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

AUG 5 2009

Report Number: A-03-07-00033

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—First State, New Castle, Delaware." 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-03-07-00033 in all correspondence.

Sincerely,

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)
Centers for Medicare & Medicaid Services
601 East 12th Street, Room 235
Kansas City, Missouri 64106
rokcmora@cms.hhs.gov

Department of Health and Human Services

**OFFICE OF INSPECTOR GENERAL**

# PAYMENTS FOR EPOGEN ADMINISTERED AT FRESENIUS MEDICAL CARE–FIRST STATE, NEW CASTLE, DELAWARE


Daniel R. Levinson
Inspector General

August 2009
A-03-07-00033

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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—First State (First State), located in New Castle, Delaware, is one of more than 1,500 renal dialysis facilities operated by Fresenius Medical Care North America. First State provides treatment for end-stage renal disease using 25 renal dialysis stations. It received payments totaling $5,916,116 for Medicare service provided from January 1, 2004, through June 30, 2006. Of this amount, $1,719,455 was for the administration of Epogen. During our audit period, First State did not use a dosing algorithm.

### OBJECTIVE

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

### SUMMARY OF FINDING

For 75 of the 100 sampled claims, First State administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in First State's medical records. However, First State did not meet the Medicare payment requirements for some dates of service for 25 claims (one of the claims had multiple errors). In those instances, we identified discrepancies in First State'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 First State, and paid by Medicare.

- For 11 claims with errors totaling $656, First State's medical and billing records reflected that more units of Epogen were administered to patients, billed by First State, and paid by Medicare than were ordered by the patients' attending physicians, resulting in overpayments. Based on the sample results, we estimate that First State received overpayments of at least $7,187 for the administration of Epogen from January 1, 2004, through June 30, 2006.

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

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

The errors related to these 25 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, First State received at least $7,187 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 First State:

- refund $7,187 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 First State, 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 $7,187 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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**APPENDIXES**

# 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—First State (First State) did not use an algorithm.

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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 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—First State

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.

First State, located in New Castle, Delaware, is one of more than 1,500 renal dialysis facilities operated by Fresenius. First State provides treatment for end-stage renal disease at 25 renal dialysis stations. It received payments totaling $5,916,116 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, $1,719,455 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 First State administered, billed, and was paid for units of Epogen consistent with the units that were ordered by attending physicians, as reflected in First State's medical records.

### Scope

Our review covered 2,571 monthly claims totaling $1,719,455 for Epogen administered by First State from January 1, 2004, through June 30, 2006.

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

We performed fieldwork at First State in New Castle, Delaware, 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 First State's policies and procedures and the Fresenius Manual;

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

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

    - selected from the sampling frame a simple random sample of 100 claims for Epogen totaling $70,520 and

    - for each sampled claim, compared the units of Epogen ordered by the First State attending physician, administered to patients, billed by First State, and paid by Medicare to determine whether such units, as reflected in First State'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 75 of the 100 sampled claims, First State administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in First State's medical records. However, First State did not meet the Medicare payment requirements for some dates of service for 25 claims (one of the claims had multiple errors). In those instances, we identified discrepancies in First State'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 First State, and paid by Medicare.

- For 11 claims with errors totaling $656, First State's medical and billing records reflected that more units of Epogen were administered to patients, billed by First State, and paid by Medicare than were ordered by the patients' attending physicians, resulting in overpayments. Based on the sample results, we estimate that First State received overpayments of at least $7,187 for the administration of Epogen from January 1, 2004, through June 30, 2006.

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

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

The errors related to these 25 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, First State received at least $7,187 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.

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

## CLAIMS FOR EPOGEN NOT CONSISTENT WITH PHYSICIANS' ORDERS

For each sample claim, we compared First State'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 First State, and (4) paid by Medicare. For 11 claims with questioned amounts totaling $656, there were discrepancies in First State's medical and billing records between the units of Epogen ordered by the attending physician and the units of Epogen administered and billed by First State, and paid by Medicare. First State administered, billed, and was paid for higher doses than ordered by the attending physician, as documented in First State's medical and billing records.

