March 10, 2010

TO: Charlene M. 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 Submitted by Spectra Laboratories for Medicare Beneficiaries With End-Stage Renal Disease Receiving Dialysis at Fresenius Medical Care North America's Facilities (A-01-08-00511)

Attached, for your information, is an advance copy of our final report on separately billed laboratory tests submitted by Spectra Laboratories for Medicare beneficiaries with end-stage renal disease receiving dialysis at Fresenius Medical Care North America's facilities. We will issue this report to Fresenius Medical Care North America within 5 business days.

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 email at George.Reeb@oig.hhs.gov or Michael J. Armstrong, Regional Inspector General for Audit Services, Region I, at (617) 565-2689 or through email at Michael.Armstrong@oig.hhs.gov. Please refer to report number A-01-08-00511.

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Office of Audit Services, Region I
John F. Kennedy Federal Building
Room 2425
Boston, MA 02203

March 18, 2010

Report Number: A-01-08-00511

Mr. Todd Kerr
Senior Vice President & Chief Compliance Officer
Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451

Dear Mr. Kerr:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of Separately Billed Laboratory Tests Submitted by Spectra Laboratories for Medicare Beneficiaries With End-Stage Renal Disease Receiving Dialysis at Fresenius Medical Care North America's Facilities." 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.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted 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 email at Stephen.Conway@oig.hhs.gov. Please refer to report number A-01-08-00511 in all correspondence.

Sincerely,

/Michael J. Armstrong/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Mr. Rodney Benson
Director
Office of Acquisition and Grants Management
Centers for Medicare & Medicaid Services
Mail Stop C2-22-08
7500 Security Boulevard
Baltimore, MD 21244-1850

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF SEPARATELY BILLED LABORATORY TESTS SUBMITTED BY SPECTRA LABORATORIES FOR MEDICARE BENEFICIARIES WITH END-STAGE RENAL DISEASE RECEIVING DIALYSIS AT FRESENIUS MEDICAL CARE NORTH AMERICA'S FACILITIES

Daniel R. Levinson
Inspector General

March 2010
A-01-08-00511

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 & 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:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

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The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

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 dialysis facilities on a per treatment basis for outpatient maintenance dialysis services provided to ESRD beneficiaries. The composite rate is a comprehensive payment for most services related to dialysis treatment. CMS specifies the ESRD-related laboratory tests (hereafter referred to as "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 frequencies 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.

Federal regulations require that all tests covered under Medicare be ordered by the physician who is treating the beneficiary and that the physician who orders the tests maintain documentation of medical necessity in the beneficiary's medical record.

Spectra Laboratories (Spectra), a wholly owned subsidiary of Fresenius Medical Care North America (Fresenius), performs tests for dialysis facilities.

Our review covered 2,771,777 claims for which Spectra was reimbursed $46,457,213 for tests provided to ESRD beneficiaries who had dialysis treatments at any one of the 1,172 Fresenius owned or managed dialysis facilities (Fresenius facilities) in calendar years (CY) 2004–2006.

OBJECTIVE

Our objective was to determine whether Medicare claims that Spectra submitted for tests provided to ESRD beneficiaries at Fresenius facilities complied with certain ESRD-related payment requirements and with Medicare requirements that items and services be reasonable and necessary.

SUMMARY OF FINDINGS

Spectra correctly did not submit claims for composite rate tests that fell within the specified frequencies or that Medicare would not have paid under the 50-percent rule, in accordance with ESRD-related payment requirements. However, some claims that Spectra submitted did not comply with Medicare requirements that items and services be reasonable and necessary. Spectra correctly billed tests in 67 of the 100 beneficiary quarters that we sampled. However, the remaining 33 beneficiary quarters contained errors totaling $1,079. This amount comprised:

- 24 beneficiary quarters containing errors totaling $891 for separately billed tests that, based on an independent medical review by National Government Services, were not reasonable and necessary and

- 12 beneficiary quarters containing errors totaling $188 for separately billed tests that were not reasonable and necessary because they were not ordered by the treating physician.

The beneficiary quarters that had errors totaled more than 33 because some beneficiary quarters had more than one type of error.

Spectra did not have sufficient procedures in place to ensure that all tests billed to Medicare were reasonable and necessary. In addition, Fresenius facilities did not have sufficient controls to ensure that tests were ordered by the treating physician and were reasonable and necessary.

Based on our sample results, we estimated that Medicare overpaid Spectra $5.4 million for separately billed tests provided to ESRD beneficiaries at Fresenius facilities during CYs 2004–2006.

RECOMMENDATIONS

We recommend that:

- Spectra refund to the Medicare program $5.4 million in overpayments for CYs 2004–2006 and

- both Spectra and the Fresenius facilities strengthen their policies and procedures to ensure that all tests billed are reasonable and necessary, in compliance with Medicare requirements.

FRESENIUS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

Fresenius disagreed with our findings that certain tests were not reasonable and necessary, as determined by independent medical review, but acknowledged that it was unable to produce sufficient documentation of a physician's order for some of the other tests billed. In addition, Fresenius disagreed with our recommendations. We maintain that claims for certain tests in our sample that were submitted by Spectra did not comply with Medicare requirements that items and services be reasonable and necessary. Thus, we maintain that our findings and recommendations are valid.

We have included Fresenius' comments as Appendix D.

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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).

CMS established a composite rate method of payment to reimburse dialysis facilities on a per treatment basis for outpatient maintenance dialysis services provided to ESRD beneficiaries. CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04 (Claims Processing Manual), chapter 8, section 10.1, defines the composite rate as a comprehensive payment for services related to dialysis treatment, "except for bad debts, physicians' patient care services, and certain laboratory services and drugs that are separately billable."

