DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

JUL 15 2009

Report Number: A-03-07-00036

Mr. Todd Kerr
Senior Vice President and Chief Compliance Officer
Fresenius Medical Care North America
920 Winter Street
Waltham, Massachusetts 02451-1457

Dear Mr. Kerr:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Payments for Epogen Administered at Fresenius Medical Care—Anacostia, District of Columbia." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

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

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

If you have any questions or comments about this report, please do not hesitate to call me at (215) 861-4470 or through email at Stephen.Virbitsky@oig.hhs.gov, or contact Bernard Siegel, Audit Manager, at (215) 861-4484 or through email at Bernard.Siegel@oig.hhs.gov. Please refer to report number A-03-07-00036 in all correspondence.

Sincerely,

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

PAYMENTS FOR EPOGEN ADMINISTERED AT FRESENIUS MEDICAL CARE – ANACOSTIA, DISTRICT OF COLUMBIA

Daniel R. Levinson
Inspector General

July 2009
A-03-07-00036

Office of Inspector General

http://oig.hhs.gov

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

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people 65 years of age and older, people under 65 with certain disabilities, and people of all ages with end-stage renal disease (permanent kidney failure requiring a kidney transplant or dialysis). The Centers for Medicare & Medicaid Services administers the program.

Section 1881(a) of the Act establishes the benefits provided by Medicare Parts A and B for individuals who have been determined to have end-stage renal disease as provided in section 226A of the Act. Benefits include injections of Epogen, usually administered during dialysis. Individuals diagnosed with end-stage renal disease often suffer from anemia and Epogen lessens the effects of anemia for those patients. Epogen doses are generally adjusted by a physician based on a review of the patient's medical record. For facilities that use a preestablished dosing algorithm, a nurse may also adjust the Epogen dose to maintain an optimal hematocrit (red blood cell) level.

As a basis for payment, section 1833(e) of the Act states: "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due . . . ." Federal regulations (42 CFR § 424.5(a)(6)) require providers to furnish sufficient information, upon request, to determine whether payment is due and, if so, the amount to be paid.

Fresenius Medical Care—Anacostia (Anacostia), located in the District of Columbia, is one of more than 1,500 renal dialysis facilities operated by Fresenius Medical Care North America. Anacostia provides treatment for end-stage renal disease using 18 renal dialysis stations. It received payments totaling $4,984,636 for Medicare services provided from January 1, 2004 through June 30, 2006. Of this amount, $1,772,035 was for the administration of Epogen. During our audit period, Anacostia used dosing algorithms to adjust patient Epogen doses.

OBJECTIVE

Our objective was to determine whether Anacostia administered, billed, and was paid for units of Epogen consistent with the units that were ordered by attending physicians, as reflected in Anacostia's medical records.

SUMMARY OF FINDING

For 76 of the 100 sampled claims, Anacostia administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Anacostia's medical records. However, Anacostia did not meet the Medicare payment requirements for some dates of services for 24 claims (two of the claims had multiple errors). In those instances, we identified discrepancies in Anacostia's medical and billing records between the units of Epogen ordered by the patients' attending physicians and the units administered to the patients, billed by Anacostia, and paid by Medicare.

- For seven claims, Anacostia's medical and billing records reflected that more units of Epogen were administered to patients, billed by Anacostia, and paid by Medicare than were ordered by the patients' attending physicians, resulting in overpayments totaling $1,396.

- For two claims, Anacostia's medical and billing records reflected discrepancies between the units of Epogen ordered by the patients' attending physicians and the units administered to patients, billed by Anacostia, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.

- For 17 claims, Anacostia's medical records reflected errors in documenting the ordering and administration of Epogen but not discrepancies in the quantities of Epogen ordered, administered, billed, or paid. For the purposes of this report, we considered these errors procedural because they did not result in overpayments.

