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OCT - 5 2007

Report Number: A-01-07-00506

Mr. Mark Tarlton
Vice President of Facilities and Support Services
Corporate Compliance Officer
Caritas St. Elizabeth's Medical Center
736 Cambridge Street Quinn 1
Boston, Massachusetts 02135

Dear Mr. Tarlton:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of Separately Billed Composite Rate Laboratory Services Under the Medicare End Stage Renal Disease Program at Caritas St. Elizabeth's Medical Center." 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.

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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-01-07-00506 in all correspondence.

Sincerely,

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Thomas W. Lenz, Consortium Administrator
Consortium for Financial Management and Fee For Service Operations
Centers for Medicare and Medicaid Services
601 E. 12th Street, Room 235
Kansas City, MO 64106

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF SEPARATELY BILLED COMPOSITE RATE LABORATORY SERVICES UNDER THE MEDICARE END STAGE RENAL DISEASE PROGRAM AT CARITAS ST. ELIZABETH'S MEDICAL CENTER

Daniel R. Levinson
Inspector General

October 2007
A-01-07-00506

Office of Inspector General

http://oig.hhs.gov

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OAS FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

Medicare's End Stage Renal Disease Program

Title XVIII of the Social Security Act, as amended, established Health Insurance for the Aged and Disabled (Medicare), a broad program of health insurance administered by the Centers for Medicare and Medicaid Services (CMS). Through its End Stage Renal Disease (ESRD) Program, Medicare provides coverage for eligible beneficiaries who have ESRD.

Composite Rate Payments

CMS established a composite rate method of payment to reimburse hospital-based and independent dialysis facilities for dialysis services provided to ESRD beneficiaries on a per-treatment basis. 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 that are included in a facility's composite rate and the frequencies at which these tests are included (e.g., per treatment, weekly, monthly, or quarterly). (See Appendix A.) When laboratory tests are performed at these frequencies, they cannot be billed separately. However, when any of these tests are performed at a frequency greater than specified, the additional tests are separately billable and payable if they are medically justified. In addition, laboratory tests not included as part of the facility's composite rate may be billed separately.

Caritas St. Elizabeth's Medical Center

Caritas St. Elizabeth's Medical Center (the Hospital) operates a hospital-based dialysis facility in Boston, Massachusetts. Medicare paid the Hospital $114,085 for dialysis-related, separately billed laboratory services provided to ESRD beneficiaries in calendar years (CY) 2004 and 2005.

OBJECTIVE

The objective of our review was to determine whether the Hospital billed Medicare in accordance with Medicare requirements for laboratory tests provided to ESRD beneficiaries during CYs 2004 and 2005.

SUMMARY OF FINDING

The Hospital did not always bill Medicare in accordance with Medicare requirements for laboratory tests provided to ESRD beneficiaries during CYs 2004 and 2005. Specifically, from a statistical sample of 100 beneficiary quarters valued at $16,065, the Hospital

incorrectly billed and was reimbursed $11,105 for ESRD-related laboratory services that did not meet Medicare reimbursement requirements. This amount comprised:

- $9,057 for hematology laboratory services included in the composite rate,
- $1,705 in automated multi-channel chemistry (AMCC) tests that did not meet specific reimbursement requirements, and
- $343 for ferritin tests billed beyond the allowable frequency without medical justification.

The Hospital incorrectly billed for these services because it did not have sufficient controls (e.g., written physician orders, correct billing policies and procedures) to ensure that all claims that it submitted were in accordance with Medicare requirements. Based on the statistical sample, we estimate that Medicare overpaid the Hospital $61,628 for laboratory services provided to ESRD beneficiaries during CYs 2004 and 2005.

RECOMMENDATIONS

We recommend that the Hospital:

- work with its fiscal intermediary to refund the Medicare program $61,628 in overpayments for CYs 2004 and 2005,
- identify and refund any Medicare payments for ESRD-related laboratory services received after our audit period that did not meet Medicare requirements, and
- strengthen its policies and procedures to ensure compliance with Medicare requirements.