End-Stage-Renal-Disease-Related Payment Requirements

CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02 (Benefit Policy Manual), chapter 11, sections 30.2.1.A and 70.2.A.1, specifies the ESRD-related laboratory tests (hereafter referred to as "tests") 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. Composite rate tests include both automated multichannel chemistry (AMCC) profile tests and non-AMCC tests.

Pursuant to the Benefit Policy Manual, chapter 11, section 30.2.1.A, when composite rate tests are performed at a frequency greater than specified, the additional tests are separately billable and payable "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 … [and s]uch information must be furnished using the ICD-9-CM coding system."

CMS guidance on AMCC tests in the Claims Processing Manual, chapter 16, section 40.6.1, uses the 50-percent rule, which specifies whether CMS will pay for these tests separately. In addition, the Benefit Policy Manual, chapter 11, section 30.2.1.B, states that certain other 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 that payment for more than one of these tests performed in a 3-month period requires medical documentation and a diagnosis other than ESRD.

Medicare Payment Requirements

Pursuant to section 1862(a)(1)(A) of the Act, "no payment may be made under [Medicare P]art A or [P]art 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.

Federal regulations (42 CFR § 410.32(a)) state: "All … diagnostic laboratory tests … must be ordered by the physician who is treating the beneficiary …. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary …."

Spectra Laboratories and Fresenius Medical Care North America

Spectra Laboratories (Spectra), a wholly owned subsidiary of Fresenius Medical Care North America (Fresenius), provides tests to ESRD beneficiaries for the 1,172 Fresenius owned or managed dialysis facilities (Fresenius facilities), as well as for non-Fresenius facilities. For each laboratory test requested by a Fresenius facility, Spectra receives a requisition that contains the name of the ordering physician. However, Spectra does not receive a copy of the actual physician order.

Spectra submits claims to its Medicare administrative contractors (MAC) for tests provided to ESRD beneficiaries. Fresenius facilities submit claims to their MACs for ESRD-related services included in the composite rate.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare claims that Spectra submitted for tests provided to ESRD beneficiaries at Fresenius facilities complied with certain ESRD-related payment requirements and with Medicare requirements that items and services be reasonable and necessary.

Scope

We limited our review to claims that Spectra submitted for tests that were subject to Medicare ESRD payment requirements. Our review covered 2,771,777 claims totaling $46,457,213 for tests that Spectra provided to ESRD beneficiaries at 1,172 Fresenius 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 Spectra's billing procedures for laboratory services provided to ESRD beneficiaries and Fresenius' policies and procedures related to medical record documentation and physician orders.

We performed our fieldwork at Fresenius' headquarters in Waltham, Massachusetts, from March through June 2008.

Methodology

To accomplish our audit objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- identified 1,172 Fresenius facilities that provided dialysis services during CYs 2004–2006;
- used data from CMS's National Claims History file to match Fresenius' ESRD composite rate paid claims with Spectra's laboratory claims based on "from" and "through" dates of service;
- identified from our computer match 764,456 beneficiary quarters[1] containing 4,612,700 line items of separately billed tests totaling $46,457,213 (Appendix B) and selected a simple random sample of 100 beneficiary quarters containing 671 lines of service totaling $7,000 (Appendix C);
- reviewed Spectra's policies and procedures applicable to separately billing ESRD claims for tests and Fresenius' policies and procedures applicable to medical record documentation and physician orders and interviewed Spectra and Fresenius officials regarding these policies and procedures;
- reviewed all beneficiary information (dialysis treatment dates, physician orders, algorithms, physician declarations, progress notes, diagnoses, drugs administered, test results, and other information from medical records) that Spectra and Fresenius provided to support the tests billed for the sampled items;[2]
- reviewed Spectra's billing records, claims, and remittance advices for the sampled items;
- determined whether the tests listed in Appendix A and included in the 100 sampled beneficiary quarters were correctly billed;
- identified tests in our sample that were at high risk of not being reasonable and necessary and requested the assistance of a MAC, National Government Services (NGS), to conduct an independent medical review of the claims for these tests using the information that Spectra and Fresenius facilities had provided to us;
- estimated the potential overpayments (Appendix C); and
- discussed the findings with Fresenius, Spectra, and CMS.

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

[2] To assist in the audit process, Fresenius provided us with those parts of the beneficiaries' medical records obtained from the ordering physician that were relevant to the specific claims being reviewed. See 42 CFR § 410.32(d)(iii)(B).

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

Spectra correctly did not submit claims for composite rate tests that fell within the specified frequencies or that Medicare would not have paid under the 50-percent rule, in accordance with ESRD-related payment requirements. However, some claims that Spectra submitted did not comply with Medicare requirements that items and services be reasonable and necessary. Spectra correctly billed tests in 67 of the 100 beneficiary quarters that we sampled. However, the remaining 33 beneficiary quarters contained errors totaling $1,079. This amount comprised:

- 24 beneficiary quarters containing errors totaling $891 for separately billed tests that, based on an independent medical review by NGS, were not reasonable and necessary and

- 12 beneficiary quarters containing errors totaling $188 for separately billed tests that were not reasonable and necessary because they were not ordered by the treating physician.

The beneficiary quarters that had errors totaled more than 33 because some beneficiary quarters had more than one type of error.

Spectra did not have sufficient procedures in place to ensure that all tests billed were reasonable and necessary. In addition, Fresenius facilities did not have sufficient controls to ensure that tests were ordered by the treating physician and were reasonable and necessary.