The errors related to these 24 claims occurred because nurses responsible for administering Epogen did not always follow the policies and procedures in the Fresenius Manual for ensuring that the units of Epogen administered were equal to the dose ordered by the attending physician as reflected in the patients' medical records. Also, attending physicians and nurses did not always follow the policies and procedures in the Fresenius Manual for ensuring that patient treatment sheets and medical records were properly documented. As a result, Anacostia received $1,396 in overpayments and patients did not always receive the amounts of Epogen ordered by attending physicians. When attending physicians' orders are not followed, quality of care may be affected.

RECOMMENDATIONS

We recommend that Anacostia:

- refund $1,396 in overpayments and

- ensure that it follows policies and procedures that are consistent with Federal requirements in order to avoid discrepancies between the units of Epogen ordered by the patients' physicians and the units administered to the patient, billed by Anacostia, and paid by Medicare.

FRESENIUS COMMENTS

In comments on our draft report (see Appendix), Fresenius stated that it will contact the intermediary about refunding the $1,396 in overpayments and that the nursing staff will undergo a training program to improve compliance with policies and procedures relating to the ordering and administration of Epogen. Fresenius also brought to our attention a technical correction regarding its algorithm policy that we have amended in the report.

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INTRODUCTION

BACKGROUND

Medicare

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people 65 years of age and older, people under 65 with certain disabilities, and people of all ages with end-stage renal disease (permanent kidney failure requiring a kidney transplant or dialysis). The Centers for Medicare & Medicaid Services (CMS) administers the program.

Epogen Therapy for End-Stage Renal Disease Patients

Section 1881(a) of the Act establishes the benefits provided by Medicare Parts A and B for individuals who have been determined to have end-stage renal disease as provided in section 226A of the Act. Benefits include injections of Epogen, usually administered during dialysis.[1]

Individuals diagnosed with end-stage renal disease often suffer from anemia, and Epogen lessens the effects of anemia for those patients. The initial dose of Epogen is based on an individual's weight and hematocrit level, a measure of the percentage of red blood cells in the blood. The target hematocrit level for dialysis patients receiving Epogen therapy is 30 to 36 percent, which represents a hemoglobin level of 10 to 12 grams per deciliter.[2] For dialysis patients, hematocrit levels above 36 percent can lead to increased risk of cardiovascular complications and death.[3]

Epogen doses are generally adjusted by a physician based on a review of the patient's medical record. Some facilities may also use a preestablished dosing algorithm. An algorithm is a formula established by attending physicians. It requires the nurse on duty to gather information from the patient's medical record and determine the correct dose of Epogen to maintain an optimal hematocrit level. Based on the algorithm, a nurse may decrease, increase, or maintain the Epogen dose or temporarily suspend the dose for one or more treatments. Fresenius Medical Care—Anacostia (Anacostia) used algorithms to determine the dose of Epogen to administer to its patients.

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[1]Epogen is an "erythropoiesis-stimulating agent," manufactured by Amgen, which stimulates the production of red blood cells.

[2]CMS "Medicare Claims Processing Manual," Pub. No. 100-04, chapter 8, section 60.4.

[3]After our audit period, the Food and Drug Administration issued a black box label warning for Epogen that "erythropoiesis-stimulating agents (ESAs) increased the risk for death and for serious cardiovascular events when administered to target a hemoglobin of greater than 12 [grams per deciliter] . . . ." Food and Drug Administration, "Epogen Label," March 9, 2007. Available online at http://www.fda.gov/cder/foi/label/2007/103234s5122lbl.pdf. Accessed on April 23, 2009.

Medicare Requirements and Payments for End-Stage Renal Disease Services

As a basis for payment, section 1833(e) of the Act states: "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due . . . ." Federal regulations (42 CFR § 424.5(a)(6)) require providers to furnish sufficient information, upon request, to determine whether payment is due and, if so, the amount to be paid.

CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, chapter 8, section 10.1, specifies that renal dialysis facilities receive a composite rate for outpatient maintenance dialysis services. The composite rate is a comprehensive payment for dialysis services except for bad debt, physicians' patient care services, separately billable laboratory services, and separately billable drugs, including Epogen. CMS contracts with fiscal intermediaries[4] to process and pay Medicare Part B claims for Epogen administered by renal dialysis facilities. Generally, for each patient, providers submit one bill per month, which includes the charges for up to 14 dialysis treatments, separately billable laboratory services, and separately billable drugs, including Epogen. Providers submitted claims that identified the total units of Epogen administered to each patient during the billing period, not the dose of Epogen administered during each treatment. Payments for Epogen are subject to Medicare Part B deductible and coinsurance requirements.

