



Office of Audit Services, Region III
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AUG 5 2009

Report Number: A-03-07-00026

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—Beckley, Beckley, West Virginia." 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-03-07-00026 in all correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen Virbitsky", with a long horizontal flourish extending to the right.

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Nanette Foster Reilly, Consortium Administrator
Consortium for Financial Management & Fee for Service Operations (CFMFFSO)
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Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PAYMENTS FOR
EPOGEN ADMINISTERED AT
FRESENIUS MEDICAL CARE—
BECKLEY,
BECKLEY, WEST VIRGINIA**



Daniel R. Levinson
Inspector General

August 2009
A-03-07-00026

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—Beckley Facility (Beckley), located in Beckley, West Virginia, is one of more than 1,500 renal dialysis facilities operated by Fresenius Medical Care North America. Beckley provides 21 renal dialysis treatment stations and received payments totaling \$4,881,172 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$1,698,935 was for the administration of Epogen. During our audit period, Beckley used dosing algorithms to adjust patient Epogen doses.

OBJECTIVE

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

SUMMARY OF FINDING

For 72 of the 100 sampled claims, Beckley administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Beckley's medical records. However, Beckley did not meet the Medicare payment requirements for some dates of service for 28 claims. In those instances, we identified discrepancies in Beckley'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 Beckley, and paid by Medicare.

- For 17 claims, with errors totaling \$1,968, Beckley billed and Medicare paid for more units of Epogen than were ordered. For 16 claims, there were discrepancies in Beckley's medical and billing records between the units of Epogen ordered by the attending physician using a preestablished dosing algorithm and the units of Epogen calculated by the administering nurse, administered and billed by Beckley, and paid by Medicare. For one claim an assigned staff member did not update the Epogen dose in the Fresenius System and a patient received higher doses than ordered by the attending physician. Based on the sample results, we estimate that Beckley received overpayments of at least \$25,886 for the administration of Epogen from January 1, 2004, through June 30, 2006.
- For one claim, Beckley's medical and billing record reflected a discrepancy between the units of Epogen ordered by the patient's attending physician and the units administered to the patient, billed by Beckley, and paid by Medicare. For purposes of this report, we considered this error procedural because it did not result in an overpayment.
- For 10 claims, Beckley'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 28 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, when nurses changed Epogen doses using the preestablished dosing algorithms ordered by attending physicians, the new doses either were not calculated correctly or physicians did not sign the order identifying the reason for deviating from the preestablished dosing algorithm. As a result, Beckley received at least \$25,886 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 Beckley:

- refund the \$25,886 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 Beckley, and paid by Medicare.

FRESENIUS COMMENTS

In comments on our draft report (see Appendix C), Fresenius stated that it will contact the intermediary about refunding the \$25,886 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.

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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—Beckley (Beckley) used algorithms to determine the dose of Epogen to administer to its patients.

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

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

³After 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 intermediaries⁴ 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—Beckley

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.

Beckley, located in Beckley, West Virginia, is one of more than 1,500 renal dialysis facilities operated by Fresenius. Beckley provides treatment for end-stage renal disease at 21 renal dialysis stations. It received payments totaling \$4,881,172 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$1,698,935 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

⁴During 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 Beckley administered, billed, and was paid for units of Epogen consistent with the units that were ordered by attending physicians, as reflected in Beckley's medical records.

Scope

Our review covered 2,829 monthly claims totaling \$1,698,935 for Epogen administered by Beckley from January 1, 2004, through June 30, 2006.

We limited our review of Beckley'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 Beckley's complete internal control structure. We did not determine the medical necessity of any items or services, including Epogen.