Based on our sample results, we estimated that Medicare overpaid Spectra $5.4 million for separately billed tests provided to ESRD beneficiaries at Fresenius facilities during CYs 2004–2006.

FEDERAL REQUIREMENTS

Pursuant to section 1862(a)(1)(A) of the Act, "no payment may be made under [Medicare P]art A or [P]art 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.

Federal regulations (42 CFR § 410.32(d)(3)(i)) require, among other things, that for a claim review, the entity that submitted the claim must provide, upon request by CMS, "[d]ocumentation of the order for the services billed," as well as diagnostic or other medical information that the entity received from the ordering physician. Furthermore, § 410.32(d)(3)(ii)

states, in part, that "[i]f the documentation … does not demonstrate that the service[s are] reasonable and necessary, CMS … [r]equests from the ordering physician … those parts of [the] beneficiary's medical record that are relevant to the specific claim(s) being reviewed." In addition, § 410.32(d)(3)(iii) states: "[t]he entity submitting the claim may request additional diagnostic and other medical information … to document that the services it bills are reasonable and necessary …." Furthermore, § 410.32(d)(4)(i) states that, subject to certain exceptions, CMS will review "all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records)" before denying a claim for services that are performed beyond the specified frequency.[3]

Federal regulations (42 CFR § 410.32(a)) state: "All … diagnostic laboratory tests … must be ordered by the physician who is treating the beneficiary …. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary …." Furthermore, 42 CFR § 410.32(d)(2)(i) states: "The physician … who orders the service must maintain documentation of medical necessity in the beneficiary's medical record." In addition, § 410.32(d)(2)(ii) requires, among other things, that the entity submitting the claim maintain documentation that it receives from the ordering physician. Section 410.32(d)(2)(iii) further states: "[t]he entity submitting the claim may request additional diagnostic and other medical information [from the ordering physician] to document that the services it bills are reasonable and necessary …."

TESTS THAT WERE NOT REASONABLE AND NECESSARY AS DETERMINED BY INDEPENDENT MEDICAL REVIEW

NGS's independent medical review, which included information from beneficiaries' medical records, found that Spectra received overpayments totaling $891 for tests that were not reasonable and necessary in 24 beneficiary quarters.[4]

[3] In practice, CMS often performs tasks such as these through its contractors. During the audit period, NGS was a carrier and has since contracted with CMS to be a MAC. CMS is in the process of transitioning contracts from fiscal intermediaries and carriers to MACs (Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173 § 911, Social Security Act, § 1874A, 42 U.S.C. §1395kk-1).

[4] NGS, in its capacity as a MAC, routinely performs postpayment medical reviews of claims. In performing its independent medical review for this report, NGS used its normal standard of review when performing postpayment medical reviews as a MAC.

Example: Tests Determined by Independent Medical Review Not To Be Reasonable and Necessary

Beneficiary A had weekly calcium and phosphorus tests performed in July in conjunction with her dialysis treatments. One calcium and one phosphorus test are included in the composite rate each month. Spectra separately billed Medicare for the additional calcium and phosphorus tests with a diagnosis other than ESRD. The beneficiary's medical record contained a standing order for monthly and weekly calcium and phosphorus tests. According to NGS's independent medical review, the additional tests were not reasonable and necessary.

TESTS THAT WERE NOT REASONABLE AND NECESSARY BECAUSE THEY WERE NOT ORDERED BY THE TREATING PHYSICIAN

Our review found that Spectra incorrectly billed and was reimbursed $188 for tests that had no physician orders in 12 beneficiary quarters. Tests that are not ordered by the treating physician are not reasonable and necessary.

Example: Tests That Were Not Ordered by the Treating Physician

Beneficiary B had three potassium tests performed during March in conjunction with his dialysis treatments. One potassium test is included in the composite rate each month. Spectra separately billed Medicare for the two additional potassium tests. Although the composite rate test was ordered by the treating physician, the beneficiary's medical records contained no physician orders for the two additional tests. Therefore, the tests were not reasonable and necessary.

INSUFFICIENT CONTROLS

Spectra did not have sufficient procedures in place to ensure that all tests billed to Medicare were reasonable and necessary. In addition, Fresenius facilities did not have sufficient controls to ensure that tests were ordered by the treating physician and were reasonable and necessary.

ESTIMATE OF UNALLOWABLE PAYMENTS

Based on our sample results, we estimated that Medicare overpaid Spectra $5.4 million for separately billed tests provided to ESRD beneficiaries during CYs 2004–2006 (Appendix C).

RECOMMENDATIONS

We recommend that:

- Spectra refund to the Medicare program $5.4 million in overpayments for CYs 2004–2006 and

- both Spectra and the Fresenius facilities strengthen their policies and procedures to ensure that all tests billed are reasonable and necessary, in compliance with Medicare requirements.

FRESENIUS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

Fresenius disagreed with our findings that certain tests were not reasonable and necessary, as determined by independent medical review, but acknowledged that it was unable to produce sufficient documentation of a physician's order for some of the other tests billed. In addition, Fresenius disagreed with our recommendations. We maintain that claims for certain tests in our sample that were submitted by Spectra did not comply with Medicare requirements that items and services be reasonable and necessary. Thus, we maintain that our findings and recommendations are valid.

We summarize Fresenius' relevant comments and our responses below and have included Fresenius' comments as Appendix D.