Fresenius Medical Care—Anacostia

Fresenius Medical Care North America (Fresenius), located in Waltham, Massachusetts, is a wholly owned subsidiary of Fresenius Medical Care AG & Company KGaA, located in Bad Homburg, Germany. Fresenius provides products and services for individuals with chronic kidney failure.

Anacostia, located in the District of Columbia, is one of more than 1,500 renal dialysis facilities operated by Fresenius. Anacostia provides treatment for end-stage renal disease at 18 renal dialysis stations. It received payments totaling $4,984,636 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, $1,772,035 was for the administration of Epogen.

Fresenius's Policy Manual and Medical Information System

To assist in its facilities' efforts to comply with requirements under Federal and State law, Fresenius established a medical record policy and documentation procedures in its Policy Manual No. 138-030-040-2 (Fresenius Manual). The Fresenius Manual requires that each facility must develop a process to identify any change in the ordered prescription drugs and enter the change and the treatment in Fresenius's Medical Information System (Fresenius System). The Fresenius System prints a treatment sheet for each patient that lists selected patient

[4]During the audit period, the Medicare Part B claims we reviewed were processed and paid by fiscal intermediaries. The Medicare Modernization Act of 2003, P. L. No. 108-173, which became effective on October 1, 2005, amended certain sections of the Act, including section 1842(a), to require that Medicare administrative contractors replace carriers and fiscal intermediaries by October 2011.

information from the previous treatment, the latest results of laboratory tests, and the required services scheduled for the day's treatment. The Fresenius Manual requires that each scheduled service on the treatment sheet must be initialed or signed by the administering nurse, as completed. The completed services, as well as any changes noted, must be entered into the Fresenius System on a timely basis.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Anacostia administered, billed, and was paid for units of Epogen consistent with the units that were ordered by attending physicians, as reflected in Anacostia's medical records.

Scope

Our review covered 2,231 monthly claims totaling $1,772,035 for Epogen administered by Anacostia from January 1, 2004, through June 30, 2006.

We limited our review of Anacostia's internal controls to the administration of and billing for Epogen, including medical recordkeeping. The objective of our review did not require an understanding or assessment of Anacostia's complete internal control structure. We did not determine the medical necessity of any items or services, including Epogen.

We performed fieldwork at Anacostia in the District of Columbia, and the Fresenius headquarters in Waltham, Massachusetts.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance related to the treatment of end-stage renal disease, renal dialysis facilities, and the administration of Epogen;

- reviewed applicable State laws, regulations, and guidance related to Anacostia's policies and procedures and the Fresenius Manual;

- reviewed Anacostia's policies and procedures, including the Fresenius Manual, and its medical recordkeeping and billing practices;

- interviewed Fresenius and Anacostia officials;

- identified and assessed the adequacy of internal controls related to the administration of and billing for Epogen; and

- identified a sampling frame of all claims in the CMS claims history file with Epogen administered at Anacostia from January 1, 2004, through June 30, 2006, and:

    - selected from the sampling frame a simple random sample of 100 claims for Epogen totaling $88,170 and

    - for each sampled claim, compared the units of Epogen ordered by the Anacostia attending physician, administered to the patient, billed by Anacostia, and paid by Medicare to determine whether such units, as reflected in Anacostia's medical and billing records, were consistent with each other.

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

For 76 of the 100 sampled claims, Anacostia administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Anacostia's medical records. However, Anacostia did not meet the Medicare payment requirements for some dates of services for 24 claims (two of the claims had multiple errors). In those instances, we identified discrepancies in Anacostia's medical and billing records between the units of Epogen ordered by the patients' attending physicians and the units administered to the patients, billed by Anacostia, and paid by Medicare.

