



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

JUL 14 2009

Report Number: A-03-07-00027

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—Artificial Kidney Center of Suffolk, Suffolk, 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.

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

If you have any questions or comments about this report, please do not hesitate to call me at (215) 861-4470 or through email at [Stephen.Virbitsky@oig.hhs.gov](mailto:Stephen.Virbitsky@oig.hhs.gov), or contact Bernard Siegel, Audit Manager, at (215) 861-4484 or through email at [Bernard.Siegel@oig.hhs.gov](mailto:Bernard.Siegel@oig.hhs.gov). Please refer to report number A-03-07-00027 in all correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen Virbitsky".

Stephen Virbitsky  
Regional Inspector General  
for Audit Services

Enclosure

**Direct Reply to HHS Action Official:**

Janet Samen  
Director, Division of Chronic Care Management  
Center for Medicare Management (CCPG/DCCM)  
Centers for Medicare & Medicaid Services  
Mail Stop C5-05-07  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850  
[Janet.Samen@cms.hhs.gov](mailto:Janet.Samen@cms.hhs.gov)

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**PAYMENTS FOR  
EPOGEN ADMINISTERED AT  
FRESENIUS MEDICAL CARE –  
ARTIFICIAL KIDNEY CENTER  
OF SUFFOLK,  
SUFFOLK, VIRGINIA**



Daniel R. Levinson  
Inspector General

July 2009  
A-03-07-00027

# ***Office of Inspector General***

<http://oig.hhs.gov>

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## ***Office of Audit Services***

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

## ***Office of Evaluation and Inspections***

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

## ***Office of Investigations***

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## ***Office of Counsel to the Inspector General***

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

# *Notices*

---

## **THIS REPORT IS AVAILABLE TO THE PUBLIC**

at <http://oig.hhs.gov>

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, Office of Inspector General reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act.

## **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—Artificial Kidney Center of Suffolk (Suffolk), located in Suffolk, Virginia, is one of more than 1,500 renal dialysis facilities operated by Fresenius Medical Care North America (Fresenius). Suffolk provides treatment for end-stage renal disease using 28 renal dialysis stations. It received payments totaling \$7,312,704 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$2,535,030 was for the administration of Epogen. During our audit period, Suffolk used dosing algorithms to adjust patient Epogen doses.

### **OBJECTIVE**

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

### **SUMMARY OF FINDING**

For 85 of the 100 sampled claims, Suffolk administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Suffolk's medical records. However, Suffolk did not meet the Medicare payment requirements for some dates of service for 15 claims. In those instances, we identified discrepancies in Suffolk'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 Suffolk, and paid by Medicare.

- For five claims reviewed, with errors totaling \$756, Suffolk billed and Medicare paid for more units of Epogen than were ordered by attending physicians.
- For seven claims, Suffolk'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 Suffolk, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.
- For three claims, Suffolk'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 15 claims occurred because administering nurses responsible for documenting and flagging the patients' files for changes in Epogen orders 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, Suffolk received \$756 in overpayments and patients did not always receive the units of Epogen ordered by attending physicians. When attending physicians' orders are not followed, quality of care may be affected.

## **RECOMMENDATIONS**

We recommend that Suffolk:

- refund \$756 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 Suffolk, 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 \$756 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.

# TABLE OF CONTENTS

	<u>Page</u>
<b>INTRODUCTION</b> .....	1
<b>BACKGROUND</b> .....	1
Medicare .....	1
Epogen Therapy for End-Stage Renal Disease Patients .....	1
Medicare Requirements and Payments for End-Stage Renal Disease Services .....	2
Fresenius Medical Care—Artificial Kidney Center of Suffolk .....	2
Fresenius’s Policy Manual and Medical Information System .....	2
<b>OBJECTIVE, SCOPE, AND METHODOLOGY</b> .....	3
Objective .....	3
Scope .....	3
Methodology .....	3
<b>FINDINGS AND RECOMMENDATIONS</b> .....	4
<b>FEDERAL REQUIREMENTS</b> .....	5
Medical Recordkeeping .....	5
Medicare Payment Procedures.....	5
<b>CLAIMS FOR EPOGEN NOT CONSISTENT WITH PHYSICIANS’ ORDERS</b> .....	5
More Units of Epogen Administered, Billed, and Paid Than Ordered .....	5
Epogen Administered More Frequently Than Ordered .....	6
More Units of Epogen Billed and Paid Than Administered .....	6
<b>CLAIMS WITH PROCEDURAL ERRORS THAT RESULTED IN DISCREPANCIES</b> .....	7
<b>CLAIMS WITH PROCEDURAL ERRORS THAT DID NOT RESULT IN DISCREPANCIES</b> .....	7
<b>FRESENIUS POLICY AND PROCEDURES NOT ALWAYS FOLLOWED</b> .....	8
<b>RECOMMENDATIONS</b> .....	9
<b>FRESENIUS COMMENTS</b> .....	9
<b>APPENDIX</b>	
<b>FRESENIUS MEDICAL CARE NORTH AMERICA COMMENTS</b>	

# 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.<sup>1</sup>

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.<sup>2</sup> For dialysis patients, hematocrit levels above 36 percent can lead to increased risk of cardiovascular complications and death.<sup>3</sup>

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—Artificial Kidney Center of Suffolk (Suffolk) used algorithms to determine the dose of Epogen to administer to its patients.

