APR 27 2009

TO: Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: Joseph E. Vengrin
Deputy Inspector General for Audit Services

SUBJECT: Review of Separately Billed Laboratory Tests Paid by National Government Services, Inc., for Medicare Beneficiaries With End-Stage Renal Disease (A-01-07-00522)

Attached is an advance copy of our final report on separately billed laboratory tests paid by National Government Services, Inc. (NGS), for Medicare beneficiaries with end-stage renal disease (ESRD). We will issue this report to NGS within 5 business days.

The Centers for Medicare & Medicaid Services (CMS) established a composite rate method of payment to reimburse hospital-based and independent dialysis facilities on a per treatment basis for dialysis services provided to ESRD beneficiaries. CMS specifies the laboratory tests that are included in the composite rate and the frequencies (e.g., per treatment, weekly, or monthly) at which the tests are reimbursable as part of that rate. When the tests are performed at the specified frequencies, they must not be billed separately. However, when the tests are performed at a frequency greater than specified, the additional tests are separately billable and payable if they are medically justified by accompanying documentation. In addition, certain routine tests that are not included as part of the composite rate may be billed separately, but payment for more than one of these tests performed in a 3-month period requires medical documentation.

Our review covered 339,342 claims totaling $7,381,070 that NGS paid for tests provided to ESRD beneficiaries by 326 dialysis facilities in calendar years 2004–2006.

Our objective was to determine whether Medicare claims paid by NGS for laboratory tests that dialysis facilities provided to ESRD beneficiaries complied with Medicare ESRD payment requirements.

Medicare claims paid by NGS for laboratory tests that dialysis facilities provided to ESRD beneficiaries did not always comply with Medicare ESRD payment requirements. ESRD-related laboratory tests were correctly billed and paid in 90 of the 360 beneficiary quarters that we

sampled. However, for the remaining 270 beneficiary quarters, dialysis facilities incorrectly billed and were reimbursed $11,325 for ESRD-related laboratory tests. This amount comprised:

- 347 beneficiary quarters containing errors totaling $10,273 for laboratory tests included in the composite rate that should not have been separately billed;

- 32 beneficiary quarters containing errors totaling $827 for separately billable tests that were billed beyond the allowed frequency without required medical documentation; and

- 9 beneficiary quarters containing errors totaling $225 for undocumented tests (i.e., no evidence that the tests were performed).

The beneficiary quarters in the individual error categories total more than 270 because some beneficiary quarters had more than one type of error.

The dialysis facilities incorrectly billed for these tests because they did not have sufficient controls to ensure that all claims complied with Medicare requirements. NGS overpaid these claims because its claim-processing system had limited ability to detect billing errors. In addition, NGS had not conducted any postpayment medical record reviews for claims submitted by dialysis facilities that separately billed ESRD-related laboratory tests.

Based on our sample results, we estimated that NGS overpaid dialysis facilities $3.9 million for laboratory tests provided to ESRD beneficiaries during calendar years 2004−2006.

We recommend that NGS coordinate with CMS and other involved Medicare administrative contractors to:

- conduct postpayment medical record reviews of claims submitted by dialysis facilities that separately billed ESRD laboratory tests to identify and recover overpayments estimated at $3.9 million and

- educate dialysis facilities about Medicare ESRD billing requirements related to the types of errors identified in our review.

In its comments on our draft report, NGS agreed with our recommendations. However, NGS noted that it no longer has jurisdiction over 2 of the 12 contracts covered by our review. We have modified our recommendations accordingly.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at George.Reeb@oig.hhs.gov or Michael J. Armstrong, Regional Inspector General for Audit Services, Region I, at (617) 565-2689 or through e-mail at Michael.Armstrong@oig.hhs.gov. Please refer to report number A-01-07-00522.

Attachment

Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203
(617) 565-2684

APR 30 2009

Report Number: A-01-07-00522

Mr. James Elmore
Regional Vice President
National Government Services
8115 Knue Road
Indianapolis, Indiana 46250

Dear Mr. Elmore:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of Separately Billed Laboratory Tests Paid by National Government Services, Inc., for Medicare Beneficiaries With End-Stage Renal Disease." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, OIG reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act. Accordingly, this report will be posted on the Internet at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Stephen Conway, Audit Manager, at (617) 565-2946 or through e-mail at Stephen.Conway@oig.hhs.gov. Please refer to report number A-01-07-00522 in all correspondence.

Sincerely,

Michael J. Armstrong

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Mr. Timothy Hill
Director & Chief Financial Officer
Office of Financial Management
Centers for Medicare & Medicaid Services
Mail Stop C3-01-24
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF SEPARATELY BILLED LABORATORY TESTS PAID BY NATIONAL GOVERNMENT SERVICES, INC., FOR MEDICARE BENEFICIARIES WITH END-STAGE RENAL DISEASE

Daniel R. Levinson
Inspector General

April 2009
A-01-07-00522

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, Office of Inspector General reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Medicare is a health insurance program administered by the Centers for Medicare & Medicaid Services (CMS). Medicare covers eligible beneficiaries who have end-stage renal disease (ESRD).