HOSPITAL'S COMMENTS

In its comments on our draft report, the Hospital agreed with our finding and recommendations.

The Hospital's comments are included in their entirety as Appendix D.

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INTRODUCTION

BACKGROUND

Medicare's End Stage Renal Disease Program

Title XVIII of the Social Security Act, as amended, established Health Insurance for the Aged and Disabled (Medicare), a broad program of health insurance administered by the Centers for Medicare and Medicaid Services (CMS). Through its End Stage Renal Disease (ESRD) Program, Medicare provides coverage for eligible beneficiaries who have ESRD.

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CMS established a composite rate method of payment to reimburse hospital-based and independent dialysis facilities for dialysis services provided to ESRD beneficiaries on a per-treatment basis. 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 that are included in a facility's composite rate and the frequencies at which such tests are included (e.g., per treatment, weekly, monthly, or quarterly). (See Appendix A.) When laboratory tests are performed at these frequencies, they cannot be billed separately. However, when any of these tests are performed at a frequency greater than specified, the additional tests are separately billable and payable if they are medically justified. In addition, laboratory tests not included as part of the facility's composite rate are separately billable.

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Caritas St. Elizabeth's Medical Center (the Hospital) operates a hospital-based dialysis facility in Boston, Massachusetts. Medicare paid the Hospital $114,085 for dialysis-related, separately billed laboratory services provided to ESRD beneficiaries in CYs 2004 and 2005.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our review was to determine whether the Hospital billed Medicare in accordance with Medicare requirements for laboratory tests provided to ESRD beneficiaries during CYs 2004 and 2005.

Scope

Our review covered separately billed and paid laboratory services that the Hospital provided to ESRD beneficiaries in CYs 2004 and 2005.

In completing our review, we established reasonable assurance that the data were authentic and accurate. Our audit was not directed toward assessing the completeness of the files from which the data were obtained. The objective of our review did not require an understanding or assessment of the Hospital's complete internal control structure. We limited our review of internal controls to obtaining an understanding of the Hospital's billing procedures for laboratory services provided to ESRD beneficiaries.

We performed our fieldwork at Caritas St. Elizabeth's Medical Center in Boston, Massachusetts, from May through June 2007.

Methodology

To accomplish our audit objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- interviewed official from the fiscal intermediary, National Government Services, Inc., to obtain an understanding of the claims processing system;
- used data from CMS's National Claims History file to match ESRD composite-rate paid claims to the Hospital's ESRD outpatient laboratory claims based on "from" and "through" dates of service;
- selected a statistical random sample of 100 beneficiary quarters[1] totaling $16,065 from the 592 beneficiary quarters totaling $87,322 for separately billed ESRD-related laboratory services that our computer match identified (see Appendix B);
- obtained an understanding of the Hospital's policies and procedures applicable to billing ESRD claims for separately billable laboratory services;
- reviewed dates of dialysis treatments, physician orders, all laboratory tests performed, and progress notes from the Hospital's supporting medical records for each sample item;
- reviewed the Hospital's billing records, claims, and remittance advices and CMS's Common Working File records;

[1] A beneficiary quarter comprises all separately billed and reimbursed composite-rate tests, AMCC tests, serum aluminum and serum ferritin tests, and blood specimen collection fees for an ESRD beneficiary during a calendar quarter.

- evaluated the 100 sample items to determine whether all paid ESRD-related laboratory services were allowable and medically justified; and

- used an unrestricted variable appraisal program for a simple random sample to estimate the potential overpayments to the Hospital (see Appendix C).

We conducted our audit in accordance with generally accepted government auditing standards.

