



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

JUN 24 2009

Report Number: A-03-07-00029

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:

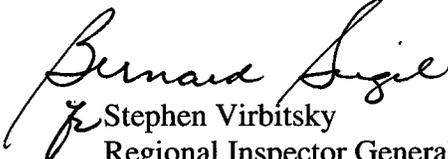
Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Payments for Epogen Administered at Fresenius Medical Care—Wynnewood, Wynnewood, Pennsylvania." We will forward a copy of this report to the HHS action official noted on the following 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-03-07-00029 in all correspondence.

Sincerely,

  
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 –  
WYNNEWOOD,  
WYNNEWOOD, PENNSYLVANIA**



Daniel R. Levinson  
Inspector General

June 2009  
A-03-07-00029

# ***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—Wynnewood (Wynnewood), located in Wynnewood, Pennsylvania, is one of more than 1,500 renal dialysis facilities operated by Fresenius Medical Care North America (Fresenius). Wynnewood provides treatment for end-stage renal disease at 31 renal dialysis stations. It received payments totaling \$8,587,820 for Medicare service provided from January 1, 2004, through June 30, 2006. Of this amount, \$2,796,452 was for the administration of Epogen. During our audit period, Wynnewood used a dosing algorithm to adjust patient Epogen doses.

Fresenius acquired Wynnewood from Renal Care Group, Incorporated, during our audit period, on March 31, 2006.

### **OBJECTIVE**

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

### **SUMMARY OF FINDING**

For 88 of the 100 sampled claims, Wynnewood administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Wynnewood's medical records. However, Wynnewood did not meet the Medicare payment

requirements for some dates of services for 12 claims (one of the claims had multiple errors). In those instances, we identified discrepancies in Wynnewood'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 Wynnewood, and paid by Medicare.

- For four claims with errors totaling \$371, Wynnewood's medical and billing records reflected that more units of Epogen were administered to patients, billed by Wynnewood, and paid by Medicare than were ordered by the patients' attending physicians, resulting in overpayments.
- For nine claims, Wynnewood'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 Wynnewood, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.

The errors related to these 12 claims occurred because nurses responsible for administering Epogen did not always follow the policies and procedures in the Renal Care Group 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 and that Epogen doses calculated by nurses were in accordance with the Wynnewood algorithm. Also, physicians did not always verify and sign their telephone orders and nurses' Epogen dose changes, based on the algorithm ordered for the patient, in a timely manner. As a result, Wynnewood received \$371 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 Wynnewood:

- refund the \$371 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 Wynnewood, and paid by Medicare.

## **FRESENIUS COMMENTS**

In comments on our draft report (see Appendix), Fresenius stated that it will refund the \$371 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—Wynnewood .....	2
Renal Care Group’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.....	6
<b>CLAIMS WITH PROCEDURAL ERRORS THAT RESULTED IN DISCREPANCIES</b> .....	6
Epogen Doses Differed From the Wynnewood Algorithm .....	7
Claim Not Correctly Billed .....	7
Fewer Units of Epogen Administered, Billed, and Paid, Than Ordered.....	8
Patient’s Medical Record Not Clearly Documented.....	8
<b>WYNNEWOOD POLICIES 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 patient's Epogen dose or temporarily suspend the dose for one or more treatments. Fresenius Medical Care—Wynnewood (Wynnewood) used an algorithm established by the attending physicians to determine the dose of Epogen to administer to patients.

---

<sup>1</sup>Epogen is an "erythropoiesis-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 debt, 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—Wynnewood**

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.

Wynnewood, located in Wynnewood, Pennsylvania, is one of more than 1,500 renal dialysis facilities operated by Fresenius. Wynnewood provides treatment for end-stage renal disease at 31 renal dialysis stations. It received payments totaling \$8,587,820 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$2,796,452 was for the administration of Epogen.

Fresenius acquired Wynnewood from Renal Care Group, Incorporated, during our audit period, on March 31, 2006.

### **Renal Care Group’s Policy Manual and Medical Information System**

To assist in its facilities’ effort to comply with requirements under Federal and State law, Renal Care Group established a medical record policy and documentation procedure in its Renal Care Group Manual, including maintenance of medical records, providing dialysis services, and use of

---

<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.

electronic signatures in the Renal Care Group automated medical record system (Wynnewood System). The Wynnewood System is an automated medical record system to document physician orders, including medications, and dialysis services. The Wynnewood System assigns each user authenticated access to authorized areas in the medical record system necessary to perform assigned tasks. The Wynnewood System automatically records the service performed, including the administration of Epogen, as well as the date and time recorded by the user. Once entered, the information cannot be altered. Wynnewood continued to use the Renal Care Group Manual and the Wynnewood System after it was acquired by Fresenius.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

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

### **Scope**

Our review covered 3,663 monthly claims totaling \$2,796,452 for Epogen administered by Wynnewood from January 1, 2004, through June 30, 2006.