CMS established a composite rate method of payment to reimburse hospital-based and independent dialysis facilities (both referred to hereafter as dialysis facilities) on a per treatment basis for dialysis services provided to ESRD beneficiaries. The composite rate is a comprehensive payment for most services related to dialysis treatment. CMS specifies the laboratory tests (including specimen collection services) that are included in the composite rate and the frequencies (e.g., per treatment, weekly, or monthly) at which the tests are reimbursable as part of that rate. When the tests are performed at the specified frequencies, they must not be billed separately. However, when the tests are performed at a frequency greater than specified, the additional tests are separately billable and payable if they are medically justified by accompanying documentation. In addition, certain routine tests that are not included as part of the composite rate may be billed separately, but payment for more than one of these tests performed in a 3-month period requires medical documentation.

As of January 1, 2007, five fiscal intermediaries representing 12 Medicare contracts were incorporated into National Government Services, Inc. (NGS). Because NGS had responsibility for the 12 contracts when we conducted our audit, we refer to NGS as the fiscal intermediary throughout this report.

CMS is currently transferring its Medicare operations—including claim processing, reimbursement, provider education, and postpayment review—from fiscal intermediaries and carriers to Part A/Part B Medicare administrative contractors (MAC). NGS will serve as the MAC for some of the 12 contracts.

Our review covered 339,342 claims totaling $7,381,070 that NGS paid for tests provided to ESRD beneficiaries by 326 dialysis facilities in calendar years 2004–2006.

OBJECTIVE

Our objective was to determine whether Medicare claims paid by NGS for laboratory tests that dialysis facilities provided to ESRD beneficiaries complied with Medicare ESRD payment requirements.

SUMMARY OF FINDINGS

Medicare claims paid by NGS for laboratory tests that dialysis facilities provided to ESRD beneficiaries did not always comply with Medicare ESRD payment requirements. ESRD-related laboratory tests were correctly billed and paid in 90 of the 360 beneficiary quarters that we

sampled. However, for the remaining 270 beneficiary quarters, dialysis facilities incorrectly billed and were reimbursed $11,325 for ESRD-related laboratory tests. This amount comprised:

- 347 beneficiary quarters containing errors totaling $10,273 for laboratory tests included in the composite rate that should not have been separately billed;

- 32 beneficiary quarters containing errors totaling $827 for separately billable tests that were billed beyond the allowed frequency without required medical documentation; and

- 9 beneficiary quarters containing errors totaling $225 for undocumented tests (i.e., no evidence that the tests were performed).

The beneficiary quarters in the individual error categories total more than 270 because some beneficiary quarters had more than one type of error.

The dialysis facilities incorrectly billed for these tests because they did not have sufficient controls to ensure that all claims complied with Medicare requirements. NGS overpaid these claims because its claim-processing system had limited ability to detect billing errors. In addition, NGS had not conducted any postpayment medical record reviews for claims submitted by dialysis facilities that separately billed ESRD-related laboratory tests.

Based on our sample results, we estimated that NGS overpaid dialysis facilities $3.9 million for laboratory tests provided to ESRD beneficiaries during calendar years 2004−2006.

RECOMMENDATIONS

We recommend that NGS coordinate with CMS and other involved MACs to:

- conduct postpayment medical record reviews of claims submitted by dialysis facilities that separately billed ESRD laboratory tests to identify and recover overpayments estimated at $3.9 million and

- educate dialysis facilities about Medicare ESRD billing requirements related to the types of errors identified in our review.

NATIONAL GOVERNMENT SERVICES, INC., COMMENTS

In its comments on our draft report, NGS agreed with our recommendations. However, NGS noted that it no longer has jurisdiction over two of the contracts covered by our review. NGS's comments are included in their entirety as Appendix E.

OFFICE OF INSPECTOR GENERAL RESPONSE

We acknowledge that NGS no longer has jurisdiction over two of the contracts covered by our review, and we have modified our recommendations accordingly. We will provide copies of this report to the additional MACs now responsible for some of the claims that we reviewed. We

will also provide NGS, CMS, and the other involved MACs with relevant claim data from our review.

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INTRODUCTION

BACKGROUND

Title XVIII of the Social Security Act (the Act), as amended, established Medicare, a health insurance program administered by the Centers for Medicare & Medicaid Services (CMS). Medicare covers eligible beneficiaries who have end-stage renal disease (ESRD).

Statutory and Regulatory Framework

Pursuant to section 1862(a)(1)(A) of the Act, no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member." In addition, section 1833(e) of the Act precludes payments to any service provider under Medicare Part B unless the provider has furnished information necessary to determine the amounts due such provider.