FINDING AND RECOMMENDATIONS

The Hospital did not always bill Medicare in accordance with Medicare requirements for laboratory tests provided to ESRD beneficiaries during CYs 2004 and 2005. Specifically, from a statistical sample of 100 beneficiary quarters valued at $16,065, the Hospital incorrectly billed and was reimbursed $11,105 for ESRD-related laboratory services that did not meet Medicare reimbursement requirements. This amount comprised:

- $9,057 for hematology laboratory services included in the composite rate,

- $1,705 for automated multi-channel chemistry (AMCC) tests that did not meet specific reimbursement requirements, and

- $343 for ferritin tests billed beyond the allowable frequency without medical justification.

The Hospital incorrectly billed for these services because it did not have sufficient controls (e.g., written physician orders, correct billing policies and procedures) to ensure that all claims that it submitted were in accordance with Medicare requirements. Based on the statistical sample, we estimate that Medicare overpaid the Hospital $61,628 for laboratory services provided to ESRD beneficiaries during CYs 2004 and 2005.

PROGRAM REQUIREMENTS

Laboratory Services Included in the Composite Rate

Publication 100-02, "Medicare Benefits Policy Manual," Chapter 11, section 30.2, Laboratory Services Included Under Composite Rate, Revision 1, 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."

Furthermore, section 30.2.1A, Routinely Covered Tests Paid Under Composite Rate, states, "The tests . . . 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." (See Appendix A for a list of composite rate tests.)

Fifty-Percent Rule

Publication 100-02, "Medicare Benefits Policy Manual," Chapter 11, section 30.2.2, Automated Multi-Channel Chemistry (AMCC) Tests, states, "To determine if separate payment is allowed for non-composite rate tests for a particular date of service, 50 percent or more of the covered tests must be non-composite rate tests." Specifically, Medicare will apply the following criteria, among others, to AMCC tests for ESRD beneficiaries:

- For a particular date of service, the intermediary must identify the AMCC tests ordered that are included in the composite rate and those that are not included.

- If 50 percent or more of the covered tests are included under the composite rate payment, then all submitted tests for that date of service 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 are composite rate tests, all AMCC tests submitted for that date of service are separately payable.

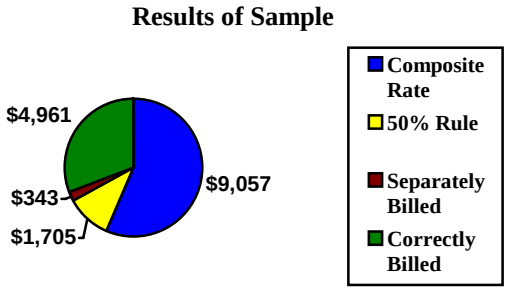
Separately Billable Tests

Publication 100-02, "Medicare Benefits Policy Manual," Chapter 11, section 30.2.1B, Separately Billable Tests, identifies ". . . certain separately billable laboratory tests [aluminum and 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 that specified, 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."

RESULTS OF STATISTICAL SAMPLE

Sample Units in Error

The Hospital incorrectly billed and was separately reimbursed for ESRD-related laboratory services. Of the $16,065 reviewed, $11,105 was unallowable. As the chart illustrates, the errors for these sample units fall into three categories: errors relating to laboratory services included in the composite rate, errors relating to the 50 percent rule, and errors relating to a separately billable test, ferritin, reimbursed beyond the allowable frequency without medical justification. (See Appendix B for a complete analysis.)



Laboratory Services Included in the Composite Rate

The Hospital incorrectly billed and was reimbursed $9,057 for composite-rate laboratory services. Specifically, a complete blood count, a monthly composite rate test, was generally performed weekly, which is above the specified frequency. However, the Hospital's medical records for these sampled items provided no medical justification to support performing complete blood counts more than once a month.