We performed fieldwork at 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 Beckley's policies and procedures and the Fresenius Manual;
- reviewed Beckley's policies and procedures, including the Fresenius Manual, and its medical recordkeeping and billing practices;
- interviewed Fresenius 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 Beckley from January 1, 2004, through June 30, 2006, and:

- selected from the sampling frame a simple random sample of 100 claims for Epogen totaling \$58,589 and
- for each sampled claim, compared the units of Epogen ordered by the Beckley attending physician, administered to the patient, billed by Beckley, and paid by Medicare to determine whether such units, as reflected in Beckley's medical and billing records, were consistent with each other.

Appendix A provides a description of the sampling methodology and Appendix B details the sample results and estimates the total overpayments for Epogen.

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 72 of the 100 sampled claims, Beckley administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Beckley's medical records. However, Beckley did not meet the Medicare payment requirements for some dates of services for 28 claims. In those instances, we identified discrepancies in Beckley'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 Beckley, and paid by Medicare.

- For 17 claims, with errors totaling \$1,968, Beckley billed and Medicare paid for more units of Epogen than were ordered. For 16 claims, there were discrepancies in Beckley's medical and billing records between the units of Epogen ordered by the attending physician using a preestablished dosing algorithm and the units of Epogen calculated by the administering nurse, administered and billed by Beckley, and paid by Medicare. For one claim an assigned staff member did not update the Epogen dose in the Fresenius System and a patient received higher doses than ordered by the attending physician. Based on the sample results, we estimate that Beckley received overpayments of at least \$25,886 for the administration of Epogen from January 1, 2004, through June 30, 2006.
- For one claim, Beckley's medical and billing record reflected a discrepancy between the units of Epogen ordered by the patient's attending physician and the units administered to the patient, billed by Beckley, and paid by Medicare. For purposes of this report, we considered this error procedural because it did not result in an overpayment.
- For 10 claims, Beckley'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 28 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, when nurses changed Epogen doses using the preestablished dosing algorithms ordered by attending physicians, the new doses either were not calculated correctly or physicians did not sign the order identifying the reason for deviating from the preestablished dosing algorithm. As a result, Beckley received at least \$25,886 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.

CLAIMS FOR EPOGEN NOT CONSISTENT WITH PHYSICIANS' ORDERS

For each sample claim, we compared Beckley'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 Beckley, and (4) paid by Medicare. For 16 claims with questioned amounts totaling \$1,938, there were discrepancies in Beckley's medical and billing records between the units of Epogen ordered by the attending physician using a preestablished dosing algorithm and the units of Epogen calculated by the administering nurse, administered and billed by Beckley, and paid by Medicare. For one claim with questioned amounts totaling \$30, an assigned staff member did not update the Epogen dose in the Fresenius System and a patient

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

received higher doses than ordered by the attending physician. Beckley administered, billed, and was paid for higher doses than ordered by the attending physician, as documented in Beckley's medical and billing records.

Epogen Doses Not Properly Calculated

For 16 claims, administering nurses did not follow the preestablished dosing algorithms, which were established by the ordering physician, to determine patients' Epogen doses. The algorithm requires that administering nurses 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.

The Fresenius Manual states that: "The algorithm must be followed 'as written'. Any deviation can only occur after the nurse has discussed the proposed deviation with the patient's physician and a specific order allowing the deviation has been written in the patient's medical record." The Fresenius Manual further states that: "Medication dose changes based upon an algorithm must be accurate."

For the 16 claims, the Beckley medical record contained a signed copy of the physicians' algorithm order used to determine the Epogen dose based on the patient's hemoglobin level. The medical record reflected that administering nurses adjusted the Epogen doses using the patients' algorithm. However, for the 16 claims administering nurses did not make changes to the Epogen doses accurately or according to the algorithm. For example:

- For one claim, the Beckley medical record included the attending physician's order for Epogen, dated January 19, 2005, using a preestablished dosing algorithm. On March 18, 2005, using the algorithm and the patient's hemoglobin level, the administering nurse established an Epogen dose of 12,800 units. However, on April 22, 2005, based on the patient's hemoglobin level of 14.4 grams per deciliter, the administering nurse decreased the Epogen dose by 25 percent, from 12,800 to 9,600 units. Using the preestablished dosing algorithm the administering nurse should have decreased the Epogen dose by 50 percent, from 12,800 to 6,400 units. The attending physician did not write a specific order allowing the deviation from the patient's algorithm. As a result, for three treatments during the month reviewed, the patient received, Beckley billed, and Medicare paid for 9,600 more units of Epogen, totaling \$75, than was ordered by the physician's algorithm.