Pursuant to 42 CFR § 410.32(a), "[a]ll . . . diagnostic laboratory tests . . . must be ordered by the physician who is treating the beneficiary . . . [and tests] not ordered by the physician who is treating the beneficiary are not reasonable and necessary . . . ." Further, 42 CFR § 410.32(d)(2) and (3) set forth requirements for maintaining and providing to CMS certain documentation regarding such tests.

Composite Rate Payments

CMS established a composite rate method of payment to reimburse hospital-based and independent dialysis facilities (both referred to hereafter as dialysis facilities) on a per treatment basis for dialysis services provided to ESRD beneficiaries. The composite rate is a comprehensive payment for all services related to dialysis treatment, except for physicians' professional services and certain drug and laboratory services that are separately billable.

CMS specifies the laboratory tests[1] that are included in a dialysis facility's composite rate and the frequencies (e.g., per treatment, weekly, or monthly) at which the tests are reimbursable as part of that rate. (See Appendix A for the composite rate tests extracted for this review.) When the tests are performed at the specified frequencies, they must not be billed separately. However, when the tests are performed at a frequency greater than specified, the additional tests are separately billable and payable if they are medically justified by accompanying documentation.

Composite rate tests include both automated multichannel chemistry (AMCC) profile tests and non-AMCC tests. CMS guidance on AMCC tests uses the 50-percent rule, which specifies whether CMS will pay for these tests separately. In addition, certain routinely provided non-AMCC tests (e.g., serum ferritin and serum aluminum) that are not included as part of the composite rate may be billed separately, but payment for more than one of these tests performed in a 3-month period requires medical documentation.

[1]The term "tests" in this report includes specimen collection services.

National Government Services

As of January 1, 2007, five fiscal intermediaries representing 12 Medicare contracts were incorporated into National Government Services, Inc. (NGS). Because NGS had responsibility for the 12 contracts when we conducted our audit, we refer to NGS as the fiscal intermediary throughout this report.

CMS is currently transferring its Medicare operations—including claim processing, reimbursement, provider education, and postpayment review—from fiscal intermediaries and carriers to Part A/Part B Medicare administrative contractors (MAC). NGS will serve as the MAC for some of the 12 contracts.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare claims paid by NGS for laboratory tests that dialysis facilities provided to ESRD beneficiaries complied with Medicare ESRD payment requirements.

Scope

We limited our review to claims paid by NGS for separately billed laboratory tests that were subject to Medicare ESRD payment requirements. Our review covered 339,342 claims totaling $7,381,070 that NGS paid for tests provided by 326 dialysis facilities in calendar years (CY) 2004–2006. The tests included in our review are listed in Appendix A.

In performing our review, we established reasonable assurance that the claim data were verifiable and accurate. We did not assess the completeness of the National Claims History file from which we obtained the data. We limited our review of internal controls to obtaining an understanding of NGS's payment controls for separately billed laboratory tests provided to ESRD beneficiaries.

We performed our audit from October 2007 through May 2008. Our audit work included contacting NGS staff in Indianapolis, Indiana, and Quincy, Massachusetts, and the 125 dialysis facilities in our sample.

Methodology

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;

- gained an understanding of NGS's claim-processing system and edits in place by developing test claims for NGS to process and discussing the results with NGS;

- used data from CMS's National Claims History file to match ESRD composite rate paid claims with the dialysis facilities' ESRD outpatient laboratory claims based on "from" and "through" dates of service;

- identified from our computer match 122,176 beneficiary quarters[2] containing separately billed ESRD-related laboratory tests totaling $7,381,070 (Appendix B) and selected a stratified random sample of 360 beneficiary quarters with payments totaling $21,472 (Appendix C);

- reviewed information in the dialysis facilities' records (including dialysis treatment dates, physician orders, laboratory tests performed, and progress notes) to support the tests billed for each sampled item but did not obtain records from physicians;[3]

- reviewed billing records, claims, and remittance advices from the 125 dialysis facilities in the sample;

- evaluated the 360 sampled beneficiary quarters to determine whether the paid ESRD-related laboratory services were allowable and medically justified;

- reviewed policies and procedures for billing ESRD claims for separately billable laboratory tests from the 95 dialysis facilities that responded to our request for this information;

- estimated the potential overpayments (Appendix C); and

- discussed the results of our review with NGS and CMS.

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 objective.

FINDINGS AND RECOMMENDATIONS

Medicare claims paid by NGS for laboratory tests that dialysis facilities provided to ESRD beneficiaries did not always comply with Medicare ESRD payment requirements. ESRD-related laboratory tests were correctly billed and paid in 90 of the 360 beneficiary quarters that we sampled. However, for the remaining 270 beneficiary quarters, dialysis facilities incorrectly billed and were reimbursed $11,325 for ESRD-related laboratory tests (Appendix D). This amount comprised:

[2]A beneficiary quarter comprises all separately billed and reimbursed services listed in Appendix A that were performed for an ESRD beneficiary during a calendar quarter.