Deference to Physician Judgment

Fresenius Comments

Fresenius asserted that "NGS's medical necessity findings amount to unlawful second-guessing of treating physicians." Specifically, Fresenius stated that NGS had failed to give "legally required deference to the good faith medical judgments of the treating physicians" when making the medical necessity determinations for this audit. Fresenius maintained that each of the medical necessity errors that NGS found involved tests that were ordered by treating physicians for seriously ill patients and submitted with a specific diagnosis code other than ESRD that supported the medical necessity of the tests. To support its position that the law requires that the decisions of treating physicians be given substantial deference, Fresenius cited legal authorities, including case law.

Additionally, Fresenius questioned the standard of review that NGS used. Fresenius maintained that NGS should have followed the standard of review applied under the Corporate Integrity Agreement (CIA) between Fresenius and the Office of Inspector General (OIG). That standard of review was limited to determining whether the medical record included the diagnosis code used as the basis for payment. Fresenius also asserted that it had asked us to explain the standard of review that NGS used but that it had never received a satisfactory answer to this question.

Office of Inspector General Response

Fresenius overstated its position in asserting that our findings amount to unlawful second-guessing of treating physicians. No clear and singular precedent requires the treating physician's opinion to be given substantial deference in the Medicare context. Furthermore, this report in no way attempts to recommend how physicians should treat patients. Rather, this report points out that, although some claims that Spectra submitted for tests provided to ESRD beneficiaries at Fresenius facilities were billable on their face, the claims were not reimbursable because they did not comply with Medicare requirements that items and services be reasonable and necessary.

As stated in the report, NGS is a MAC, and in that capacity, it routinely performs postpayment medical reviews of claims on behalf of CMS. In performing its independent medical review for this report, NGS used the same standard of medical review that it would apply when performing postpayment medical reviews as a MAC. The standards for postpayment medical reviews are set forth in CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08.

Finally, this audit was not bound by the terms of the CIA. Tests must be reasonable and necessary to be reimbursable (section 1862(a)(1)(A) of the Act). Even if a test meets ESRD billing requirements or could potentially pass the standard of review under the CIA, it may not be reasonable and necessary. Fresenius acknowledged in its comments that a test that meets ESRD billing requirements is "subject to review to determine whether it was 'in fact reasonable and necessary.' "

Therefore, we maintain that NGS's medical review represents a sound process to determine the medical necessity of tests billed, that NGS applied the same standard of medical review that it would have applied had NGS conducted the review as part of the formal medical review process, and that this review was appropriate.

Basis for Recommending Stronger Controls

Fresenius Comments

Fresenius maintained that we had no basis for our conclusion that Spectra did not have sufficient procedures in place to ensure that all tests billed to Medicare were reasonable and necessary. Fresenius stated that "Spectra already effectively controls against the ordering of unnecessary testing by screening out and not billing for" certain tests that are not billable, as evidenced by some of the report findings, and that NGS and OIG failed to identify any actions by Spectra that caused or contributed to physicians' ordering "allegedly medically unnecessary testing." Fresenius asserted that following the OIG recommendation would effectively require Spectra to engage in an impossible permanent prepayment claim review process. Fresenius further stated that it was unclear what other controls could be implemented to address the audit findings.

Office of Inspector General Response

As noted in the 1998 OIG *Compliance Program Guidance for Clinical Laboratories* (CPG), a laboratory "should take all reasonable steps to ensure that it is not submitting claims for services

that are not covered, reasonable and necessary" (63 Fed. Reg. 45076, 45079). The CPG also cautions that "Medicare may deny payment for a test that [a] physician believes is appropriate, but which does not meet the Medicare coverage criteria … or where documentation … does not support that the tests were reasonable and necessary for a given patient." The CPG offers a number of steps that laboratories may take to "ensure that the claims they submit to Federal or private health care programs meet the appropriate program requirements." These steps provide a structure for establishing internal controls.

In response to Fresenius' comment that Spectra effectively controls against the ordering of unnecessary tests and that NGS and OIG failed to identify actions by Spectra that caused or contributed to the ordering of such tests, we note that those issues are beyond the scope of this report and reiterate that the focus of this report is on whether tests that Spectra billed were reasonable and necessary. We have clarified the body of our report to better reflect this focus.

We therefore continue to recommend that both Spectra and the Fresenius facilities strengthen their policies and procedures to ensure that all tests billed are reasonable and necessary, in compliance with Medicare requirements.

Limitation of Liability Determinations

Fresenius Comments

Fresenius stated that NGS failed to make the Medicare-required limitation of liability determinations in connection with its review. Citing the Act, Fresenius stated that these necessary determinations "essentially provide financial relief to providers by obligating Medicare to pay even for services that are determined to be unnecessary, provided the entity supplying the services did not know, and could not reasonably have been expected to know, that the services were not medically necessary at the time they were performed or is otherwise without fault for the overpayment." Fresenius concluded that the limitation of liability should extend to Spectra for certain claims at issue.

Office of Inspector General Response

In the OIG audit context, NGS is not required to make limitation of liability determinations. CMS (as the action official), through a MAC or other contractor, will determine whether the potential overpayment of $5.4 million exists and, if necessary, determine whether the limitation of liability provisions apply.

Estimated Unallowable Payments for Certain Tests

Fresenius Comments

Fresenius acknowledged that it was "not able to produce sufficient documentation of the physician's testing order" for certain claims but noted that this issue involved only 2.7 percent of our sample payments. Fresenius stated that, under OIG's guidelines, the 2.7 percent would not

justify estimating an overpayment. Fresenius further stated that it would "work with CMS to refund the overpayments for these individual claims."