In total, for these 16 claims, patients received, Beckley billed, and Medicare paid for 247,400 more units of Epogen, totaling \$1,938, than was reflected in the physicians' preestablished dosing algorithm orders.

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

For one claim, Beckley's medical records included the attending physician's order for Epogen dated May 23, 2006, using a preestablished dosing algorithm that reduced the units of Epogen prescribed from 4,000 to 3,000 units, but an assigned staff member did not record the changes in

the Fresenius System. Consequently, the Fresenius System printed treatment sheets showing the original 4,000 units, which were administered for four treatments during the month reviewed. In total, the patient received, Beckley billed and Medicare paid for 4,000 more units of Epogen, totaling \$30, than were ordered.

Estimate of Overpayments

Based on the sample results, we estimate that Beckley received net overpayments of at least \$25,886 for the administration of Epogen from January 1, 2004, through June 30, 2006, for which Beckley'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 Beckley, and paid by Medicare.

CLAIM WITH A PROCEDURAL ERROR THAT RESULTED IN A DISCREPANCY

For one claim, Beckley's medical and billing records reflected a discrepancy between the units of Epogen ordered by the patient's attending physician and the units administered to the patient, billed by Beckley, and paid by Medicare for one date of service during the month reviewed that did not result in an overpayment and is, for purposes of this report, considered a procedural error. The patient received a lower dose than ordered.

For one claim, Beckley's medical record included the attending physician's order, dated February 24, 2004, to increase the units of Epogen from 10,000 to 12,000 units. The order was entered into the Fresenius System on a timely basis, and the treatment sheet for February 26, 2004, reflected the change to 12,000 units; however, the printed amount was crossed out and the nurse administered 10,000 units for one treatment. The medical record did not reflect the reason for this change. Beckley administered, billed, and was paid for fewer units of Epogen than ordered.

CLAIMS WITH PROCEDURAL ERRORS THAT DID NOT RESULT IN DISCREPANCIES

The West Virginia Code, Chapter 30, Article 7, defines registered nursing, including licensing requirements, to include the administration of medications and treatments as prescribed by a licensed physician. Also, the West Virginia Board of Examiners for Registered Professional Nurses stated that registered nurses are responsible and accountable for the administration and clinical management of intravenous therapy, which includes the administration of Epogen.⁶

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. Nurses are responsible to ensure all medications provided to patients have accurately documented physician orders. It also requires a physician's signature for prescription orders, and a signature or initials of the administering nurse on the treatment sheet that the Epogen has been administered.

⁶The West Virginia Board of Examiners for Registered Professional Nurses position statement "The Role of the Registered Professional Nurse and the Licensed Practical Nurse in Intravenous Therapy," dated June 15, 2005

For 10 claims (one claim had multiple errors), the Beckley medical records reflected errors in documenting the ordering and administering of Epogen because patients' medical records lacked the signature of the nurse who administered the Epogen, the patient treatment sheets were missing, or the medical records lacked attending physicians' orders, as required by Beckley's internal policies, including those in the Fresenius Manual. Beckley administered and billed and Medicare paid for the units ordered or administered.