[3]Federal regulations (42 CFR § 410.32(d)(3)(ii)) state that, in certain circumstances, CMS will request relevant portions of beneficiaries' medical records from ordering physicians.

- 347 beneficiary quarters containing errors totaling $10,273 for laboratory tests included in the composite rate that should not have been separately billed;

- 32 beneficiary quarters containing errors totaling $827 for separately billable tests that were billed beyond the allowed frequency without required medical documentation; and

- 9 beneficiary quarters containing errors totaling $225 for undocumented tests (i.e., no evidence that the tests were performed).

The beneficiary quarters in the individual error categories total more than 270 because some beneficiary quarters had more than one type of error.

The dialysis facilities incorrectly billed for these tests because they did not have sufficient controls to ensure that all claims complied with Medicare requirements. NGS overpaid these claims because its claim-processing system had limited ability to detect billing errors. In addition, NGS had not conducted any postpayment medical record reviews for claims submitted by dialysis facilities that separately billed ESRD-related laboratory tests.

Based on our sample results, we estimated that NGS overpaid dialysis facilities $3.9 million for laboratory tests provided to ESRD beneficiaries during CYs 2004−2006.

TESTS INCLUDED IN THE COMPOSITE RATE

The 125 dialysis facilities in our sample had errors in 347 beneficiary quarters that resulted in overpayments totaling $10,273 for laboratory tests included in the composite rate that should not have been separately billed. This amount consisted of $7,746 for tests that were performed within the specified frequency, $1,908 for tests that were performed beyond the specified frequency but lacked required documentation, and $619 for tests that did not meet Medicare's 50-percent rule.

Federal Requirements

The CMS "Medicare Benefits Policy Manual," Pub. No. 100-02 (the Manual), chapter 11, section 30.2, states: "The costs of certain ESRD laboratory services performed by either the facility's staff, or an independent laboratory, are included in the composite rate calculations . . . . Therefore, payment for all of the tests is included in the facility's composite rate, and the tests may not be billed separately to the Medicare program."

The Manual, chapter 11, section 30.2.1.A, designates the laboratory tests that are included in the composite rate and the frequencies at which these tests are included (e.g., per treatment, weekly, or monthly) for beneficiaries receiving hemodialysis, intermittent peritoneal dialysis, continuous cycling peritoneal dialysis, and hemofiltration. Furthermore, it states:

> The tests listed [in this section 30.2.1.A] are usually performed for dialysis patients and are routinely covered at the frequency specified in the absence of indications to the contrary, i.e., no documentation of medical necessity is required

> other than knowledge of the patient's status as an ESRD beneficiary. When any of these tests is performed at a frequency greater than that specified, the additional tests are separately billable and are covered only if they are medically justified by accompanying documentation. A diagnosis of ESRD alone is not sufficient medical evidence to warrant coverage of the additional tests. The nature of the illness or injury (diagnosis, complaint, or symptom) requiring the performance of the test(s) must be present on the claim. Such information must be furnished using the ICD-9-CM coding system.

The Manual, chapter 11, section 70.2.A.1, designates the laboratory tests that are included in the monthly composite rate for beneficiaries receiving continuous ambulatory peritoneal dialysis.

The Manual, chapter 11, section 30.A, states: "Items and services included under the composite rate must be furnished by the facility, either directly or under arrangements to all of its dialysis patients. Examples of such items and services are: . . . [s]taff time used to collect specimens for all laboratory tests." In addition, the "Medicare Claims Processing Manual," Pub. No. 100-04, chapter 16, section 60.1.3, provides that:

> Special rules apply when [specimen collection] services are furnished to dialysis patients. The specimen collection fee is not separately payable for . . . patients dialyzed in the facility or for patients dialyzed at home under [R]eimbursement Method I. Payment for [specimen collection] service[s] is included under the ESRD composite rate, regardless of whether the laboratory test itself is included in the composite rate or is separately billable.

The CMS "Medicare Claims Processing Manual," Pub. No. 100-04, chapter 16, section 40.6.1, states that, for a particular date of service, the dialysis facility must identify "the AMCC tests ordered that are included in the composite rate and those that are not included." Specifically, when ordering an AMCC test, the dialysis facility must specify whether the test (1) "[i]s part of the composite rate and not separately payable;" (2) "[i]s a composite rate test but is, on the date of the order, beyond the frequency covered under the composite rate and thus is separately payable;" or (3) "[i]s not part of the ESRD composite rate and thus is separately payable." Pursuant to the same section of the "Medicare Claims Processing Manual," Medicare uses this information to apply the following rules, among others, to AMCC tests for ESRD beneficiaries:

- "If 50 percent or more of the covered tests [on a given date of service] are included [in] the composite rate payment, then all submitted tests [for that date] are included in the composite [rate] payment. In this case, no separate payment in addition to the composite rate [payment] is made for any of the separately billable tests."

