DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

Office of Audit Services, Region III
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Philadelphia, PA 19106-3499

JUL 15 2009

Report Number: A-03-07-00035

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—Northeast, 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.

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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-03-07-00035 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 – NORTHEAST, DISTRICT OF COLUMBIA

Daniel R. Levinson
Inspector General

July 2009
A-03-07-00035

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

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—Northeast (Northeast), located in the District of Columbia,, is one of more than 1,500 renal dialysis facilities operated by Fresenius Medical Care North America. Northeast provides treatment for end-stage renal disease at 20 dialysis treatment stations. It received payments totaling $6,579,233 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, $2,298,987 was for the administration of Epogen. During our audit period, Northeast used dosing algorithms to adjust patient Epogen doses.

OBJECTIVE

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

SUMMARY OF FINDING

For 66 of the 100 sampled claims, Northeast administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Northeast's medical records. However, Northeast did not meet the Medicare payment requirements for some dates of service for 34 claims (one of the claims had multiple errors). In those instances, we identified discrepancies in Northeast'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 Northeast, and paid by Medicare.

- For five claims with questioned amounts totaling $275, there were discrepancies in Northeast's medical and billing records between the units of Epogen ordered by the attending physician and the units of Epogen administered, billed by Northeast, and paid by Medicare.

- For 17 claims, Northeast's medical and billing records reflected discrepancies between the units of Epogen ordered by patients' attending physicians and units administered to patients, billed by Northeast, and paid by Medicare. For the purposes of this report, we considered these errors procedural because they did not result in overpayments.

- For 13 claims, Northeast'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 34 claims occurred because attending physicians and/or administering nurses responsible for documenting and flagging the patients' files for changes in ordered Epogen amounts did not always follow the policy and procedures in the Fresenius Manual for ensuring that changes in the units of Epogen ordered were properly identified and entered into the Fresenius System. As a result, Northeast received $275 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 Northeast:

- refund $275 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 patients' physicians and the units administered to the patient, billed by Northeast, 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 $275 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—Northeast (Northeast) used dosing algorithms to adjust patient Epogen doses.

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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 at http://www.fda.gov/cder/foi/label/2007/103234s5122lbl.pdf. Accessed on April 24, 2009.

Medicare Requirements and Payment 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 debts, 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—Northeast

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.

Northeast, located in the District of Columbia, is one of more than 1,500 renal dialysis facilities operated by Fresenius. Northeast provides treatment for end-stage renal disease at 20 renal dialysis stations. It received payments totaling $6,579,233 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, $2,298,987 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 Northeast administered, billed, and was paid for units of Epogen consistent with the units that were ordered by attending physicians, as reflected in Northeast's medical records.

Scope

Our review covered 2,863 monthly claims totaling $2,298,987 for Epogen administered by Northeast from January 1, 2004, through June 30, 2006.

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

We performed fieldwork at Northeast 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 Northeast's policies and procedures and the Fresenius Manual;

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

- interviewed Fresenius and Northeast 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 Northeast from January 1, 2004, through June 30, 2006, and:

    - selected from the sampling frame a simple random sample of 100 claims for Epogen totaling $77,821 and

    - for each sampled claim, compared the units of Epogen ordered by the Northeast attending physician, administered to the patient, billed by Northeast, and paid by Medicare to determine whether such units, as reflected in Northeast'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 66 of the 100 sampled claims, Northeast administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Northeast's medical records. However, Northeast did not meet the Medicare payment requirements for some dates of service for 34 claims (one of the claims had multiple errors). In those instances, we identified discrepancies in Northeast'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 Northeast, and paid by Medicare.

- For five claims with questioned amounts totaling $275, there were discrepancies in Northeast's medical and billing records between the units of Epogen ordered by the attending physician and the units of Epogen administered, billed by Northeast, and paid by Medicare.

