they would be (i.e., only selecting claims if the dates overlapped with another claim), they were set up the way CGS intended using multiple factors." CGS stated: "By selecting claims with over-utilization (based on claims billed by multiple suppliers with overlapping dates within an 83 day period), CGS is targeting the claims most likely to be denied and which can be managed within funding/staffing levels as designed in the [medical review strategy]." CGS also stated that, for test strips, it has "a manual review prepay complex edit and

two automated edits … that utilize multiple factors, including claims billed by multiple suppliers in an 83 day period and overutilization."

Office of Inspector General Response

We explain in our report that CGS's edit was designed to select high-utilization claims submitted by multiple suppliers, and CGS acknowledged in its comments that its edit was not designed to select claims only in cases in which the service dates overlapped with another claim. During interviews with CGS officials, they stated that their edits were for high-utilization claims, not specifically for claims with overlapping service dates, and that the 80-day "look-back" period helps detect claims with overlapping service dates.

ESTIMATE OF POTENTIAL OVERPAYMENT MAY BE INCORRECT

Auditee Comments

CGS disagreed with our estimate that $7.6 million could have been saved if its system edit had been designed to identify for review test strip claims submitted by multiple suppliers with overlapping service dates. CGS stated that this assumes that medical review would have had the capacity to review all of the claims meeting this parameter. CGS also stated that CMS had declined its request for additional funding to conduct 100-percent prepayment review of these types of claims. Further, CGS stated that our estimate assumes that medical review "would not have otherwise reviewed any of these claims; however, it is likely that some of the claims would have been reviewed through the prepayment automated routine and complex edits that existed within Medical Review in 2012."

Office of Inspector General Response

We explain in our report that our estimate represents potential overpayments and that we could not conclusively determine whether the $7.6 million represents overpayments. Further, when creating our sampling frame, we requested a list of test strip claims that had been reviewed by CGS. The line items included in those claims were removed from our sampling frame; therefore, our estimate included only line items that had not been selected for review by any of CGS's system edits.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicare Market Shares of Mail Order Diabetes Test Strips 3–6 Months After the Start of the National Mail Order Program	OEI-04-13-00682	11/25/2014
Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail Order Program	OEI-04-13-00681	6/20/2014
Medicare Market Shares of Mail Order Diabetes Test Strips From July – September 2013	OEI-04-13-00680	6/13/2014
Results of Reviews at Three Suppliers of Diabetic Testing Supplies	A-09-13-02032	3/4/2014
Inappropriate and Questionable Medicare Billing for Diabetes Test Strips	OEI-04-11-00330	8/26/2013
Supplier Billing for Diabetes Test Strips and Inappropriate Supplier Activities in Competitive Bidding Areas	OEI-04-11-00760	11/7/2012
Medicare Contractors Lacked Controls To Prevent Millions in Improper Payments for High Utilization Claims for Home Blood-Glucose Test Strips and Lancets	A-09-11-02027	6/13/2012
Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction B	A-09-08-00044	2/17/2011
Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction D	A-09-08-00046	2/4/2011
Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C	A-09-08-00045	1/21/2011
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	8/30/2010

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

We obtained CY 2012 claim data consisting of 3,214,925 line items for test strips for which CGS paid $268,974,290 to suppliers. A line item represented a supply of test strips included on a claim with service beginning and ending dates (e.g., May 22, 2012, through August 21, 2012). We analyzed the claim data and identified 105,933 line items that each had service dates that overlapped the service dates of a line item on a prior claim submitted by a different supplier for test strips dispensed to the same beneficiary. CGS paid $10,339,648 to suppliers for the 105,933 line items. We reviewed a random sample of 100 of these line items.

We reviewed the claim data and supplier documentation to determine whether each line item of test strips on the prior claim was nearly exhausted when the new supply of test strips was dispensed (i.e., whether the test strips were dispensed sooner than 10 calendar days before the expected end of usage for the current product). We did not review the sampled line items for compliance with other Medicare requirements. Also, because we did not have a medical review contractor review the supplier documentation, the medical necessity of the test strips dispensed to the beneficiaries in our sample was not determined. Therefore, our determination as to whether CGS made overpayments for the sampled line items was limited.