- "If less than 50 percent of the covered tests [on a given date of service] are composite rate tests, all AMCC tests submitted for that [date of service] for that beneficiary are separately payable."

Separately Billed Tests That Were Already Reimbursed Through the Composite Rate

The dialysis facilities in our sample incorrectly billed and were reimbursed $7,746 for tests that were reimbursed through the composite rate. Specifically, the facilities were reimbursed for non-AMCC tests (e.g., complete blood counts, hematocrit, hemoglobin, and prothrombin time) that were performed within the specified frequency and for specimen collection services included in the composite rate.

Example: Tests Included in the Composite Rate

Beneficiary A had blood drawn (specimen collection) for a hemoglobin test with each dialysis treatment. Specimen collection services and one hemoglobin test are included in the composite rate for each treatment. However, the dialysis facility separately billed NGS for both the specimen collection services and the test each time the test was performed.

Separately Billed Tests That Were Performed Beyond the Specified Frequency But Lacked Accompanying Documentation

The dialysis facilities in our sample incorrectly billed and were reimbursed $1,908 for both AMCC and non-AMCC composite rate tests that were performed beyond the specified frequency without accompanying documentation that medically justified the additional tests.

Example: Separately Billable Composite Rate Tests Billed Without Accompanying Documentation

Beneficiary B had a potassium test four times during April in conjunction with his dialysis treatments. One potassium test is included in the composite rate each month. The dialysis facility separately billed NGS for three potassium tests performed in April after the first test. However, the dialysis facility's records did not contain accompanying documentation that medically justified the three additional tests.

Separately Billed Tests That Did Not Meet the 50-Percent Rule

The dialysis facilities in our sample incorrectly billed and were reimbursed $619 for AMCC tests when 50 percent or more of the tests performed on the date of service were included in the composite rate. The claims that dialysis facilities submitted for these tests were either incorrectly coded or incomplete. Because NGS thus applied the 50-percent rule to incorrectly coded or incomplete data, the facilities received overpayments.

Examples: Payment Determinations Using the 50-Percent Rule

Incorrect Coding: Beneficiary C had a calcium test and phosphorus test (both AMCC composite rate tests) on a single date of service. According to the dialysis facility's records, this date of service was the only time during the month that these two tests were performed. Therefore, these tests were composite rate tests within the specified frequency. However, the dialysis facility incorrectly coded the claim to indicate that the tests were composite rate tests beyond the specified frequency. NGS applied the 50-percent rule to this information (0 divided by 2) and thus separately paid for both tests. Because 100 percent of the tests actually performed were composite rate tests (2 divided by 2), these two tests were not separately payable.

Incomplete Billing: Beneficiary D had 10 AMCC tests on a single date of service. According to the dialysis facility's records, six of these tests were composite rate tests within the specified frequency, and four were not composite rate tests. However, the dialysis facility billed only for the four non-composite-rate tests and did not include the six composite rate tests on its claim. Because of this omission, NGS calculated that 100 percent (4 divided by 4) of the tests were not composite rate tests and separately paid the claim based on the 50-percent rule. Because 60 percent of the tests were actually composite rate tests (6 divided by 10), these 10 tests were not separately payable.

SEPARATELY BILLABLE TESTS NOT INCLUDED IN THE COMPOSITE RATE

Federal Requirements

The Manual, chapter 11, section 30.2.1.B, identifies:

> [C]ertain separately billable laboratory tests [i.e., serum aluminum and serum ferritin] that are covered routinely, i.e., without documentation of medical necessity other than knowledge of the patient's status as an ESRD beneficiary, when furnished at the specified frequencies. If they are performed at a frequency greater than [once every 3 months], they are covered only if accompanied by medical documentation. A diagnosis of ESRD alone is not sufficient documentation. The medical necessity of the test(s), the nature of the illness or injury (diagnosis, complaint or symptom) requiring the performance of the test(s) must be present on the claim. Such information must be furnished using the ICD-9-CM coding system.

Serum Ferritin Tests Billed Beyond the Allowed Frequency Without Accompanying Documentation

The dialysis facilities in our sample incorrectly billed and were reimbursed $827 for errors in 32 beneficiary quarters for serum ferritin tests that were performed beyond the allowable frequency of once every 3 months. In each of these quarters, the dialysis facilities' records did not have the accompanying medical documentation for the additional tests.

Example: Additional Serum Ferritin Tests Billed Without Accompanying Documentation

Beneficiary E had three serum ferritin tests during a 3-month period in 2006 in conjunction with his dialysis treatments. Serum ferritin tests are not included as part of the composite rate and may be billed separately, but payment for more than one test performed during a 3-month period requires medical documentation. The dialysis facility separately billed NGS for three ferritin tests. However, the dialysis facility's records did not contain the accompanying medical documentation for the two additional tests.