- For 17 claims, Northeast's medical and billing records reflected discrepancies between the units of Epogen ordered by patients' attending physicians and units administered to patients, billed by Northeast, and paid by Medicare. For the purposes of this report, we considered these errors procedural because they did not result in overpayments.

- For 13 claims, Northeast'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 34 claims occurred because attending physicians and/or administering nurses responsible for documenting and flagging the patients' files for changes in ordered Epogen amounts did not always follow the policy and procedures in the Fresenius Manual for ensuring that changes in the units of Epogen ordered were properly identified and entered into

the Fresenius System. As a result, Northeast received $275 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 for 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.

Beginning April 1, 2006, CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, chapter 8, section 60.4, required that renal dialysis facilities reduce the Epogen dose by 25 percent for patients whose hematocrit reading exceeded 39 percent in the preceding month. If the renal dialysis facility did not reduce the dose by 25 percent, CMS would reduce the reimbursement for Epogen by 25 percent. To avoid the reduced reimbursement, the provider was required to include a "GS" modifier on the claim to indicate that it had reduced the Epogen dose by 25 percent. We reviewed only sample claims for the period April 1 through June 30, 2006, for compliance with this payment adjustment guidance.

CLAIMS FOR EPOGEN NOT CONSISTENT WITH PHYSICIANS' ORDERS

For each sample claim, we compared Northeast's medical and billing records with respect to the units of Epogen (1) ordered by the patient's attending physicians, (2) administered by the nurse to the patient, (3) billed by Northeast, and (4) paid by Medicare. For five claims with questioned amounts totaling $275, there were discrepancies in Northeast'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.

between the units of Epogen ordered by the attending physician and the units of Epogen administered, billed by Northeast, and paid by Medicare. For two of the five claims, Northeast billed and Medicare paid for more units of Epogen than ordered by the attending physician and administered to the patient.

More Units of Epogen Billed and Paid Than Ordered and Administered

For two claims covering two patients, Northeast's medical records reflected one or more attending physicians' orders for units of Epogen during the months reviewed. For some dates of service, the patients' treatment sheets reflected units of Epogen that differed from the attending physicians' orders. Northeast nurses administered units of Epogen printed on treatment sheets that were more than the units ordered. Also, for two dates of service, Northeast billed for more units of Epogen than were order or administered.

- For one claim, the attending physician's order, dated January 14, 2004, prescribed a dose of Epogen of 3,400 units. On March 8 the attending physician increased the dose to 7,000 units and on March 30 increased the dose to 12,000 units. Northeast medical records did not include any other orders between January 14 and March 30. The patient's treatment sheet reflected that the patient received 5,600 units from March 2–6, 7,000 units from March 9–13, 9,000 units from March 16–27, and 12,000 units on March 30. Also, although the patient treatment sheet for March 13 reflected that the nurse administered 7,000 units of Epogen, Northeast billed and Medicare paid for 9,000 units of Epogen. In total, Northeast was overpaid $165 for 20,600 more units of Epogen than was ordered and administered.

    - For nine treatments, the patient received, Northeast billed, and Medicare paid for 18,600 more units of Epogen, totaling $149, than was ordered.

    - For one treatment, Northeast billed and Medicare paid for 2,000 more units of Epogen, totaling $16, than ordered by the attending physician and administered to the patient.

- For one claim, Northeast's medical record reflected an attending physician's order, dated March 19, 2004, prescribing a dose of Epogen of 1,000 units. The medical record did not include any other physician order between March 19 and April 30. During April, the month reviewed, Northeast nurses administered 1,500 units of Epogen during nine treatments from April 12–30. Also, on April 9, Northeast billed for 1,500 units but the patient's treatment sheet reflected that only 1,000 units were administered and on April 30, Northeast billed for 1,700 units but the patient's treatment sheet reflected that only 1,500 units were administered. In total, Northeast was overpaid $42 for 5,200 more units of Epogen than was ordered and administered.

    - For nine treatments, the patient received, Northeast billed, and Medicare paid for 4,500 more units of Epogen, totaling $36, than was ordered.