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

We conducted our audit from August 2013 to August 2014 and performed fieldwork at CGS's office in Nashville, Tennessee.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CGS officials to obtain an understanding of Medicare reimbursement requirements and claim processing procedures for test strips;
- obtained from CMS's National Claims History file the Medicare Part B claims for test strips;
- created a sampling frame that consisted of 105,933 line items for test strips dispensed in CY 2012 that had service dates that overlapped the service dates on prior claims by more than 10 calendar days submitted by different suppliers for test strips dispensed to the same beneficiary;
- selected a simple random sample of 100 line items;

- requested supporting documentation from the supplier of each sampled line item and from the supplier that submitted the prior claim for test strips that had service dates that overlapped the service dates for the sampled line item;

- reviewed claim data and supplier documentation to determine whether the beneficiary's existing supply of test strips was nearly exhausted when the sampled line item was dispensed by:[14]

    - determining the number of days between the beginning dates on the 2 claims (i.e., the claim with the sampled line item and the prior claim),

    - multiplying the number of days between the 2 claims by the testing frequency on the physician's order to determine how many test strips the beneficiary would have been expected to use during that time period,[15]

    - subtracting the number of test strips expected to have been used from the number of test strips dispensed prior to our sampled line item to determine the number of test strips that the beneficiary would have been expected to have when the sampled line item was dispensed,

    - multiplying the testing frequency by 10 to determine the maximum number of test strips that the beneficiary should have had when the sampled line item was dispensed, and

    - comparing the number of test strips that the beneficiary would have been expected to have when the sampled line item was dispensed with the maximum number of test strips that the beneficiary should have had when the sampled line item was dispensed;

- estimated the amount of unallowable payments that may have been made to suppliers that dispensed test strips when the beneficiaries had not nearly exhausted the supplies previously dispensed by different suppliers; and

- shared the results of our review with CGS.

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

[14] To determine whether the beneficiary's existing supply of test strips was nearly exhausted, we assumed that the beneficiary used test strips at the frequency prescribed by the ordering physician.

[15] If the testing frequency shown on the physician's order provided by the supplier of the sampled line item was different from the testing frequency on the physician's order provided by the supplier of the prior supply of test strips, we used the higher testing frequency. If either of the orders was missing, we used the testing frequency on the physician's order that we had or the testing frequency in the utilization guidelines (i.e., one time per day for non-insulin-treated beneficiaries or three times per day for insulin-treated beneficiaries), whichever was greater.

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 C: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population consisted of line items paid by CGS with overlapping service dates for test strips dispensed to the same beneficiary by multiple suppliers.

SAMPLING FRAME

The sampling frame consisted of 105,933 line items for test strips dispensed in CY 2012 that each had service dates that overlapped service dates of a line item on a prior claim submitted by a different supplier for test strips dispensed to the same beneficiary.[16] CGS paid $10,339,648 for these line items.

SAMPLE UNIT

The sample unit was a line item on a claim for test strips.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

The sample size was 100 line items.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the sample units in the sampling frame from 1 to 105,933. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the amount of the unallowable payments that may have been made to suppliers that dispensed test strips when the beneficiaries had not nearly exhausted the test strips previously dispensed by different suppliers.