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

For 11 claims covering 11 patients, First State's medical records contained attending physicians' orders that reduced the units of Epogen prescribed, but an assigned staff member did not record the changes in the Fresenius System.[6] Consequently, the Fresenius System printed treatment sheets showing the original units, which were administered to the patients, billed by First State, and paid by Medicare.

- For six claims the attending physicians' orders decreased the units of Epogen prescribed 1 to 2 months prior to the month reviewed. The six patients each received a higher amount than ordered for 1 to 13 treatments during the month reviewed. First State corrected the units administered during the month reviewed for one patient and the physician increased the units prescribed during the month reviewed for two patients. However, First State continued to administer more units of Epogen than ordered throughout the month reviewed for two patients. In total, these six patients received, First State billed, and Medicare paid for 44,800 more units of Epogen, totaling $351, than was ordered.[7]

- For four claims the attending physicians' orders decreased the units prescribed for four patients during the month reviewed but each patient continued to receive the higher amount for two to six treatments through the end of that month. In total, these four patients received, First State billed, and Medicare paid for 39,000 more units of Epogen, totaling $303, than was ordered.

- For one claim the attending physician's order decreased the units prescribed for one patient during the month reviewed but the patient received a higher amount for one treatment. First State did not administer Epogen on the last treatment of the month

[6]The change in the units of Epogen prescribed appeared in the progress notes of the patients' medical record for nine patients and in the physician order section of the patients' medical record for the remaining two patients.

[7]From the dates of the orders to reduce the number of units of Epogen through the end of the month reviewed, the six patients each received more units than ordered for 11 to 36 treatments, resulting in the administration of 103,400 more units of Epogen, totaling $807, than was ordered. We included only the administered, billed, and paid units that exceeded the ordered amounts during the sampled months in our estimate of overpayments.

reviewed. The patient received, First State billed, and Medicare paid for 300 more units of Epogen, totaling $2, than was ordered

### Estimate of Overpayments

Based on the sample results, we estimate that First State received overpayments of at least $7,187 for the administration of Epogen from January 1, 2004, through June 30, 2006, for which First State'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 First State, and paid by Medicare.

## CLAIMS WITH PROCEDURAL ERRORS THAT RESULTED IN DISCREPANCIES

For nine claims, First State'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 First State, 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 seven of these claims, patients received lower doses than ordered. The documentation for one claim had conflicting orders for dose changes signed on the same day by the same attending physician. One claim was billed without the appropriate modifier.

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

For seven claims, First State's medical records included attending physicians' orders to increase the units of Epogen but the changes were not entered into the Fresenius System on a timely basis. As a result, the ordered amounts did not appear on the treatment sheets. Nurses continued to administer the lower amounts for 1 to 10 treatments. First State administered, billed, and was paid for fewer units of Epogen than ordered.

### Contradictory Orders in Patient's Medical Records

For one claim the patient's medical record contained two contradictory orders for Epogen, both signed by the same attending physician and dated February 24, 2005. One order, in the "order section," said to "decrease Epogen to 5,000 units" [emphasis added]. The other order, in the "progress notes," decreased the Epogen dose to 3,500 units. The prior dose was 4,000 units and the patient's hematocrit level was 41.1 percent. However, for the last two treatments in the month we reviewed, the nurse administered and First State billed the 5,000 units indicated in the order section (an increase rather than a decrease in the amount ordered). The contradictory attending physician's orders did not reflect the time ordered; therefore, we were unable to determine whether there was an overpayment for this claim.

### 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 9,000 to 6,700 units, a reduction of 25 percent, as required by CMS for full reimbursement. First State continued to administer 9,000 units during the first four treatments in April but reduced the dose to 6,700 units for the remaining eight treatments for that month.

For this claim, First State administered and billed for a total of 89,600 units instead of the 80,400 units ordered (6,700 units for 12 treatments). However, First State did not include the necessary "GS" modifier on the claim to indicate that it had complied with CMS's requirement to reduce the Epogen dose for the final eight treatments. Accordingly, CMS reduced the total payment amount by 25 percent.