Office of Inspector General Response

Contrary to Fresenius' assertions, OIG does not use a minimum error rate threshold to determine whether to estimate unallowable payments based on the results of a sample. Our estimate of unallowable payments was based on all of the reported findings in total, complied with OIG policies and procedures, and was based on a statistically valid methodology. For tests not ordered by the treating physician, we found that 12 beneficiary quarters contained errors totaling $188. This finding represents an estimated overpayment of $1.4 million[5] using statistically valid methods of estimation.

[5] We calculated the point estimate by dividing $188 by 100 sampled items and multiplying the resulting amount ($1.88) by the number of units in the sampling frame (764,456).

APPENDIXES

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

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

CPT Code[2]	Non-AMCC[3] 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] Source: *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 11, sections 30, 30.2.1, 30.2.2, and 70.2(A).

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

[3] 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

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

APPENDIX B: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population was all laboratory tests, grouped by beneficiary, calendar year, and quarter, that were provided by Spectra Laboratories, a wholly owned subsidiary of Fresenius Medical Care North America (Fresenius), and paid during calendar years (CY) 2004–2006. The population included only those laboratory tests listed in Appendix A that were provided to beneficiaries with end-stage renal disease at Fresenius owned or managed dialysis facilities .

SAMPLING FRAME

The sampling frame was a database consisting of 764,456 beneficiary quarters during which laboratory tests were provided by Spectra Laboratories and paid during CYs 2004–2006.

SAMPLE UNIT

The sample unit was a beneficiary quarter.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

The sample size was 100 beneficiary quarters.

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 the sampling frame from 1 through 764,456. After generating 100 random numbers, we selected the corresponding sample items.

ESTIMATION METHODOLOGY

We used the Office of Inspector General, Office of Audit Services, statistical software to estimate the value of unallowable payments.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Sample Results

Frame Size	Sample Size	Value of Sample	Number of Beneficiary Quarters With Unallowable Payments	Value of Unallowable Payments
764,456	100	$7,000	33	$1,079

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

Point estimate	$8,245,499
Lower limit	5,410,712
Upper limit	11,080,286

Fresenius Medical Care
North America

November 19, 2009

Michael J. Armstrong
Regional Inspector General for Audit Services
U.S. Department of Health & Human Services
Office of Inspector General, Region I
Office of Audit Services
John F. Kennedy Federal Building
Boston, MA 02203

Re: Audit Report A-01-08-00511 – Review of Separately Billed Laboratory Tests Submitted by Spectra Laboratories for Medicare Beneficiaries with End-Stage Renal Disease at Fresenius Medical Care North America's Facilities

Dear Mr. Armstrong:

On behalf of Fresenius Medical Care North America ("FMCNA"), we appreciate this opportunity to comment on the above-referenced audit report. As an initial matter, we believe it is particularly noteworthy that the audit found 100 percent compliance with the Medicare billing rules for end stage renal disease (ESRD) related laboratory testing, including the composite rate frequency rules and the so-called "50/50 rule." Given that these are among the most complicated billing rules in the Medicare program, it is a testament to Spectra Laboratories and its commitment to compliance that not a single billing error was found in nearly 700 lines of service reviewed by the OIG.

Unfortunately, however, Spectra's achievement is largely overshadowed by the audit's findings on medical necessity, which account for the vast majority of the asserted $5.4 million overpayment. As the OIG's report indicates, those findings are based entirely on a medical record review conducted at the OIG's direction by National Government Services ("NGS"), a Medicare administrative contractor (or "MAC"). We have two fundamental disagreements with this review and with the findings and recommendations resulting from it:

- First, in assessing medical necessity, NGS and the OIG have failed to adequately consider and give the legally required weight to the clinical judgment of the patients' treating physicians, even though those physicians are in the best position to objectively determine which laboratory tests are necessary for monitoring the care of their serious and chronically ill patients; and

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- Second, we object to the OIG's conclusion that Spectra and FMCNA do not have sufficient controls in place to prevent the performing of, and billing for, tests that the patients' physicians have reasonably determined are medically necessary.

The comments that follow set forth the bases for these objections in greater detail, as well as note the fact that NGS and the OIG failed to make the limitation of liability determinations required by Medicare law. We also address below the audit's other findings on documentation of physician orders, which we accept as valid, but which involve less than three percent of the claims at issue in the audit sample.

NGS's Medical Necessity Findings Amount to Unlawful Second-Guessing of Treating Physicians

To understand our objections to the audit's medical necessity findings, it is helpful to begin by briefly restating the applicable Medicare laws, rules, and guidelines for determining whether the ESRD-related lab services reviewed in this audit are covered as reasonable and necessary in accordance with Section 1862(a)(1)(A) of the Social Security Act. In focusing the audit on ESRD-related lab services, the OIG examined Spectra's billing for those tests that are either included in the Medicare composite rate for dialysis (such as monthly serum calcium, phosphorous and potassium tests, for example) or that are routinely paid at specified frequencies for dialysis patients (such as quarterly ferritin testing). As the report notes, for these tests to be separately payable, additional testing beyond the Medicare-specified frequencies must be (1) ordered by the beneficiary's treating physician, and (2) accompanied by documentation in the form of an ICD-9 diagnosis code *other than ESRD* that justifies the specific medical need for more frequent testing. 42 C.F.R. § 410.32(a); Medicare Benefit Policy Manual (Pub. 100-02), Ch. 11, § 30.2.1.[*] In Medicare terms, there is a "presumption of medical necessity" for tests that meet these requirements, but the claim is subject to review to determine whether it was "in fact reasonable and necessary." *See* Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services (Final Rule), 66 Fed. Reg. 58787, 58810 (Nov. 23, 2001).