- For six claims, covering six patients, the Beckley medical records lacked the signature of the administering nurse as required by Beckley's internal policies, including those in the Fresenius Manual. The administering nurse failed to initial or sign the treatment sheet reflecting the units of Epogen administered. Beckley billed for and was reimbursed for the units ordered and administered.
- For three claims, covering three patients, the Beckley medical records did not reflect the treatment sheets for Epogen for one date of service. Because Beckley medical records did not include the patients' treatment sheets, we used the units of Epogen reflected on the attending physicians' orders as the number of units administered by Beckley. Beckley administered and billed, and Medicare paid for the total units of Epogen prescribed by the attending physicians' orders for the periods reviewed.
- For two claims, covering two patients, the Beckley medical records lacked the attending physicians' orders covering one or more treatments, as required by Beckley's internal policies, including those in the Fresenius Manual. The nurse administered, Beckley billed and Medicare paid for the units of Epogen reflected on the dialysis treatment sheets.

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 the administering nurse to begin a new medication or to change the dose of a medication.⁷

⁷The Fresenius Manual permits a physician to provide telephone orders; however, the physician must sign the order during the next facility visit.

- 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 Beckley had controls in place as specified in the Fresenius Manual, based on our review, Beckley personnel did not always follow all of these procedures. Administering nurses’ determinations of the Epogen doses to administer were not always calculated in accordance with the Beckley algorithm. Attending physicians’ orders changing the dose of Epogen were not always identified and entered into the Fresenius System in accordance with signed physicians’ orders. Therefore, the units of Epogen ordered by the attending physicians did not always appear on patients’ treatment sheets.

Also, attending physician orders, treatment sheets, and signatures of administering nurses were not always reflected in the Beckley medical records.

RECOMMENDATIONS

We recommend that Beckley:

- refund the \$25,886 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 Beckley, and paid by Medicare.

FRESENIUS COMMENTS

In comments on our draft report, Fresenius stated that it will contact the intermediary about refunding the \$25,886 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’s comments are included in Appendix C.

APPENDIXES

SAMPLING METHODOLOGY

POPULATION

The population included 2,829 claims that were paid by Medicare to Fresenius Medical Care—Beckley for end-stage renal disease services provided from January 1, 2004, through June 30, 2006.

SAMPLING FRAME

Our sampling frame included 2,829 Medicare claims for the administration of Epogen that totaled \$1,698,935.

SAMPLE DESIGN

The audit used a simple random variable sample.

SAMPLE SIZE

The statistical sample consisted of 100 Medicare claims for the administration of Epogen.

SAMPLE RESULTS AND ESTIMATES

CLAIMS FOR EPOGEN DOSAGE NOT CONSISTENT WITH PHYSICIANS' ORDERS

Sample Results

Number of Claims in Sampling Frame	2,829
Value of Sampling Frame	\$1,698,935
Number of Claims in Sample	100
Value of Sample	\$58,589
Number of Claims with Errors	17
Value of Errors	\$1,968

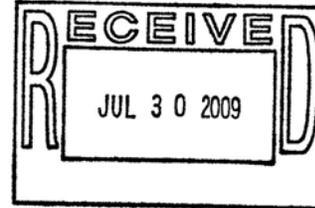
Estimate of Claims Not Consistent With Physicians' Orders
(Limits calculated for a 90-percent confidence interval)

Estimated Unallowable Costs

Point estimate	\$55,683
Lower limit	\$25,886
Upper limit	\$85,479



Fresenius Medical Care
North America



July 29, 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-03-07-00026, Payments for Epogen Administered at
Fresenius Medical Care – Beckley, West Virginia.

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 \$58,588.26 in claims reviewed, \$1,968.00 was
identified by the audit as not eligible for Medicare reimbursement – reflecting
3.36% 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 Beckley, and paid by Medicare”.

Fresenius Medical Care North America

Corporate Headquarters: 920 Winter Street Waltham, MA 02451-1457 (781) 699-9000

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Fresenius Corrective Action Taken or Planned:

While the payment error rate is consistent with the CERT audit rate, 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 algorithm dose change calculations; (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 Assessment and 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 \$25,866 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.

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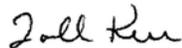
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Finally, I note that in the Background section of the Introduction, the audit states:

“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
Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451

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