UNDOCUMENTED TESTS

Federal Requirements

Section 1833(e) of the Act precludes payments to any service provider under Medicare Part B unless the provider has furnished information necessary to determine the amounts due such provider. Further, 42 CFR § 410.32(d)(3)(i) requires entities that submit claims for diagnostic laboratory tests to provide certain information to CMS upon request.

Tests Billed Separately Without Any Documentation

In nine beneficiary quarters, the dialysis facilities in our sample separately billed $225 for laboratory tests without providing any documentation that the tests were actually performed. Specifically, the dialysis facilities either did not respond to our multiple requests for documentation or, in one case, billed for a test that was not performed. In this instance, staff at the dialysis facility told us that they had performed a glucose stick test but incorrectly billed Medicare for an intravenous glucose test.

INSUFFICIENT CONTROLS

The dialysis facilities incorrectly billed for the tests discussed in this report because they generally did not have sufficient controls (e.g., correct billing policies and procedures) to ensure that all submitted claims complied with Medicare requirements. Specifically, dialysis facilities that responded to our billing questions cited the following reasons for the incorrect billing:

- They were unaware of CMS's billing guidelines.

- Their billing systems were inadequate.

- They did not track the number of times that they billed serum ferritin tests to Medicare.

NGS overpaid these claims because its claim-processing system relied on dialysis facilities to bill correctly. The system had limited ability to detect billing errors and prevent overpayments. In addition, NGS did not conduct any postpayment medical record reviews for claims submitted by dialysis facilities that separately billed ESRD laboratory tests.

ESTIMATE OF UNALLOWABLE PAYMENTS

Based on our sample results, we estimated that dialysis facilities incorrectly billed and were reimbursed $3.9 million for ESRD-related laboratory tests that did not meet Medicare requirements (Appendix C).

RECOMMENDATIONS

We recommend that NGS coordinate with CMS and other involved MACs to:

- conduct postpayment medical record reviews of claims submitted by dialysis facilities that separately billed ESRD laboratory tests to identify and recover overpayments estimated at $3.9 million and

- educate dialysis facilities about Medicare ESRD billing requirements related to the types of errors identified in our review.

NATIONAL GOVERNMENT SERVICES, INC., COMMENTS

In its comments on our draft report, NGS agreed with our recommendations. However, NGS noted that it no longer has jurisdiction over two of the contracts covered by our review. NGS's comments are included in their entirety as Appendix E.

OFFICE OF INSPECTOR GENERAL RESPONSE

We acknowledge that NGS no longer has jurisdiction over two of the contracts covered by our review, and we have modified our recommendations accordingly. We will provide copies of this report to the additional MACs now responsible for some of the claims that we reviewed. We will also provide NGS, CMS, and the other involved MACs with relevant claim data from our review.

APPENDIXES

LABORATORY TESTS[1] SUBJECT TO END-STAGE RENAL DISEASE PAYMENT REQUIREMENTS[2] AND EXTRACTED FOR REVIEW

Hemodialysis, Intermittent Peritoneal Dialysis, Continuous Cycling Peritoneal Dialysis, and Hemofiltration

CPT Code[3]	Non-AMCC[4] Tests Included in the Composite Rate
Per Treatment	
85013	Spun microhematocrit
85014	Hematocrit (Hct)
85018	Hemoglobin (Hgb)
Weekly	
85610	Prothrombin time
Monthly	
85007	Blood smear, microscopic examination with manual differential white blood count (WBC)
85025	Complete blood count (CBC), automated (Hgb, Hct, red blood count [RBC] WBC, and platelet count) and automated differential WBC count
85027	CBC, automated (Hgb, Hct, RBC, WBC, and platelet count)

CPT Code	AMCC Tests Included in the Composite Rate
Weekly	
82565	Creatinine; blood
Thirteen per Quarter	
84520	Urea nitrogen; quantitative

[1]The term "tests" in this report includes specimen collection services.

[2]Source: "Medicare Benefits Policy Manual," Pub. No. 100-02, chapter 11, sections 30.2.1, 30.2.2, and 70.2(A).

[3]The Current Procedural Terminology (CPT) code set is maintained by the American Medical Association to communicate uniform information about medical services and procedures.

[4]AMCC = automated multichannel chemistry.