Our primary objection to this audit is that testing covered under the foregoing Medicare policies is being denied without good cause and without giving the legally required deference to the good faith medical judgments of the treating physicians. Notably, each of the medical necessity errors asserted in this audit involves tests that, in accordance with the Medicare rules, were (1) ordered by treating physicians for seriously ill ESRD patients under their direct care, and (2) submitted

[*] In addition, automated multi-channel chemistry ("AMCC") tests are subject what is commonly referred to as the "50/50 rule," which essentially provides that when multiple AMCC tests are performed on the same day, then (1) if 50 percent or more of those tests are included within the composite rate, then none of the AMCC tests are separately payable, and (3) if less than 50 percent of the tests are composite rate tests, then all of the AMCC tests are separately payable. Id. at § 30.2.2.

with a specific diagnosis code, other than ESRD, that supported the medical necessity of the testing and that was confirmed through the audit to be documented in the medical record. Thus, all of the tests at issue are presumptively covered by Medicare policy, so that the proposed denials amount to the NGS reviewers second-guessing the medical judgments of treating physicians as to *how often* otherwise covered testing was needed for individual patients. This is not permitted under the laws governing the Medicare program.

Indeed, the Medicare statute literally begins with the prohibition "Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395. One logical corollary to this prohibition is that the beneficiary's physician generally should decide what services are medically necessary. Thus, in assessing medical necessity, courts have long employed what is known as the "treating physician rule," which provides that the judgment of the treating physician should be given "extra weight" or "a reasoned basis…[should be supplied] for declining to do so." State of New York *ex rel*. Holland v. Sullivan, 927 F.2d 57, 60 (2d Cir. 1991). *See also* Bergeron v. Shalala, 855 F. Supp. 665, 668 (D. Vt. 1994); Klementowski v. Secretary, Department of Health and Human Services, 801 F. Supp. 1022, 1025-26 (W.D.N.Y. 1992); Gartmann v. Secretary of United States Department of Health and Human Services, 633 F. Supp. 671, 680-81 (E.D.N.Y. 1986). The concept of giving special weight to the opinion of the treating physician originated in Social Security disability benefits cases "because the treating source is inherently more familiar with a claimant's medical condition than are other sources." Schisler v. Bowen, 851 F.2d. 43, 47 (2d Cir. 1988); *see also* Magallanes v. Bowen, 881 F.2d 747, 751 (9th Cir. 1989) (greater weight is afforded to the treating physician because "he is employed to cure and has a greater opportunity to know and observe the patient"). As the court noted in Gartmann:

> This rule may well apply with even greater force in the context of Medicare reimbursement. The legislative history of the Medicare statute makes clear the essential role of the attending physician in the statutory scheme: **"***The physician is to be the key figure in determining utilization of health services*.**"**

633 F. Supp. at 680-81 (emphasis supplied), *quoting* 1965 U.S. Code Cong. and Ad. News 1943, 1986.

In other words, under the treating physician rule, a Medicare claims reviewer is not permitted to simply substitute his or her medical judgment for that of the treating physician. Rather, the treating physician's good faith medical judgments are entitled to substantial deference, meaning they should be overturned in a post-payment claims review *only if* no reasonable physician would consider the item or service under review necessary in the diagnosis, care, or treatment of the patient.

Accordingly, for eight years between 2000 and 2008, the standard of review under our Corporate Integrity Agreement ("CIA") with the OIG for laboratory claims generated by FMCNA facilities was whether the diagnosis code used as the basis for payment was stated in the medical record. If it was, the independent review organization could "not question that determination by the physician." It is puzzling to us why this standard – which gives proper deference to the treating physician to determine how frequently covered testing needs to be performed – was not applied in the present audit. It is abundantly clear, however, that it was not.

Indeed, it appears that no consideration – or at least no "extra weight" – was given to the medical judgments of the treating physicians in the NGS medical review. It should be understood that none of these physicians have a financial interest in Spectra Laboratories, nor do they stand to profit in any way from their Medicare lab test orders. These physicians do have a tremendous responsibility in caring for ESRD beneficiaries, who are among the sickest individuals in the health care system. In addition to ESRD, virtually all dialysis patients have additional medical complications, such as anemia, heart disease, bone disease, and diabetes, which add significantly to the complexity of their care. In any given year, up to a quarter of ESRD patients on dialysis die from complications related to their disease. Timely and regular laboratory testing is essential to the effective care and treatment of these beneficiaries. Yet, NGS gives no extra weight to the treating physicians in this audit as to how often testing should occur for their seriously ill ESRD beneficiaries, or any reason for declining to do so.

Consider, for example, the following findings from the NGS medical review:

- In Sample 24, the NGS reviewer denies a monthly ferritin test performed after the treating physician also ordered the administration of the drug EPOGEN® and intravenous iron two months earlier for treatment of the patient's anemia. The stored iron measured by the ferritin test is essential to effective EPOGEN therapy. Thus, the denied test was not only reasonably ordered by the treating physician, but was in accordance with highly regarded clinical practice guidelines from the National Kidney Foundation's Kidney Dialysis Outcomes Quality Initiative (the "KDOQI Guidelines"), which recommend that iron status tests be performed *every month* during initial EPOGEN treatment *until the patient is on a stable dose*. Notably, the patient's EPOGEN and IV iron doses were adjusted multiple times throughout the audit period, and the patient's hemoglobin level dropped below the target level on tests performed the week before and the day of the denied ferritin test.