Improper Application of the Fifty-Percent Rule

The Hospital incorrectly billed and was reimbursed $1,705 for AMCC tests when 50 percent or more of the tests performed on the date of service were included in the composite rate. Although the Hospital's policy was not to bill Medicare for any AMCC tests performed on ESRD patients during our audit period, the Hospital's billing clerk inadvertently repeatedly billed for three specific noncomposite AMCC tests. The percentage of AMCC composite rate tests that the Hospital performed on a given date was greater than 50 percent. However, the percentage of composite rate tests billed on a given date was less than 50 percent because the Hospital billed for only the three specific noncomposite rate tests. As a result, Medicare incorrectly paid for these AMCC tests.

Lack of Medical Justification for Separately Billable Tests

The Hospital incorrectly billed and was reimbursed $343 for ferritin tests, which were separately billable but were performed beyond the allowable frequency of once a quarter. The Hospital did not have any medical documentation to support the medical necessity for performing the additional tests for 17 beneficiaries. Hospital officials stated that the Hospital's Patient Financial Services Department does not track the number of times this test is billed to Medicare.

INSUFFICIENT CONTROLS

The Hospital incorrectly billed for these services because it did not have sufficient controls (e.g., written physician orders, correct billing policies and procedures) to ensure that all claims that it submitted were in accordance with Medicare requirements. However, during our audit, Hospital officials stated that they had corrected the Hospital's policy of performing and billing complete blood counts.

ESTIMATE OF UNALLOWABLE PAYMENTS

Based on the statistical sample, we estimate that the Hospital incorrectly billed and was reimbursed $61,628 for ESRD-related laboratory services that did not meet Medicare requirements.

RECOMMENDATIONS

We recommend that the Hospital:

- work with its fiscal intermediary to refund the Medicare program $61,628 in overpayments for CYs 2004 and 2005,

- identify and refund any Medicare payments for ESRD-related laboratory services received after our audit period that did not meet Medicare requirements, and

- strengthen its policies and procedures to ensure compliance with Medicare requirements.

HOSPITAL'S COMMENTS

In its comments on our draft report, the Hospital agreed with our finding and recommendations.

We have included the Hospital's comments in their entirety as Appendix D.

APPENDIXES

LABORATORY SERVICES EXTRACTED FOR REVIEW

CPT CODE[2]	LABORATORY TESTS INCLUDED IN THE COMPOSITE RATE
Per Treatment	
85013	Spun microhematocrit
85014	Hematocrit (Hct)
85018	Hemoglobin (Hgb)
Weekly	
85610	Prothrobin time
Monthly	
85007	Blood count automated blood smear, microscopic examination with manual differential WBC count
85025	Complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count
85027	Complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)

CPT CODE	AMCC[3] TESTS INCLUDED IN THE COMPOSITE RATE
Weekly	
82565	Creatinine; blood
84520	Urea nitrogen; quantitative
Monthly	
82040	Albumin; serum
82310	Calcium; total
82374	Carbon dioxide (bicarbonate)
82435	Chloride; blood
83615	Lactic dehydrogenase (LD), (LDH)
84075	Phosphate, alkaline
84100	Phosphorous inorganic (phosphate)
84132	Potassium; serum
84155	Protein, total, except by refractometry; serum
84450	Transferase; aspartate amino (AST) (SGOT)

[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 Multi-Channel Chemistry.

CPT CODE	OTHER AMCC TESTS USED TO CALCULATE THE FIFTY-PERCENT RULE
82247	Bilirubin; total
82248	Bilirubin; direct
82465	Cholesterol, serum or whole blood count
82550	Creatine kinase (CK), (CPK); total
82947	Glucose; quantitative, blood (except reagent strip)
82977	Glutamyltransferase, gamma (GGT)
84295	Sodium; serum
84460	Transferase; alanine amino (ALT) (SGPT)
84478	Triglycerides
84550	Uric acid; blood

CPT CODE	SEPARATELY BILLABLE TESTS NOT INCLUDED IN THE COMPOSITE RATE – LIMITED IN FREQUENCY

One Time per Quarter

82108	Aluminum
82728	Ferritin

CPT CODE	SERVICES PERFORMED IN CONJUNCTION WITH LABORATORY TESTS
36415/ G0001	Routine Venipuncture