Monthly

82040	Albumin; serum
82310	Calcium; total
82374	Carbon dioxide (bicarbonate)
82435	Chloride; blood
83615	Lactate dehydrogenase
84075	Phosphatase, alkaline
84100	Phosphorus inorganic (phosphate)
84132	Potassium; serum
84155	Protein, total, except by refractometry; serum
84450	Transferase; aspartate amino

CPT Code	**Non-Composite-Rate AMCC Tests Used To Calculate the 50-Percent Rule**
82247	Bilirubin; total
82248	Bilirubin; direct
82465	Cholesterol, serum or whole blood, total
82550	Creatine kinase; total
82947	Glucose; quantitative, blood (except reagent strip)
82977	Glutamyltransferase, gamma
84295	Sodium; serum
84460	Transferase; alanine amino
84478	Triglycerides
84550	Uric acid; blood

CPT Code	**Separately Billable Tests Not Included in the Composite Rate – Limited in Frequency**

One Every 3 Months

82108	Serum aluminum
82728	Serum ferritin

CPT Code	**Specimen Collection Services Included in the Composite Rate**
36415	Collection of venous blood by venipuncture
G0001	Routine venipuncture for collection of specimen(s)

Continuous Ambulatory Peritoneal Dialysis

CPT Code	**Non-AMCC Tests Included in the Composite Rate**

Monthly

85014	Hematocrit (Hct)
85018	Hemoglobin (Hgb)

CPT Code	AMCC Tests Included in the Composite Rate
Monthly	
82040	Albumin; serum
84075	Alkaline phosphatase
84450	Transferase; aspartate amino
82310	Calcium; total
82374	Carbon dioxide (bicarbonate)
82565	Creatinine; blood
83615	Lactate dehydrogenase
83735	Magnesium
84100	Phosphorus inorganic (phosphate)
84132	Potassium; serum
84155	Protein, total, except by refractometry; serum
84295	Sodium; serum
84520	Urea nitrogen; quantitative

CPT Code	Non-Composite-Rate AMCC Tests Used To Calculate the 50-Percent Rule
84460	Transferase; alanine amino
82247	Bilirubin, total
82248	Bilirubin, direct
82435	Chloride; blood
82465	Cholesterol, serum or whole blood, total
82550	Creatine kinase; total
82977	Glutamyltransferase, gamma
82947	Glucose; quantitative, blood (except reagent strip)
84478	Triglycerides
84550	Uric acid; blood

CPT Code	Separately Billable Tests Not Included in the Composite Rate – Limited in Frequency
One Every 3 Months	
85048	Leukocyte WBC, automated
85041	RBC, automated
85049	Platelet count, automated

CPT Code	Specimen Collection Services Included in the Composite Rate
36415	Collection of venous blood by venipuncture
G0001	Routine venipuncture

SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consisted of 122,176 beneficiary quarters containing Medicare laboratory tests that were provided by dialysis facilities to beneficiaries with end-stage renal disease (ESRD) and paid by National Government Service (NGS) during calendar years (CY) 2004–2006. Our population included only the laboratory tests listed in Appendix A. The population of 122,176 beneficiary quarters was distributed throughout NGS's 12 contracts as follows:

NGS Contract Number	NGS Contract	Beneficiary Quarters	Value of Laboratory Tests
00130	AdminaStar – Indiana	6,942	$469,246
00131	AdminaStar – Illinois	9,715	529,871
00160	AdminaStar – Kentucky	1,322	93,692
00180	Associated Hospitals – Maine	2,209	90,474
00181	Associated Hospitals – Massachusetts	1,038	56,470
00270	Anthem Health Plans – New Hampshire	4,077	193,564
00308	Empire Medicare Services – New York	44,414	2,692,221
00332	AdminaStar – Ohio	10,565	660,288
00450	United Government Services – Wisconsin	13,790	546,115
00452	United Government Services – Michigan	7,811	532,968
00453	United Government Services – Virginia	3,292	203,729
00454	United Government Services – California	17,001	1,312,432
Total		**122,176**	**$7,381,070**

SAMPLING FRAME

The sampling frame was 12 database tables, one for each of NGS's contract numbers, containing all ESRD-related laboratory tests provided during CYs 2004–2006, grouped by CY, quarter, and beneficiary.

SAMPLE UNIT

The sample unit was a beneficiary quarter.

SAMPLE DESIGN

We used a stratified random sample made up of 12 strata, one for each of the 12 NGS contracts.

SAMPLE SIZE

The sample size was 30 sample units for each of the 12 strata, for a total of 360 units.

SOURCE OF THE RANDOM NUMBERS

We generated the random numbers using the Office of Inspector General, Office of Audit Services, statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the beneficiary quarters in each stratum in the frame from 1 through the total number of beneficiary quarters in the stratum. After generating 30 random numbers for each of the 12 strata, we selected the corresponding sample items.

ESTIMATION METHODOLOGY

We used the Office of Inspector General, Office of Audit Services, statistical software to estimate the potential overpayments.