[16] We included only the line items for beneficiaries whose use of test strips exceeded the utilization guidelines during CY 2012 (i.e., non-insulin-treated beneficiaries who received more than 400 test strips and insulin-treated beneficiaries who received more than 1,200 test strips). In addition, we included only the line items whose service dates overlapped more than 10 calendar days with a line item on the immediately preceding claim (based on the service beginning dates), which was dispensed by a different supplier, for the same beneficiary. We did not include line items that had been reviewed by CGS or the recovery audit contractors.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 1: Sample Results

No. of Line Items in Sampling Frame	Value of Line Items in Sampling Frame	Sample Size	Value of Sample	No. of Potentially Unallowable Sampled Line Items	Value of Potentially Unallowable Sampled Line Items
105,933	$10,339,648	100	$10,262	71	$7,211

Table 2: Estimated Value of Potentially Unallowable Payments
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	$7,639,072
Lower limit	6,484,849
Upper limit	8,793,295

APPENDIX E: AUDITEE COMMENTS

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April 15, 2015

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

RE: CGS Response to draft OIG Report A-09-14-02015

Dear Ms. Ahlstrand,

CGS Administrators, LLC, the Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C, appreciates the opportunity to comment on the Office of Inspector General's draft report entitled *CGS Administrators, LLC made Medicare payments for home blood-glucose test strips when beneficiaries had not nearly exhausted previously dispensed supplies.* In addition to requesting comments on the report, you ask that CGS state concurrence or nonconcurrence with each of the three recommendations in the report.

The OIG makes one (1) recommendation in its report. This recommendation is that CGS implement a system edit to identify for review claims submitted by multiple suppliers with overlapping service dates for test strips dispensed to the same beneficiary. CGS does not concur with the findings of the report or the recommendation. Our reasoning and comments are outlined below.

CGS disagrees with the methodology utilized by the OIG in the development of their data and results. As stated in the report, medical review was not conducted on the claims in the sample the OIG reviewed. Conducting medical review on the claim and medical documentation is the only way to definitively establish the medical necessity of additional testing supplies and that the claim should be paid. Consequently, the overpayment amount stated in the sample may be overestimated. The OIG's extrapolation of their calculated error rate, which includes potential errors by multiple providers and CGS, only exaggerates the impact of incorrectly categorizing any sample claim as "not reasonable and necessary." This factor can have significant implications for the final estimated overpayment amount.

The report states "Medicare covers up to 100 test strips every month for insulin-treated diabetics and every 3 months for non-insulin-treated diabetics (utilization guidelines)". This statement gives the impression that payment coverage terminates at 100 test strips per month for insulin-treated diabetics and 100 test strips per three month period for non-insulin treated diabetics. However, the LCD defines this as average usage, and also states that testing more frequently may be warranted if medical necessity requires it. One of the key issues with the OIG report is that it does not consider medical necessity when determining whether or not payment should have been made. Instead, a hard line was drawn at the point of average usage and any additional test strips were assumed unnecessary.

Using average testing guidelines as a cut off value for determining overpayment can be problematic, depending upon the distribution of beneficiary usage. If actual usage of all beneficiaries for the HCPCS code follows the standard normal distribution, then using an average guideline as a cutoff will result in 50% denial rate of claims since, by definition, 50% of all claims would fall above the mean. If the distribution is negatively skewed, then the percentage of claims denied would be even higher. However, without medical review (MR) it is impossible to know if these supplies were necessary or not. The LCD is not written to indicate exactly how many strips an individual must use; but, rather to define guidelines that are followed in accordance with medical necessity. However, without medical review this necessity cannot be determined, so it is unknown whether or not the claims are substantiated.

The OIG report states "These potential overpayments occurred because CGS' system edit was not designed to identify for review claims submitted by multiple suppliers with overlapping service dates for test strips dispensed to the same beneficiary. Rather, the system edit was designed to identify claims with a quantity of test strips that exceeded the utilization guidelines." This is not correct. CGS conducts multiple types of editing for glucose monitoring supplies, including complex edits designed to identify overutilization by comparing claims from multiple suppliers in an 83 day period (essentially overlapping dates). Although the MR edits may not have been designed the way the OIG thought they would be (i.e., only selecting claims if the dates overlapped with another claim), they were set up the way CGS intended using multiple factors. By selecting claims with over-utilization (based on claims billed by multiple suppliers with overlapping dates within an 83 day period), CGS is targeting the claims most likely to be denied and which can be managed within funding/staffing levels as designed in the MR Strategy. CGS has a manual review prepay complex edit and two automated edits for HCPCS code A4253 (test strips) that utilize multiple factors, including claims billed by multiple suppliers in an 83 day period and overutilization.