---

<sup>1</sup>Epogen is an "erythropoietin stimulating agent," manufactured by Amgen, which stimulates the production of red blood cells.

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

<sup>3</sup>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<sup>4</sup> 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—Artificial Kidney Center of Suffolk**

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.

Suffolk, located in Suffolk, Virginia, is one of more than 1,500 renal dialysis facilities operated by Fresenius. Suffolk provides treatment for end-stage renal disease at 28 renal dialysis stations. It received payments totaling \$7,312,704 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$2,535,030 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).

---

<sup>4</sup>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.

The Fresenius System prints a treatment sheet for each patient that lists selected patient 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 Suffolk administered, billed, and was paid for units of Epogen consistent with the units that were ordered by attending physicians, as reflected in Suffolk's medical records.

### **Scope**

Our review covered 3,293 monthly claims totaling \$2,535,030 for Epogen administered by Suffolk from January 1, 2004, through June 30, 2006.

We limited our review of Suffolk'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 Suffolk'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 Suffolk's policies and procedures and the Fresenius Manual;
- reviewed Suffolk'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 Suffolk from January 1, 2004, through June 30, 2006, and:
  - selected from the sampling frame a simple random sample of 100 claims for Epogen totaling \$71,687 and
  - for each sampled claim, compared the units of Epogen ordered by the Suffolk attending physician, administered to the patient, billed by Suffolk, and paid by Medicare to determine whether such units, as reflected in Suffolk’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 85 of the 100 sampled claims, Suffolk administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Suffolk’s medical records. However, Suffolk did not meet the Medicare payment requirements for some dates of service for 15 claims. In those instances, we identified discrepancies in Suffolk’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 Suffolk, and paid by Medicare.

- For five claims reviewed, with errors totaling \$756, Suffolk billed and Medicare paid for more units of Epogen than were ordered by attending physicians.
- For seven claims, Suffolk’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 Suffolk, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.
- For three claims, Suffolk’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 15 claims occurred because administering nurses responsible for documenting and flagging the patients’ files for changes in Epogen orders 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, Suffolk received \$756 in overpayments and patients did not always receive the units 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).<sup>5</sup> 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 the 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 Suffolk's medical and billing records with respect to the units of Epogen (1) ordered by the patients' attending physician, (2) administered by the nurse to the patient, (3) billed by Suffolk, and (4) paid by Medicare. For five claims reviewed, with errors totaling \$756, Suffolk billed and Medicare paid for more units of Epogen than was ordered by the attending physicians.

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

For three claims covering three patients, Suffolk's medical records contained attending physicians' orders that changed the units of Epogen prescribed, but an assigned staff member did not record the changes in the Fresenius System accurately or on a timely basis. Consequently, the Fresenius System printed treatment sheets showing incorrect units or frequency of Epogen, which were administered to the patients, billed by Suffolk, and paid by Medicare.

---

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

- For one claim, the attending physician's order, dated May 25, 2004, prescribed 20,000 units of Epogen to be administered with each treatment; however, the dose for Tuesday was to be administered subcutaneously and the doses for Thursday and Saturday were to be administered intravenously. Treatment sheets for three of the four Tuesdays in December 2004 reflected that the patient receive two doses of Epogen: 20,000 units subcutaneously and 20,000 units intravenously. As a result, Suffolk administered and billed, and Medicare paid for 60,000 units more of Epogen, totaling \$480, than was ordered.
- For one claim, the attending physician's order, dated December 10, 2004, suspended the administration of Epogen for one week but ordered that the patient receive 6,000 units of Epogen with each treatment thereafter. Although nurses did not administer Epogen on December 10, 2004, they did administer 6,000 units of Epogen on December 13 and 15, 2004. As a result, Suffolk administered and billed, and Medicare paid for 12,000 units more of Epogen, totaling \$96, than was ordered.
- For one claim, the attending physician's order, dated September 28, 2005, decreased the prescribed Epogen dose from 3,000 units to 1,500 units. On September 29, 2005, the treatment sheet reflected the original dose of 3,000 units of Epogen. Suffolk, administered and billed, and Medicare paid for 1,500 units more of Epogen, totaling \$12, than was ordered.

In total for these three patients, Suffolk administered and billed, and Medicare paid for 73,500 more units of Epogen, totaling \$588, than was ordered.

### **Epogen Administered More Frequently Than Ordered**

For one claim, the attending physician order, dated May 24, 2004, prescribed 20,000 units of Epogen to be administered once a week but the treatment sheet and the Suffolk medical records did not reflect which day of the week to administer the dose. The Suffolk medical record reflected that the patient did not always arrive for the dialysis treatment and often left before the treatment was completed, against medical advice. However, during one week in June 2004, Suffolk administered 20,000 units of Epogen during two treatments. As a result, Suffolk administered and billed, and Medicare paid for 20,000 units more of Epogen, totaling \$160, than was ordered.