RESULTS OF SAMPLE

Sample Number	Sample Amount	Composite Rate	50% Rule	Separately Billable	Correctly Billed
1	$182.88	$122.98	$21.84	$19.03	$19.03
2	$187.13	$110.30	$22.20		$54.63
3	$240.62	$113.94	$21.84	$19.03	$85.81
4	$163.85	$122.98	$21.84		$19.03
5	$134.53	$65.10	$14.80		$54.63
6	$147.59	$106.72	$21.84		$19.03
7	$200.40	$104.90	$21.84	$19.03	$54.63
8	$154.81	$113.94	$21.84		$19.03
9	$179.55	$103.08	$21.84		$54.63
10	$52.60	$45.20	$7.40		
11	$148.67	$94.04			$54.63
12	$64.09	$9.04			$55.05
13	$164.21	$122.98	$22.20		$19.03
14	$165.41	$79.60			$85.81
15	$163.29	$86.82	$21.84		$54.63
16	$28.68				$28.68
17	$186.65	$113.94	$22.20		$50.51
18	$145.71	$112.12	$14.56		$19.03
19	$64.35	$30.76	$14.56		$19.03
20	$145.77	$104.90	$21.84		$19.03
21	$173.84	$113.94	$21.84	$19.03	$19.03
22	$72.68	$57.88	$14.80		
23	$196.19	$122.98	$18.58		$54.63
24	$225.00	$103.08	$14.80		$107.12
25	$209.44	$113.94	$21.84	$19.03	$54.63
26	$136.67	$103.08	$14.56		$19.03
27	$187.50	$85.00	$14.80		$87.70
28	$145.71	$112.12	$14.56		$19.03
29	$195.36	$99.50	$22.20	$19.03	$54.63
30	$107.93	$37.98	$15.32		$54.63
31	$164.21	$122.98	$22.20		$19.03
32	$156.99	$115.76	$22.20		$19.03
33	$153.66	$95.86	$22.20		$35.60
34	$731.61	$74.14	$7.40		$650.07
35	$179.91	$103.08	$22.20		$54.63
36	$154.12	$86.82	$29.24	$19.03	$19.03
37	$109.55	$75.96	$14.56		$19.03
38	$180.73	$104.90	$22.20		$53.63
39	$164.21	$122.98	$22.20		$19.03
40	$46.33	$19.90	$7.40		$19.03
41	$146.13	$104.90	$22.20		$19.03
42	$145.77	$104.90	$21.84		$19.03
43	$45.26	$37.98	$7.28		