- For seven claims, Anacostia's medical and billing records reflected that more units of Epogen were administered to patients, billed by Anacostia, and paid by Medicare than were ordered by the patients' attending physicians, resulting in overpayments totaling $1,396.

- For two claims, Anacostia's medical and billing records reflected discrepancies between the units of Epogen ordered by the patients' attending physicians and the units administered to patients, billed by Anacostia, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.

- For 17 claims, Anacostia's medical records reflected errors in documenting the ordering and administration of Epogen but not discrepancies in the quantities of Epogen ordered, administered, billed, or paid. For the purposes of this report, we considered these errors procedural because they did not result in overpayments.

The errors related to these 24 claims occurred because nurses responsible for administering Epogen did not always follow the policies and procedures in the Fresenius Manual for ensuring that the units of Epogen administered were equal to the dose ordered by the attending physician

as reflected in the patients' medical records. Also, attending physicians and nurses did not always follow the policies and procedures in the Fresenius Manual for ensuring that patient treatment sheets and medical records were properly documented. As a result, Anacostia received $1,396 in overpayments and patients did not always receive the amounts of Epogen ordered by attending physicians. When attending physicians' orders are not followed, quality of care may be affected.

FEDERAL REQUIREMENTS

Medical Recordkeeping

As a condition of coverage during our audit period, renal dialysis facilities were required to centralize all clinical information in each patient's medical record in accordance with accepted professional standards and practices (42 CFR § 405.2139).[5] The medical records were required to be "completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information." Subsection (a) of 42 CFR § 405.2139 further stated that medical records must contain certain general categories of information, including "diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings . . . ."

Medicare Payment Procedures

As a basis for payment, section 1833(e) of the Act states that "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period."

Federal regulations (42 CFR § 424.5(a)(6)) require providers to furnish sufficient information, upon request, to determine whether payment is due and, if so, the amount to be paid.

CLAIMS FOR EPOGEN NOT CONSISTENT WITH PHYSICIANS' ORDERS

For each sample claim, we compared Anacostia's medical and billing records with respect to the units of Epogen (1) ordered by the patients' attending physicians, (2) administered by the nurse to the patient, (3) billed by Anacostia, and (4) paid by Medicare. For seven claims with questioned amounts totaling $1,396, there were discrepancies in Anacostia's medical and billing records between the units of Epogen ordered by the attending physician and the units of Epogen administered and billed by Anacostia, and paid by Medicare. Anacostia administered, billed, and was paid for higher doses than ordered by the attending physician, as documented in Anacostia's medical and billing records.

[5]This condition for coverage was amended effective October 14, 2008. The amended condition for coverage is now at 42 CFR § 494.170.

More Units of Epogen Billed and Paid Than Administered

For two claims covering two patients, Anacostia billed and Medicare paid for 9,000 more units of Epogen, totaling $70, than administered and ordered.

- For one claim, the Anacostia medical and billing record reflected a change in the dose, dated May 1, 2006, that increased the units of Epogen from 10,000 to 15,000. The patient's treatment sheet for May 1, 2006, reflected that Anacostia administered 10,000 units of Epogen; however, Anacostia billed and Medicare paid for 15,000 units. As a result, Anacostia billed and Medicare paid for 5,000 more units of Epogen, totaling $38, than was administered.

- For one claim, the Anacostia medical and billing record reflected a prescribed dose, dated January 24, 2004, of 2,000 units of Epogen. The treatment sheet for April 29, 2004, reflected that Anacostia administered 2,000 units of Epogen but Anacostia billed and Medicare paid for 6,000 units of Epogen units. As a result, Anacostia billed, and Medicare paid for 4,000 more units of Epogen, totaling $32, than was ordered and administered.

More Units of Epogen Administered, Billed, and Paid Than Ordered

For five claims covering five patients, Anacostia's medical records reflected attending physicians' orders that prescribed Epogen, but the nurse administered, Anacostia billed, and Medicare paid for 170,000 more units of Epogen, totaling $1,326 than was ordered.