- In Sample 40, twice monthly calcium and phosphorous tests are deemed medically unnecessary by the NGS reviewer despite six occasions of abnormal phosphorus levels during the audit period, four occasions of abnormal calcium levels, and a documented need for Vitamin D drug therapy (Zemplar®) – all issues of concern to a treating physician and reasonable grounds for more frequent testing. Patients with phosphorous

imbalances are at risk of many complications, including potentially life threatening calcification of soft tissue. Similarly, calcium imbalances can lead to severe organ and muscle dysfunction when calcium levels are too low, or mental state deterioration when levels are too high.

- In Sample 53, the NGS reviewer denies calcium and phosphorous tests ordered in accordance with the Zemplar package insert, which recommends monitoring *at least* every two weeks for three months after initiation of the drug. Thus, the testing in this case again was not only reasonable, but also specifically recommended in FDA-approved labeling.

- In Samples 63 and 73, the NGS reviewer rejects weekly potassium testing as unnecessary. Yet, the medical records document evidence of serious potassium imbalances, with abnormally high values 11 times during the audit period in Sample 63 and eight times in Sample 73. High potassium levels can cause cardiac arrhythmia that may lead to sudden cardiac death, and even small changes may increase the risk of heart rhythm disturbances. As a result, the physician treating a patient with elevated potassium levels often will monitor lab values very closely, with a thought towards modifying the plan of care as necessary. In Sample 63, for example, medical record documentation shows that the physician responded to the abnormally high potassium readings by lowering the potassium level in the patient's dialysis solution, which requires additional close monitoring against the potassium levels fluctuating too rapidly.

- In Samples 13 and 72, the NGS reviewer denied calcium and phosphorous tests on the grounds that they were ordered more frequently than the every two weeks called for in a physician's Zemplar dosing algorithm. Of course, it is neither required nor desirable for physicians to follow algorithms in every case. Indeed, the decision to depart from an algorithm may actually reflect appropriate attention to a patient's individualized medical needs. Sample 13 also includes the denial of testing performed in accordance with the algorithm's every two week frequency because the testing occurred during the fifth week of a five-week month, which the NGS reviewer inexplicably concluded "should be ignored." The NGS reviewer also deems unnecessary testing performed following the conclusion of Vitamin D therapy because, in the reviewer's judgment, it should have been performed two weeks after discontinuation, rather than one week post-treatment, as ordered by the treating physician.

Similar findings are made throughout the NGS review, with abnormal lab results, documented physician and nurse monitoring of test results, and documented treatment changes repeatedly deemed insufficient justification for testing ordered by treating physicians for seriously ill ESRD patients. On the other hand, test results in the normal range were, at times, considered by the reviewer to be irrefutable evidence that the tests were unnecessary. Clearly, such a position is

unreasonable. A diagnostic test is, by definition, a test performed to help make a diagnosis, not merely to confirm what one already knew.

Simply put, this audit is not about physicians carelessly or self-interestedly over-ordering tests for a relatively healthy patient population. Rather, the documentation we furnished to the OIG in support of these claims makes clear that the tests at issue were considered medically necessary by treating physicians whose only motivation was to provide optimal care to their seriously ill and medically complex patients. NGS and the OIG have not met their legal burden of demonstrating that these judgments were unreasonable.

During the course of this audit, we repeatedly asked the OIG to explain the standard of review that was applied by NGS. The actual standard was never articulated to us. The only thing resembling an answer appears in footnote 4 of the report that was furnished to us for comment, which merely states that "NGS used the same standard of review that it usually applies when performing post-payment reviews as a MAC." Whatever that standard is, it clearly is not one that gives proper deference to the treating physician, as required by law. Thus, we are confident that the overwhelming majority of proposed medical necessity denials from the NGS review would not withstand scrutiny through the Medicare appeals process.

There is No Basis for the OIG's Finding of Insufficient Controls on Medical Necessity

Our second concern is with the OIG's finding that "Spectra did not have sufficient procedures in place to ensure that all tests performed and billed were reasonable and necessary." As a result of that finding, the OIG recommends that "both Spectra and Fresenius facilities strengthen their policies and procedures to ensure that all tests billed are reasonable and necessary."

We cannot disagree more strongly with these statements. As the audit found, Spectra already effectively controls against the ordering of unnecessary testing by screening out and not billing for thousands of tests per month that are not accompanied by a more specific diagnosis from the ordering physician – other than just ESRD – to support the medical necessity of the testing. This is what the Medicare rules require of clinical laboratories. Moreover, there is nothing in this audit to suggest that Spectra performed an unusually high number of tests compared to other laboratories that service dialysis facilities. Nor did NGS or the OIG identify any actions or conduct on the part of Spectra that either caused or contributed to the ordering of allegedly medically unnecessary testing.

Rather, in looking beyond the patients' diagnoses to challenge how often physicians order testing in individual cases, the OIG's findings with respect to medical necessity are nothing short of a federal agency substituting its judgment for that of physicians who have no financial interest themselves in the tests performed, and are concerned only for the well-being of the patients in their care. As if this were not sufficiently troubling, the OIG then proceeds to recommend that Spectra and FMCNA, corporations that are not licensed to practice medicine, somehow perform

this role on a going-forward basis. This is not something that a laboratory or dialysis facility is qualified or able to do as a legal or practical matter, given their roles in the health care system in relation to physicians and the sheer volume of testing performed each day.