Sample Number	Sample Amount	Composite Rate	50% Rule	Separately Billable	Correctly Billed
44	$9.04	$9.04			
45	$196.19	$122.98	$18.58		$54.63
46	$107.97	$74.14	$14.80		$19.03
47	$151.41	$117.58	$14.80		$19.03
48	$40.84				$40.84
49	$189.32	$79.60	$22.20	$19.03	$68.49
50	$54.42	$47.02	$7.40		
51	$197.99	$121.16	$22.20		$54.63
52	$46.21	$19.90	$7.28		$19.03
53	$169.92	$112.12	$22.20		$35.60
54	$190.77	$113.94	$22.20		$54.63
55	$190.77	$113.94	$22.20		$54.63
56	$73.45	$47.02	$7.40		$19.03
57	$199.81	$122.98	$22.20		$54.63
58	$186.08	$125.94	$22.08	$19.03	$19.03
59	$10.86	$10.86			
60	$129.51	$88.64	$21.84		$19.03
61	$145.77	$104.90	$21.84		$19.03
62	$145.18	$122.98	$22.20		
63	$34.20				$34.20
64	$140.55	$106.72	$14.80		$19.03
65	$118.83	$85.00	$14.80		$19.03
66	$174.20	$113.94	$22.20	$19.03	$19.03
67	$209.44	$113.94	$21.84	$19.03	$54.63
68	$153.67	$97.68	$21.96		$34.03
69	$190.41	$113.94	$21.84		$54.63
70	$190.41	$113.94	$21.84		$54.63
71	$196.19	$122.98	$18.58		$54.63
72	$206.18	$113.94	$18.58	$19.03	$54.63
73	$190.77	$113.94	$22.20		$54.63
74	$169.92	$112.12	$22.20		$35.60
75	$31.18				$31.18
76	$182.88	$122.98	$21.84	$19.03	$19.03
77	$155.17	$113.94	$22.20		$19.03
78	$221.59	$113.94	$21.84		$85.81
79	$182.88	$122.98	$21.84	$19.03	$19.03
80	$190.77	$113.94	$22.20		$54.63
81	$163.85	$122.98	$21.84		$19.03
82	$135.27	$94.04	$22.20		$19.03
83	$127.94	$77.78	$14.56		$35.60
84	$146.13	$104.90	$22.20		$19.03
85	$15.13				$15.13
86	$209.44	$113.94	$21.84	$19.03	$54.63
87	$156.99	$115.76	$22.20		$19.03
88	$185.65	$106.72	$21.84	$38.06	$19.03

Sample Number	Sample Amount	Composite Rate	50% Rule	Separately Billable	Correctly Billed
89	$146.26	$95.86	$14.80		$35.60
90	$127.87	$94.04	$14.80		$19.03
91	$131.93	$66.92	$14.80		$50.21
92	$144.82	$122.98	$21.84		
93	$109.79	$75.96	$14.80		$19.03
94	$18.26	$10.86	$7.40		
95	$192.84	$122.98	$22.20		$47.66
96	$136.73	$95.86	$21.84		$19.03
97	$209.44	$113.94	$21.84	$19.03	$54.63
98	$164.21	$122.98	$22.20		$19.03
99	$154.81	$113.94	$21.84		$19.03
100	$1,063.68	$50.66	$7.28		$1,005.74
TOTAL	**$16,065.38**	**$9,056.76**	**$1,705.40**	**$342.54**	**$4,960.68**

SAMPLING METHODOLOGY, RESULTS, AND PROJECTIONS

OBJECTIVE

The objective of our review was to determine whether the Hospital billed Medicare in accordance with Medicare requirements for laboratory tests provided to end stage renal disease (ESRD) beneficiaries during calendar years 2004 through 2005.

POPULATION

Our population included separately billed composite rate tests, AMCC tests, separately billable tests (aluminum and ferritin), and blood specimen collection fees that were billed and reimbursed for a beneficiary during a calendar quarter (e.g., January through March).

Our population comprised 592 beneficiary quarters from January 1, 2004, through December 31, 2005, containing 10,837 line items of separately billed laboratory services totaling $87,322.30 that were furnished by Caritas St. Elizabeth's Medical Center.

SAMPLE DESIGN

We designed a simple random sample.

SAMPLE SIZE

We selected a statistical random sample of 100 beneficiary quarters with a value of $16,065.38. Because a sample unit has several lines of service with different types of ESRD-related laboratory services, a sample item can have more than one type of error.

SAMPLE RESULTS

Of the 100 sample units reviewed, 95 contained payment errors totaling $11,104.70.