### **More Units of Epogen Billed and Paid Than Administered**

For one claim, Suffolk billed and Medicare paid for more units of Epogen than were administered to the patient during the month reviewed. The Suffolk medical record showed that the attending physician ordered 1,000 units of Epogen beginning on February 17, 2004. Based on the patient's treatment sheets, Suffolk administered the ordered dose during five treatments, totaling 5,000 units, but billed Medicare for 6,000 units. Suffolk billed and Medicare paid for 1,000 units more of Epogen, totaling \$8, than was ordered and administered.

## **CLAIMS WITH PROCEDURAL ERRORS THAT RESULTED IN DISCREPANCIES**

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

- For three claims, the Suffolk medical records reflected that attending physicians' orders increased the dose of Epogen for three patients. The treatment sheet continued to reflect the original lower dose for one treatment following the effective date of the physicians' orders and nurses continued to administer the lower doses.
- For three claims, the Suffolk medical records reflected that attending physicians' orders decreased the dose of Epogen for two patients and increased the dose of Epogen for one patient. The physicians' orders reflected the effective date for the new dose. However, treatment sheets for one or more treatments preceding the effective date reflected the new dose because designated Suffolk staff entered the change in the Epogen dose in the Fresenius System with the wrong effective date. Nurses administered the new dose reflected on the treatment sheet.
- For one claim, the Suffolk medical record reflected that on September 15, 2005, the attending physician's order decreased the dose of Epogen from 1,500 to 1,000 units. However, the treatment sheets for September 12 and 14 reflected that nurses administered the lower dose before the effective date of the physician's order. On September 28 and 30, nurses administered a lower dose of 800 units of Epogen without a new attending physician order.

Suffolk administered and billed, and Medicare paid for the units administered to the patient that were higher or lower than was ordered.

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

In Virginia, the Nurse Practice Act defines nursing, including licensing requirements, in the Code of Virginia (54.1 Va. C. § 3000) to include the administration of medications and treatments as prescribed by any person authorized by law to prescribe such medications and treatment. Also, the code requires nurses to carry out treatment care, medication administration, lab tests, procedures, and other treatments based on physician orders (54.1 Va. C. § 2901 (A)(4)). 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 for ensuring 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 to show that the Epogen has been administered.

For three claims, the Suffolk medical records reflected errors in documenting the ordering and administering of Epogen because patients' medical records either lacked the attending physicians' orders or the attending physician's order lacked the signature/initials of the physician, as required by Suffolk's internal policies, including those in the Fresenius Manual. Suffolk administered and billed and Medicare paid for the units ordered and administered.

- For two claims covering two patients, the Suffolk medical records did not reflect attending physicians' orders for Epogen for dates of service reviewed. Because Suffolk medical records did not include the attending physicians' orders, we used the units of Epogen reflected on the prescribed section of the patient's treatment sheets as the number of units ordered and administered by Suffolk. Also, during the months reviewed, the medical records reflected physician orders that referred to a previous Epogen order. Suffolk administered and billed, and Medicare paid for the total units of Epogen reflected on the patients' treatment sheets.
- For one claim covering one patient, the Suffolk medical record reflected the attending physician order increasing a patient's Epogen dose from 11,000 to 15,000 units; however, the attending physician did not sign the order. Suffolk administered and billed, and Medicare paid for the 15,000 units of Epogen reflected on the unsigned order

## **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.<sup>6</sup>
- 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.

---

<sup>6</sup>The Fresenius Manual permits a physician to provide telephone orders; however, the physician must sign the order during the next facility visit.

- 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 Suffolk had controls in place as specified in the Fresenius Manual, based on our review, Suffolk 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 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 were not always signed or reflected in the Suffolk medical records.

## **RECOMMENDATIONS**

We recommend that Suffolk:

- refund \$756 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 Suffolk, and paid by Medicare.

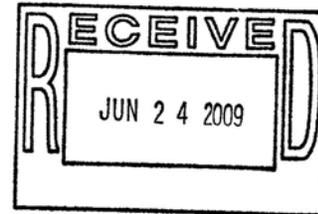
## **FRESENIUS COMMENTS**

In comments on our draft report, Fresenius stated that it will contact the intermediary about refunding the \$756 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-03-07-00027, Payments for Epogen Administered at  
Fresenius Medical Care-Artificial Kidney Center of Suffolk, Suffolk 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 \$71,687.00 in claims reviewed, \$756 was identified by the audit as not eligible for Medicare reimbursement – reflecting 1.05% 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 Suffolk, 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:

**Fresenius Medical Care North America**

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

- 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 \$756 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

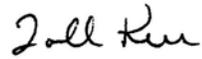
**Fresenius Medical Care North America**

---

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

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