SAMPLE RESULTS AND ESTIMATES

Sample Results

NGS Contract Number	Frame Size	Sample Size	Value of Sample	Number of Beneficiary Quarters With Unallowable Payments	Value of Unallowable Payments
00130	6,942	30	$1,956	29	$1,318
00131	9,715	30	1,673	24	1,118
00160	1,322	30	2,076	25	484
00180	2,209	30	1,878	20	1,172
00181	1,038	30	1,281	26	855
00270	4,077	30	1,737	13	508
00308	44,414	30	1,608	19	842
00332	10,565	30	1,632	21	636
00450	13,790	30	1,191	14	326
00452	7,811	30	1,761	29	1,097
00453	3,292	30	1,754	25	1,222
00454	17,001	30	2,925	25	1,747
Total	**122,176**	**360**	**$21,472**	**270**	**$11,325**

Estimates of Unallowable Payments
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	$3,903,956
Lower limit	3,387,335
Upper limit	4,420,578

SAMPLE UNITS BY TYPES OF ERRORS

Type of Error	Units	Unallowable Payments
Tests in composite rate	347	$10,273
Separately billable errors	32	827
Undocumented tests	9	225
Total	**388**[1]	**$11,325**

Tests in Composite Rate

NGS Contract Number	Tests Within Frequency		Tests Beyond Frequency		50% Rule Errors		Total	
	Units	Unallowable Payments	Units	Unallowable Payments	Units	Unallowable Payments	Units[2]	Unallowable Payments
00130	29	$1,074	11	$132	4	$65	44	$1,270
00131	20	717	4	86	2	16	26	820
00160	8	154	16	162	15	108	39	425
00180	11	499	7	569	7	66	25	1,134
00181	20	667	3	30	6	136	29	832
00270	10	397	6	92	0	0	16	489
00308	12	486	9	224	2	9	23	719
00332	11	460	8	111	3	14	22	585
00450	9	161	6	129	1	22	16	312
00452	25	898	4	41	3	26	32	964
00453	25	1,066	1	6	7	36	33	1,108
00454	18	1,167	14	326	10	121	42	1,614
Total	**198**	**$7,746**	**89**	**$1,908**	**60**	**$619**	**347**	**$10,273**

[1]This total exceeds 270 beneficiary quarters because some beneficiary quarters had more than one type of error.

[2]The total units in each NGS contract could exceed 30 beneficiary quarters because some beneficiary quarters had more than one type of error.

NGS Contract Number	Separately Billable Errors	
	Units	Unallowable Payments
00130	3	$47
00131	5	153
00160	3	57
00180	2	38
00181	1	19
00270	1	19
00308	3	76
00332	2	38
00450	0	0
00452	4	133
00453	4	114
00454	4	133
Total	**32**	**$827**

NGS Contract Number	Undocumented Tests	
	Units	Unallowable Payments
00130	0	$0
00131	2	146
00160	1	2
00180	0	0
00181	1	3
00270	0	0
00308	2	47
00332	1	13
00450	2	14
00452	0	0
00453	0	0
00454	0	0
Total	**9**	**$225**

National Government Services

National Government Services, Inc.
P.O. Box 7181
Indianapolis, Indiana 46207-7181
A CMS Contracted Agent

Medicare

March 10, 2009

Michael J. Armstrong
Regional Inspector General for Audit Services
Office of Inspector General
Region 1
John F. Kennedy Federal Building
Boston, MA 02203

Dear Mr. Armstrong:

National Government Services has reviewed the report title Review of Separately Billed Laboratory Tests Paid by National Government Services, Inc. for Medicare Beneficiaries with End-Stage Renal Disease. We concur with the recommendations to:

- Conduct postpayment medical record reviews to identify and recover the overpayments made to providers
- Educate dialysis facilities about Medicare ESRD billing requirements related to the types of errors identified during the OIG review.

The NGS Medical Review Department will incorporate this referral into our prioritization of workload for our Title XVIII contracts with the following exceptions:

Contract Number 00454 Palmetto GBA, Inc. serves as the Medicare Administrative Contractor (MAC) for California (Jurisdiction 1).

Contract Number 00308 National Government Services serves as the Medicare Administrative Contractor (MAC) for New York (Jurisdiction 13). We are required to seek technical direction from the Project Officer before initiating work on this request.

Medical Review will conduct the review of providers in compliance with the CMS guidelines for Progressive Corrective Action (PCA) methodology.

An NGS work team convened in 2008 to review, and revise as appropriate, the corporate ESRD module as part of the shared claims processing system. That review is now complete and NGS is moving forward to implement the module that complies with CMS national coverage guidelines for laboratory services.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

NGS Provider Outreach & Education area will be conducting provider education as part of the ESRD module initiative and the issues found in the recommendation are consistent with that education program.

Sincerely,

David C. Crowley (mjs)

David C. Crowley
Staff Vice President
Claims Management

cc: Melanie Alexander, Director, Medical Review
Mark Humphreys, Director, Medical Review
Dr. James Cope, Medical Director
Sarah Litteral, Director, Claims