- For one claim, the attending physician's order reflected in the Medical Summary Report (Hemodialysis Standing Orders) prescribed a dose of 30,000 units of Epogen. For the month reviewed, nurses administered 40,000 units of Epogen with each treatment, the amount reflected on the treatment sheets. As a result, the patient received, Anacostia billed, and Medicare paid for 130,000 more units of Epogen, totaling $1,015, than was ordered.

- For one claim, the attending physician's order, dated April 11, 2006, suspended the Epogen dose; however, nurses administered 8,000 units of Epogen on April 20 and 22 that were covered by the physician order to suspend Epogen. The patient's treatment sheets for the two days reflected a dose of 8,000 units of Epogen with each treatment. As a result, the patient received, Anacostia billed, and Medicare paid for 16,000 more units of Epogen, totaling $119, than was ordered.

- For one claim, the attending physician's order prescribed a dose of 15,000 units of Epogen and the treatment sheet reflected 15,000 units. However, 30,000 units of Epogen were administered, billed, and paid. The patient's treatment sheet for that day reflected a dose of 15,000 units but the nurse crossed out the printed dose and wrote 30,000 units on the treatment sheet. As a result, the patient received, Anacostia billed, and Medicare paid for 15,000 more units of Epogen, totaling $120, than was ordered.

- For one claim, the attending physician's signed telephone order prescribed a dose of 1,000 units of Epogen; however, for one treatment, the nurse administered 6,000 units of Epogen. The patient's treatment sheet for that day reflected a dose of 1,000 units but the nurse crossed out the printed dose and wrote 6,000 units on the treatment sheet. As a result, the patient received, Anacostia billed, and Medicare paid for 5,000 more units of Epogen, totaling $40, than was ordered.

- For one claim, the attending physician's order increased the units of Epogen prescribed for one patient from 5,000 to 6,000 units; however, for one treatment the nurse administered 10,000 units of Epogen. The patient's treatment sheet for that day reflected a dose of 5,000 units but the nurse crossed out the printed dose and wrote 10,000 units on the treatment sheet. As a result, the patient received, Anacostia billed, and Medicare paid for 4,000 more units of Epogen, totaling $32, than was ordered.

CLAIMS WITH PROCEDURAL ERRORS THAT RESULTED IN DISCREPANCIES

For two claims, Anacostia's medical and billing records reflected discrepancies between the units of Epogen ordered by the patients' attending physicians and the units administered to the patients, billed by Anacostia, and paid by Medicare for one or more dates of service during the month reviewed. These claims did not result in overpayments and are, for purposes of this report, considered procedural errors. For one claim, the patient received lower doses than ordered. One claim was not correctly billed.

Fewer Units of Epogen Administered, Billed, and Paid Than Ordered

For one claim, Anacostia's medical records included a physician order, dated September 9, 2005, to increase the units of Epogen from 16,000 to 20,000 units. During November 2005 and January 2006, the patient was hospitalized. The Anacostia medical records did not reflect the doses of Epogen that were administered to the patient during hospitalization. Also, for February 2006, the month reviewed, the Anacostia medical records did not reflect the dose of Epogen ordered, but nurses administered 10,000 units of Epogen for the 12 treatments in February 2006. The last physician order was for 20,000 units per treatment. Anacostia administered, billed, and was paid for fewer units of Epogen than ordered.

Claim Not Correctly Billed

For one claim, the Anacostia medical and billing records included a physician's order, dated April 29, 2004, to decrease the units of Epogen from 30,000 to 10,000 units. The treatment sheet for April 28, 2004, reflected that Anacostia administered 30,000 units of Epogen. However, Anacostia billed and Medicare paid for 10,000 units of Epogen. As a result, Anacostia was paid for 20,000 fewer units of Epogen, totaling $160, than was ordered and administered.

CLAIMS WITH PROCEDURAL ERRORS THAT DID NOT RESULT IN DISCREPANCIES

The District of Columbia Municipal Regulations, title 17, chapter 46, requires that "[a] licensed physician shall maintain a record for each patient which accurately reflects the evaluation and treatment of the patient." (17 DCMR § 4612 (1989)) Chapter 54 describes the practice of registered nursing to include "the administration of medications and treatment as prescribed by a legally authorized healthcare professional licensed in the District of Columbia." (17 DCMR § 5414 (2004)). To assist facilities in documenting compliance with Federal and State requirements, the Fresenius Manual requires an order for all new medications or whenever a medication dose changes, along with the signature of the ordering physician. Nurses are responsible for ensuring that all medications provided to patients have accurately documented physician orders. Administering nurses are required to sign or initial on the treatment sheet to show that a medication, including Epogen, has been administered.