SAMPLE PROJECTION

The sample results produced the following estimates:

Point Estimate	65,740
Confidence Level	90%
Lower Confidence Limit	61,628
Upper Confidence Limit	69,851
Sample Precision	6.25%

Caritas St. Elizabeth's Medical Center

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September 18, 2007

Michael J. Armstrong
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General
Office of Audit Services, Region I
JFK Federal Building
Boston, MA 02203

Re: Report Number: A-01-07-00506

Dear Mr. Armstrong:

In the late spring of 2007, the U.S. Department of Health and Human Services, Office of the Inspector General (OIG) conducted a "Review of Separately Billed Composite Rate Laboratory Services under the Medicare End Stage Renal Disease Program (ESRD) at Caritas Saint Elizabeth Medical Center (CSEMC)." Over an approximate 2 month period, auditors from the OIG were on sight at CSEMC conducting a chart to bill review of selected ESRD accounts to determine whether the Hospital billed Medicare in accordance with Medicare requirements for laboratory tests provided to ESRD beneficiaries during CYs 2004 and 2005.

In August 2007, CSEMC received a letter and supporting documentation from the OIG regarding the findings and results of this audit. A summary of findings from the OIG included:

- "*The Hospital did not always bill Medicare for laboratory tests provided to ESRD beneficiaries in accordance with Medicare requirements during CY 2004 and 2005. Specifically, from a statistical sample of 100 beneficiary quarters valued at $16,065, the Hospital incorrectly billed and was reimbursed for $11,105 [1] for ESRD-related laboratory services that did not meet Medicare reimbursement requirements.*" The OIG letter / Report Number A-01-07-00506 further defines their approach, dollar value, and appendices associated with each test deemed to be billed in error.

Note 1: See OIG Report for methodology on estimate of unallowable payments for a total impact of $61,628.

This correspondence outlines the response/corrective actions required in response to the OIG findings.

1. OIG Recommendation: Work with its fiscal intermediary to refund the Medicare program $61,628 in overpayments for CYs 2004 and 2005.

Response/Corrective Action: CSEMC has accepted the OIG findings and sampling methodology that resulted in overpayments of $61,628. Options were evaluated as to whether the amount owed by CSEMC should be managed through the Medicare Cost Report or through a direct payment to the fiscal intermediary. CSEMC has chosen to process the monies owed as a refund to the intermediary at:

National Government Services, Inc.
Attention: Linda Oakes
Overpayment Recovery
225 North Michigan Ave -22nd Floor
Chicago, Illinois 60601

2. OIG Recommendation: Identify and refund any Medicare payments for ESRD-related laboratory services received after our audit period that did not meet Medicare requirements.

Response/Corrective Action: CSMEC has drafted a detailed plan to conduct a self-audit of the CSEMC ESRD services for CY2006 and CY April 2007 YTD. Depending on the findings and results of the self-audit, a more detailed corrective action plan will be developed and repayments made to the fiscal intermediary as warranted.

3. OIG Recommendation: Strengthen its policies and procedures to ensure compliance with the Medicare requirements.

Response/Corrective Action: Since the onset of the OIG ESRD audit and in conjunction with ongoing efforts to maintain a comprehensive program to ensure compliance with applicable laws, rules, and regulations related to the billing for the provision of health care services, CSEMC has undertaken a number of actions to help safeguard against incorrect billing of laboratory ESRD services and prevent future re-occurrences. These actions include but are not limited to the following:

a) Staff re-education on the program requirements of ESRD laboratory billing;

b) Billing automation and claim form logic changes; moved from a highly manual claims submission process to a more automated billing function in April 2007;

c) Documented departmental procedure updates that reflect changes in laboratory test order entry and claim submission practices;

d) Installation and utilization of a leading industry CDM software package (Craneware) that maintains and tracks historical changes and monitors potential non compliant charge capture items;

e) Ongoing review of guidelines, bulletins, and other directives to train appropriate staff including but not limited to billing staff, compliance, clinical leaders and other finance department personnel; and

f) Working in conjunction with Corporate Compliance and Fiscal and Clinical Integration to conduct future random audits to monitor program compliance.

If you have questions regarding these items in the corrective action plan or require more detailed information, please do not hesitate to contact me at 617.789.2233.

Sincerely,

M. A. Tarlton

Mark Tarlton
Corporate Compliance Officer

cc: Andrea Williams
Mary Calloe