The OIG estimates $7.6 million would have been saved with multi-supplier editing; however, this assumes that medical review would have had the capacity to review all of the claims meeting this parameter. As noted in previous responses to OIG reports, CGS has requested additional funding from CMS to conduct 100% prepayment review of these types of claims. CMS had declined to fund the additional activities. The OIG estimate also assumes that MR would not have otherwise reviewed any of these claims; however, it is likely that some of the claims would have been reviewed through the prepayment automated routine and complex edits that existed within Medical Review in 2012.

Since 2011 and working collaboratively with CMS, CGS has submitted proposals advocating for a multi-supplier automated editing solution that would avoid manual review of diabetic testing supplies. [redacted]* CGS is confident that a solution based on automated system editing will be implemented in the near future. Utilizing this CMS solution will satisfy the OIG recommendation found in this report.

CGS was aware that a systematic automated editing solution was a long-term goal to resolving utilization issues with glucose monitor supplies. While awaiting a CMS-approved automated editing change, CGS continued to seek out additional strategies to address the overutilization of glucose monitor testing supplies. Since 2011, CGS has taking the following actions:

- Medical Review routine and complex prepayment edits for A4253 denied over $20 million in 2012 alone and over $57 million from 2011-2014.
- CGS expanded a clinically believable edit (CUE) which started with one state (FL) in 2011. Using a phased-in approach to mitigate potential appeals volumes, seven additional states were added in 2014. The remaining 7 states and 2 US territories in Jurisdiction C were added in March 2015. These edits, which have very low reversal rates upon appeal, have resulted in program savings of approximately $9 million in 2012 and approximately $15 million in total for 2011-2014.
- CGS conducted an in-depth claim review of a large national diabetic supplier via statistical sampling with overpayment extrapolation (SSOE). CGS assessed an overpayment of $157 million that resulted in a bankruptcy settlement with CMS.
- CGS submitted a Recalcitrant Provider Referral to CMS in 2014 for a high volume supplier of glucose monitoring testing supplies that has maintained a very high denial rate between 85-100% despite a probe review, targeted prepayment review, and education.

In all, since the OIG report in 2011, CGS has conducted medical review of diabetic testing supplies resulting in over $229 million in initial savings to the Medicare program.

This multi-pronged approach to addressing issues with glucose testing supplies has achieved impressive results, not just in program dollars saved but also when measured in the context of the Comprehensive Error Rate Testing (CERT) program. While awaiting implementation of the automated editing solution mentioned in the above paragraph, the additional actions taken by CGS have resulted in a 23% reduction in the CERT error rate in Jurisdiction C for the Glucose Monitors policy group. Moreover, as a policy group, glucose monitors and testing supplies has fallen in priority ranking from #2 to #9 in Jurisdiction C, based on dollars paid in error.

CGS continues to search for actions that will reduce inappropriate payments for diabetic testing supplies while being mindful of provider burden. CGS currently collaborates with CMS and other DME MACs to coordinate reviews of providers of diabetic testing supplies participating in the national mail order competitive bidding program. This collaborative effort is structured to

* We redacted confidential information that was included in CGS's comments.

divide the workload for auditing activities and avoid overlapping claim review with prescribed limits on claim development for any single provider. CGS and the DME MACs monitor this activity closely to anticipate future impacts to a provider's business operations.

In summary, CGS Administrators, LLC is fully aware of the concerns outlined in draft report A-09-14-0015 and, as demonstrated above, has taken aggressive and extensive steps to address those concerns. In addition, CGS believes that the forthcoming solution by CMS will satisfy the recommendation outlined in OIG Report A-09-414-02015. Should you have any additional questions, please feel to contact Jacqueline Yarbrough at 615.782.4671 or Jacqueline.Yarbrough@cgsadmin.com.

Sincerely,

John F Kimball

John F. Kimball