For 17 claims, the Anacostia medical records reflected errors in documenting the ordering and administration of Epogen. However, Anacostia billed for and was reimbursed for the units ordered or administered.

- For 10 of these claims, the patients' medical records lacked the signature/initials of the attending physician, as required by Anacostia's internal policies, including those in the Fresenius Manual. The attending physician provided these orders by telephone and the nurses documented them in the patients' medical records. However, the attending physician did not sign the order in accordance with Anacostia and Fresenius policies and procedures. The administering nurse administered the units of Epogen consistent with the attending physician's telephone order.

- For three of these claims, the treatment sheets for one date of service were not in the Anacostia medical record. Anacostia billed and Medicare paid for the units of Epogen prescribed by the attending physicians order for the period reviewed.

- For three of these claims, the attending physicians' orders for the months reviewed were not in the medical record. Although the physicians' orders were missing for the month reviewed, the medical record for two claims included documents that reflected prior physician orders with higher units of Epogen than administered, and the other claim reflected a physician order that referred to a previous Epogen order. Anacostia billed and Medicare paid for the units of Epogen reflected on the dialysis treatment sheets.

- For one of these claims, the patient's medical record did not include an attending physician order and the patient treatment sheets for the month reviewed.

FRESENIUS POLICY AND PROCEDURES NOT ALWAYS FOLLOWED

To assist in its facilities' efforts to comply with requirements under Federal law and States' respective Nurse Practice Acts, Fresenius established the Fresenius Manual, which includes medical record policies and documentation procedures. The Fresenius Manual requires that each facility develop a process to record in the Fresenius System the results of each treatment and changes to existing treatments, including the dose of Epogen to be administered.

- The Fresenius System prints a treatment sheet for the patient's next treatment. Administering nurses and patient care technicians provide treatment according to instructions printed on treatment sheets and administering nurses must ensure that all medications provided to the patient have been accurately documented with signed attending physician orders. Section A of the Fresenius Manual, "Physician Orders," states that "[p]roviding service without physician orders is in violation of nurse practice acts." Accordingly, the attending physician must provide a written order for an administering nurse to begin a new medication or to change the dose of a medication.[6]

- Each facility must develop a process by which the attending physician "flags" charts that have new or changed orders so that authorized support personnel can identify that a change has occurred and enter the change in the Fresenius System. Also, the Fresenius Manual identifies the duties and responsibilities for accurately documenting and updating its Fresenius System with changes to a patient's treatment. After entry into the Fresenius System, those changes will be reflected on the patient's next treatment sheet.

- Results of a patient's treatment, documented on the treatment sheet, must not be entered into the Fresenius System until the treatment is completed. A treatment sheet is considered completed after the administering nurse has given the treatment to the patient, administered all medications ordered, and confirmed the completion of these tasks by including their initials or signatures on the treatment sheet where appropriate.

Although Anacostia had controls in place as specified in the Fresenius Manual, based on our review, Anacostia personnel did not always follow all of these procedures. Nurses responsible for administering Epogen did not always follow the policies and procedures in the Fresenius Manual for ensuring that the units of Epogen administered were equal to the dose ordered by the attending physician as reflected in the patients' medical records.

Also, attending physicians did not always sign orders for Epogen, nurses did not always sign patient treatment sheets, and Anacostia medical records did not always include physician orders or patient treatment sheets.

[6]The Fresenius Manual permits a physician to provide telephone orders; however, the physician must sign the order during the next facility visit.