Spectra and FMCNA do believe they have an appropriate role to play in the care of the beneficiaries that extends beyond the existing controls validated during this audit. That role relates to the continuing education of physicians. Fortunately, medical science offers new findings every day, and we strive to keep the physicians who practice in our facilities up-to-date with regard to best medical practices. That role, however, must stop short of prescribing care for a particular patient or refusing to carry out a doctor's orders. As the OIG itself recognizes in its *Compliance Program Guidance for Clinical Laboratories*, "laboratories do not and cannot treat patients or make medical necessity determinations" and "physicians…must be able to order any tests that they believe are appropriate for the treatment of their patients." 63 Fed. Reg. 45076, 45079 (Aug. 24, 1998).

While we view it as Spectra's legal obligation to continue to perform the tests ordered by its physician customers, responding to the OIG's recommendation would require Spectra to carry out its own medical records review relating to each test prior to submitting the claim for the test to Medicare, presumably using its own independent medical judgment (as NGS apparently has done in this audit). It should go without saying to the OIG that this would be an impossible undertaking, no different than permanent "pre-payment review" of all of its claims. Yet, it is not clear to us what other controls could be put in place to address the OIG's findings from this audit.

NGS Did Not Make the Limitation of Liability Determinations Required by Medicare Law

There also is no indication that NGS made the limitation of liability determinations that are required from MACs in post-payment reviews. *See* Medicare Program Integrity Manual (Pub. 100-08), Ch. 3, § 3.4.1.B ("When a claim is denied, in full or in part, because an item or service is not reasonable and necessary, contractors make and document §§ 1879, 1870 and 1842(l) limitation of liability determinations as appropriate"). Such determinations are made necessary by the cited provisions of the Social Security Act, which essentially provide financial relief to providers by obligating Medicare to pay even for services that are determined to be unnecessary, provided the entity supplying the services did not know, and could not reasonably have been expected to know, that the services were not medically necessary at the time they were performed or is otherwise without fault for the overpayment. The Centers for Medicare & Medicaid Services ("CMS") has explicitly confirmed that these limitation of liability provisions are "equally applicable to laboratory services." Negotiated Rulemaking Final Rule, 66 Fed. Reg. at 58790.

In applying the limitation of liability provisions to the NGS medical necessity findings, it again is relevant that each test in question was originally accompanied by an ICD-9 diagnosis code

from the ordering physician that indicated to Spectra that the test was covered under the Medicare composite rate billing rules (i.e., they were justified by a diagnosis other than ESRD). Like all clinical laboratories, Spectra must rely on the diagnosis information it receives from ordering physicians at the time of testing. Moreover, since the Spectra labs perform nearly four million tests per month, they clearly are not in a position to confirm whether or not particular tests are medically necessary, especially since the labs do not see the patients nor have access to their medical records. Indeed, because much of the testing is performed during the night, and in many instances the results are returned to the physician the next day, further inquiry into the medical necessity of the testing before it is performed – beyond confirming that the diagnosis provided is consistent with the applicable coverage rules, which, again, Spectra did *without error* in this audit sample – would be impossible.

In historical correspondence and Medicare appeals decisions that we furnished to the OIG during the course of this audit, CMS and administrative law judges have found that in such situations, because the laboratory could not reasonably have known that the services would not be covered, it should not be held liable for overpayments under the limitation of liability provisions. Likewise, even if some of the tests proposed for denial by NGS arguably were not medically necessary, limitation of liability protection should extend to Spectra for those services.

Other Documentation Errors Involve Less Than Three Percent of the Sampled Claims

We acknowledge that there were some cases in the audit sample where we were not able to produce sufficient documentation of the physician's testing order. With regard to this finding, it should be understood that in the dialysis setting, individual test requisitions typically are completed by facility staff based on physician orders that are maintained in the patients' medical records. Thus, these documentation errors amount to the facility misfiling or otherwise not being able to produce the underlying order for testing that the facility requested from the lab.

Without denying our duty to provide documentation of the physician's order, it is important to put this aspect of the OIG's findings in proper perspective:

- First, the order documentation issue involves only 2.7% of the payments in the audit sample, which compares favorably to the national Medicare CERT error rate (3.7% in 2008) and which, under the OIG's own guidelines, would not be sufficient to justify an extrapolated overpayment. We will work with CMS to refund the overpayments for these individual claims.

- Second, these are clerical errors of the sort that are inevitable in a still predominantly paper-based health care system, recognizing that the claims in the audit sample date back five years to 2004. This, of course, is one of the reasons why Congress has provided

incentives to accelerate the transition to electronic medical records in the HITECH Act enacted into law earlier this year.

In the case of FMCNA, we have already committed over $100 million to implementing electronic record-keeping solutions that will minimize these kinds of clerical errors. In the meantime, we have enhanced our internal controls on maintaining signed physician orders in the medical records, including increased training for dialysis facility staff and the addition of routine reviews of order documentation to our internal facility quality assessment and improvement processes.

Closing Comments

While we respect the important role that the OIG plays in protecting the integrity of the Medicare program, this audit is simply wrong on both the facts and the law with regard to medical necessity. We urge you to reconsider your findings under an appropriate standard of review that gives due deference to the treating physicians and that recognizes – in accordance with long-standing OIG guidance quoted above – that laboratories do not and cannot treat patients or make medical necessity determinations.

Absent further clarification from the OIG, every clinical laboratory in the nation should be concerned if it is the new policy of the OIG that, not only do the "treating physician rule" and "limitation of liability" provisions no longer apply to clinical laboratory claims submitted for Medicare reimbursement, but on a going-forward basis, clinical laboratories should have controls in place to prevent the "performing and billing" for such tests in the first place. This simply is not a lawful or workable approach to assessing medical necessity.

If necessary, we will address our concerns with the audit findings with CMS and through the Medicare appeals process.

Sincerely yours,

Todd J. Kerr
Senior Vice President &
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