First State should have received a payment totaling $600 for the 80,400 units supported by an attending physician's order, but instead received $502: payment for the 89,600 units administered less the 25 percent reduction. First State never questioned the reduction in the amount paid. First State personnel administered 9,200 more units of Epogen than were ordered during the month. However, because First State failed to use the "GS" modifier, CMS reduced the entire month's payment by 25 percent, and there was, therefore, no overpayment for this claim.

## CLAIMS WITH PROCEDURAL ERRORS THAT DID NOT RESULT IN DISCREPANCIES

In Delaware, the Nurse Practice Act requires that the authorized person administering a drug "verif[y] the properly prescribed drug order, . . . records the time and dose given and assesses the patient following the administration of medication for possible untoward side effects." (24 Del. C. § 1902(a)). To assist facilities in documenting compliance with Federal and State requirements, the Fresenius Manual requires a physician's signature for prescription orders and a signature or initials of the administering nurse on the treatment sheet to show that the Epogen has been administered.

For six other claims the patients' medical records lacked the signature/initials of the administering nurse, as required by First State's internal policies, including those in the Fresenius Manual. The administering nurse administered the units of Epogen consistent with the patients' attending physicians' orders, but did not sign or initial the treatment sheet to document the administration of Epogen for one date of service for six patients. First State billed for and was reimbursed for the units ordered and administered.

## 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.[8]

- 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 First State had controls in place as specified in the Fresenius Manual, based on our review, First State 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 on a timely basis. Therefore, changes to the attending physicians' orders did not always appear on subsequent treatment sheets.

Also, entries on the treatment sheet were not always initialed or signed.

## DISCREPANCIES BETWEEN UNITS OF EPOGEN ORDERED, ADMINISTERED, BILLED, AND PAID

Because First State personnel did not always follow the procedures required by the Fresenius Manual, attending physicians' orders were not always updated in the Fresenius System on a timely basis. As a result, patients did not always receive the units of Epogen ordered by the attending physician and First State received at least $7,187 in overpayments. When physicians' orders are not followed, quality of care may be affected.

[8]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 First State:

- refund $7,187 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 First State, and paid by Medicare.

## FRESENIUS COMMENTS

In comments on our draft report, Fresenius stated that it will contact the intermediary about refunding the $7,187 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 Appendix C.

# APPENDIXES

**APPENDIX A**

# SAMPLING METHODOLOGY

## POPULATION

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

## SAMPLING FRAME

Our sampling frame included 2,571 Medicare claims for the administration of Epogen that totaled $1,719,455.

## SAMPLE DESIGN

The audit used a simple random variable sample.

## SAMPLE SIZE

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

**APPENDIX B**

## SAMPLE RESULTS AND ESTIMATES

## CLAIMS FOR EPOGEN DOSAGE NOT JUSTIFIED BY DOCUMENTATION

### Sample Results

| | |
|---|---|
| Number of Claims in Sampling Frame | 2,571 |
| Value of Sampling Frame | $1,719,455 |
| Number of Claims in Sample | 100 |
| Value of Sample | $70,520 |
| Number of Claims with Errors | 11 |
| Value of Errors | $656 |

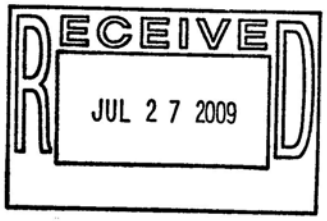
### Estimate of Claims Not Meeting Documentation Requirements

*(Limits Calculated for a 90-percent confidence interval)*

### Estimated Unallowable Costs

| | |
|---|---|
| Point estimate | $16,854 |
| Lower limit | $7,187 |
| Upper limit | $26,522 |

Fresenius Medical Care
North America




July 13, 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-03-07-00033, Payments for Epogen Administered at Fresenius Medical Care – First State, New Castle, Delaware.

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 $70,520.00 in claims reviewed, $656.00 was identified by the audit as not eligible for Medicare reimbursement – reflecting 0.9% 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 First State, 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 $7,187 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.

**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:

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

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