RECOMMENDATIONS

We recommend that Anacostia:

- refund $1,396 in overpayments and

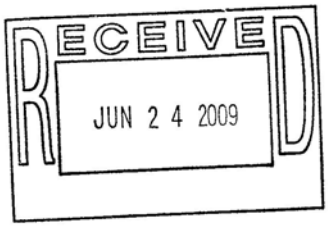
- ensure that it follows policies and procedures that are consistent with Federal requirements in order to avoid discrepancies between the units of Epogen ordered by the patients' physicians and the units administered to the patient, billed by Anacostia, and paid by Medicare.

FRESENIUS COMMENTS

In comments on our draft report, Fresenius stated that it will contact the intermediary about refunding the $1,396 in overpayments and that the nursing staff will undergo a training program to improve compliance with policies and procedures relating to the ordering and administration of Epogen. Fresenius also brought to our attention a technical correction regarding its algorithm policy that we have amended in the report. Fresenius's comments are included in the Appendix.

APPENDIX

Fresenius Medical Care
North America



June 19, 2009

Stephen Virbitsky
Regional Inspector General for Audit Services
Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

Re: Audit Draft A-03-07-00036, Payments for Epogen Administered at Fresenius Medical Care-Anacostia, District of Columbia

Dear Mr. Virbitsky:

Thank you for the opportunity to review and respond to your office's Draft Report.

The results of this draft report are consistent with other Medicare claims reviews conducted internally by Fresenius staff (as part of Fresenius' ongoing compliance audit program activities) and with other external reviews such as CERT and PERM. Of the $88,170.00 in claims reviewed, $1,396 was identified by the audit as not eligible for Medicare reimbursement – reflecting 1.58% of the sampled claims. This payment error rate compares favorably to the most recent May 2008 3.7% CERT national paid claims error rate.

In response to these audit findings Fresenius will take the following steps:

OIG Audit Recommendation:

"ensure that it follows policies and procedures that are consistent with Federal requirements in order to avoid discrepancies between the units of Epogen ordered by the patients' physicians and the units administered to the patient, billed by Anacostia, and paid by Medicare".

Fresenius Corrective Action Taken or Planned:

While the payment error rate is low, we recognize the need for the facility to improve its compliance with policies and procedures relating to the ordering and administration of Epogen. Therefore, the clinic will take the following steps:

- All nursing staff will undergo an in-service program designed to inform the staff of: (a) the statutes and regulations relating to creating and maintaining medical record documentation; (b) the applicable Fresenius policies, including but not limited to documentation of physician orders and documentation of care furnished while the computer medical record is down; (c) the responsibility of each staff member to conform to applicable statutes, regulations, and policies; and (d) the consequences of failing to comply with applicable Fresenius policies. All new nursing staff members will continue to undergo Fresenius training which includes the foregoing topics.
- Consistent with the Part 494 Conditions for Coverage (42 CFR Section 494.110 Condition: Quality assessment and performance improvement) for the next 12 months the facility's Quality Assessment and Improvement Process will review a sampling of active medical records to monitor improved compliance with applicable Fresenius medical record documentation policies.
- The 2010 Fresenius Compliance Audit program will include a review of (a) the training activity above, to ensure that all affected employees were trained; (b) the (quality improvement process) to ensure that the aforementioned reviews occurred; and (c) an assessment of whether the training and monitoring has been effective in causing the facility to conform to applicable Fresenius policies.

OIG Audit Recommendation:

"refund the $1,396 in overpayments"

Fresenius Corrective Action Taken or Planned:

- Given the age of these claims, we will contact the intermediary to determine the process to repay overpayments.

Finally, I note that in the Background section of the Introduction, the audit states:

> "Some facilities may also use a preestablished dosing algorithm. The algorithm is a formula established by the facility Medical Director and ordered by the physician."

At Fresenius Medical Care clinics, while the facility Medical Director and Governing Body review and approve algorithms ordered by staff physicians, it is the staff physician (and not the medical director) who establishes the algorithm for the staff physician's patients. While often all physicians at the clinic (including the staff physician who serves as medical director) agree to use a single algorithm, it is the staff physician rather than the medical director who establishes an algorithm for a particular patient.

Sincerely,

Todd Kerr
Senior Vice President and Chief Compliance Officer
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