- For two treatments, Northeast billed and Medicare paid for 700 more units of Epogen, totaling $6, than ordered by the attending physician and administered to the patient.

In total Northeast billed and Medicare paid for 25,800 units of Epogen, totaling $207, in excess of the attending physician order.

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

For three claims covering two patients, Northeast's medical records contained attending physicians' orders that changed the units of Epogen prescribed, but an assigned staff member did not accurately record the changes in the Fresenius System. Consequently, the doses reflected on the patients' treatment sheets, administered to the patients, billed by Northeast, and paid by Medicare were more than ordered by the attending physicians.

- For one claim, the attending physician's order, dated December 23, 2005, decreased the dose of Epogen ordered from 29,800 to 23,100 units. However, an assigned staff member recorded the new dose as 23,900 units and the Fresenius System printed treatment sheets for seven treatments during the month reviewed that reflected the incorrect units of Epogen to be administered to the patients. As a result, the patient received, Northeast billed, and Medicare paid for 5,600 more units of Epogen, totaling $43, than was ordered.

- For two claims the attending physician's order, dated March 19, 2004, decreased the dose of Epogen ordered from 31,000 to 26,000 units. However, an assigned staff member recorded the new dose as 26,400 units and the Fresenius System printed treatment sheets for eight treatments during the months reviewed that reflected the incorrect units of Epogen to be administered to the patient. As a result, the patient received, Northeast billed, and Medicare paid for 3,200 more units of Epogen, totaling $25, than was ordered.

In total, for these two patients, Northeast was overpaid $68 for 8,800 more units of Epogen than was ordered.

CLAIMS WITH PROCEDURAL ERRORS THAT RESULTED IN DISCREPANCIES

For 17 claims (one of the claims had two errors), Northeast'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 Northeast, and paid by Medicare for one or more dates of service during the month reviewed that did not result in an overpayment and are, for purposes of this report, considered procedural errors. For nine claims, patients received lower doses than ordered. For four claims, Northeast billed and Medicare paid for fewer units of Epogen than ordered and administered. For three claims, the Northeast medical records did not have a copy of the attending physicians' orders. For one claim, the nurse administered a higher Epogen dose before the effective date of the attending physician's order increasing the Epogen dose. For one claim, Northeast billed without the appropriate modifier.

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

For nine claims, Northeast's medical records included attending physicians' orders to increase the dose of Epogen for seven claims and decrease the dose of Epogen for two claims. However, treatment sheets following the effective dates of the physicians' orders reflected fewer units of Epogen than physicians ordered and nurses administered the lower doses for 1 to 12 treatments. Northeast billed, and Medicare paid for the units of Epogen administered to the patient that were fewer than ordered.

Fewer Units of Epogen Billed and Paid Than Ordered and Administered

For four claims, covering four patients, Northeast's medical records included attending physicians' orders that prescribed that patients receive Epogen doses. For the months reviewed, patients received the Epogen doses prescribed. For one date of service for each of the four claims, Northeast did not bill and Medicare did not pay for the units of Epogen ordered by the attending physicians and administered to the patients. In total, Northeast did not bill for 13,800 units of Epogen, totaling $109, that were ordered and administered.

Epogen Orders Did Not Support Epogen Administered

For three claims, the Northeast medical records did not include attending physicians' orders that reflected the units of Epogen administered to three patients. For all three claims, the most recent attending physician orders in the Northeast medical records did not include the units of Epogen administered and were dated 1 to 2 months prior to the dates the units of Epogen were administered. The units of Epogen administered for the three claims were not the dose included in the attending physician order prior to the most recent order in Northeast's medical records. Based on our review of the documentation provided, we believe that the actual attending physician order for the units of Epogen administered were missing from Northeast's medical records rather than nurses administering units of Epogen exceeding the physicians' orders. Northeast billed, and Medicare paid for the units administered to the patients.

Epogen Dose Changed Before the Date of the Physician's Order

For one claim, the Northeast medical record reflected that an attending physician's order increased the dose of Epogen for one patient. However, the treatment sheet for one treatment preceding the effective date reflected the new dose because designated Northeast staff entered the change in the Epogen dose in the Fresenius System with the wrong effective date. The attending physician's order dated April 29, 2004 increased the prescribed Epogen dose from 20,000 to 25,000 units for each treatment. However, the treatment sheet for April 27 reflected an Epogen dose of 25,000 units and a nurse administered a dose of 25,000 units even though the physician's order increasing the dose was not effective until April 29. The Northeast medical record did not reflect why the Epogen dose was changed before the physician's order was effective.

Claim Not Correctly Billed

For one claim with dates of service during April 2006, the patient had a hematocrit level higher than 39 percent in the preceding month. On March 31, 2006, the attending physician's order reduced the units of Epogen prescribed from 8,000 to 6,800 units, a reduction of less than 25 percent. On April 7, 2006, the attending physician's order reduced the units of Epogen prescribed to 5,400 units, which resulted in an overall reduction of greater than 25 percent. CMS required that the Epogen dose be reduced by at least 25 percent for full reimbursement. During April 2006, Northeast administered a total of 56,800 units of Epogen and reduced the total Epogen administered for the month by 25 percent. Although Northeast reduced the total Epogen administered during April 2006, Northeast failed to use the "GS" modifier and CMS reduced the payment by 25 percent. Northeast should have received $424 for the 56,800 units of Epogen ordered and administered but instead received $318, an underpayment of $106.

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 § 5412 (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 13 claims (1 of the claims had two errors), the Northeast medical records reflected errors in documenting the ordering and administering of Epogen. However, Northeast billed for and was reimbursed for the units ordered or administered.

- For seven claims, the patient's medical record lacked the signature/initials of the administering nurse, as required by Northeast's internal policies, including those in the Fresenius Manual. The administering nurse administered the units of Epogen consistent with the attending physicians' orders, but did not sign or initial the treatment sheets to document the administration of Epogen for one date of service.

- For four claims, the patients' medical records lacked the signature/initials of the attending physician, as required by Northeast's internal policies, including those in the Fresenius Manual. The nurse updated the Fresenius System and administered the units of Epogen consistent with the attending physicians' orders. Northeast billed and Medicare paid for the units of Epogen ordered by the attending physician and administered to the patients.

- For three claims, the patient's medical record did not include the patient treatment sheets for one or more dates of service for the month reviewed. Northeast billed and Medicare paid for the units of Epogen ordered by attending physicians and administered to the patients.

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 Northeast had controls in place as specified in the Fresenius Manual, based on our review, Northeast personnel did not always follow all of these procedures. Attending physicians' orders changing the dose of Epogen were not always identified and entered into the Fresenius System accurately or on a timely basis. Therefore, changes to the attending physicians' orders did not always appear on subsequent treatment sheets.

Also, attending physician orders and treatment sheets were not always signed or reflected in the Northeast medical records.

[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 Northeast:

- refund $275 in overpayments and

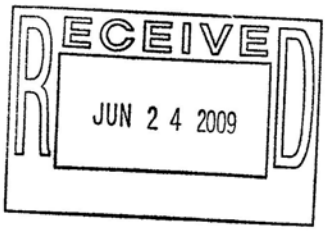
- ensure that it follows policies and procedures that are consistent with Federal requirements in order to avoid discrepancies between the units of Epogen ordered by patients' physicians and the units administered to the patient, billed by Northeast, and paid by Medicare.

FRESENIUS COMMENTS

In comments on our draft report, Fresenius stated that it will contact the intermediary about refunding the $275 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-03-07-00035, Payments for Epogen Administered at Fresenius Medical Care-Northeast, 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 $77,821.00 in claims reviewed, $275 was identified by the audit as not eligible for Medicare reimbursement – reflecting 0.35% 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 Northeast, 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 $275 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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