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

We performed fieldwork at Wynnewood in Wynnewood, Pennsylvania, 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 Wynnewood's policies and procedures and the Renal Care Group Manual;
- reviewed Wynnewood's policies and procedures, including the Renal Care Group Manual, and its medical recordkeeping and billing practices;
- interviewed Fresenius and Wynnewood officials;

- identified and assessed the adequacy of internal controls related to the administration of and billing for Epogen; and
- identified a sample frame of all claims in the CMS claims history file with Epogen administered at Wynnewood from January 1, 2004, through June 30, 2006, and:
  - selected from the sampling frame a simple random sample of 100 claims for Epogen totaling \$83,910 and
  - for each sampled claim, compared the units of Epogen ordered by the Wynnewood attending physician, administered to patients, billed by Wynnewood, and paid by Medicare to determine whether such units, as reflected in Wynnewood'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 88 of the 100 sampled claims, Wynnewood administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Wynnewood's medical records. However, Wynnewood did not meet the Medicare payment requirements for some dates of services for 12 claims (one of the claims had multiple errors). In those instances, we identified discrepancies in Wynnewood'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 Wynnewood, and paid by Medicare.

- For four claims with errors totaling \$371, Wynnewood's medical and billing records reflected that more units of Epogen were administered to patients, billed by Wynnewood, and paid by Medicare than were ordered by the patients' attending physicians, resulting in overpayments.
- For nine claims, Wynnewood'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 Wynnewood, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.

The errors related to these 12 claims occurred because nurses responsible for administering Epogen did not always follow the policies and procedures in the Renal Care Group 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 and that Epogen doses calculated by nurses were in accordance with the algorithm ordered for the patient. Also, physicians did not

always verify and sign their telephone orders and nurses' Epogen dose changes, based on the algorithm ordered for the patient, in a timely manner. As a result, Wynnewood received \$371 in overpayments and patients did not always receive the amounts of Epogen ordered by attending physicians. When attending physicians' orders are not followed, quality of care may be affected.

## **FEDERAL REQUIREMENTS**

### **Medical Recordkeeping**

As a condition of coverage during our audit period, renal dialysis facilities were required to centralize all clinical information in each patient's medical record in accordance with accepted professional standards and practices (42 CFR § 405.2139).<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 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. Beginning January 1, 2006, the hematocrit reading included on the bill to Medicare should reflect the patient's most recent reading taken before the start of the billing period.

## **CLAIMS FOR EPOGEN NOT CONSISTENT WITH PHYSICIANS' ORDERS**

For each sample claim, we compared Wynnewood's medical and billing records with respect to the units of Epogen (1) ordered by the patients' attending physicians, (2) administered by the

---

<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.

nurse to the patient, (3) billed by Wynnewood, and (4) paid by Medicare. For four claims with questioned amounts totaling \$371, there were discrepancies in Wynnewood's medical and billing records between the units of Epogen ordered by the attending physician and the units of Epogen administered, billed by Wynnewood, and paid by Medicare. Wynnewood administered, billed, and was paid for higher doses than ordered by the attending physician, as documented in Wynnewood's medical and billing records.

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

For the four claims, covering four patients, Wynnewood's medical records contained attending physicians' orders for lower or less frequent doses of Epogen than administered by the attending nurse.

- For one claim the attending physician's order prescribed that the patient receives units of Epogen once every other week; however, the patient received units of Epogen four times during the month reviewed. The patient received, Wynnewood billed, and Medicare paid for 32,000 more units of Epogen, totaling \$256, than was ordered.
- For two claims the attending physician's orders increased the units prescribed for two patients during the month reviewed but each patient received two doses on the date the units were increased—the original dose plus the new dose prescribed by the attending physicians on that date. In total, these two patients received, Wynnewood billed, and Medicare paid for 14,300 more units of Epogen, totaling \$112, than was ordered.
- For one claim the attending physician's order prescribed that the patient receives 15,000 units of Epogen with each dialysis treatment. For one date of service during the month reviewed the nurse administered 15,400 units to the patient. Wynnewood billed and Medicare paid for 400 more units of Epogen, totaling \$3, than was ordered.

Wynnewood administered, billed, and was paid for 46,700 units more, totaling \$371, than was ordered.

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

In Pennsylvania, the Professional Nursing Law establishes standards for nursing schools and the conduct of nursing programs and defines the practice of medical nursing to include executing medical regimens as prescribed by a licensed physician. Pennsylvania's Administrative Code (49 Pa. Code Chapter 21) further regulates the profession of nursing, including the administration of prescription medications.

For nine claims, Wynnewood'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 Wynnewood, and paid by Medicare for one or more dates of service during the month reviewed. These claims did not result in an overpayment and are, for purposes of this report, considered procedural errors. For five of the nine claims, the nurse calculated a higher dose than suggested by the algorithm ordered for the patient. For two claims, Wynnewood

included incorrect information on the claims resulting in underpayments. For one claim, Wynnewood administered, billed and was paid for fewer units of Epogen than ordered and for one claim, the documentation of the amount of Epogen administered was confusing.

### **Epogen Doses Differed From the Wynnewood Algorithm**

For five claims, Wynnewood's medical records included nurses' changes to the dose of Epogen that did not follow the algorithm ordered by the attending physician. Wynnewood nurses are permitted to establish a patient's Epogen dose using the algorithm. All changes are updated in the Wynnewood System alerting attending physicians to electronically sign any changes to the dose of Epogen made by a nurse.

- For two claims, the algorithm directed that the doses of Epogen be suspended for 2 weeks or until the patient's hematocrit level was below 40 percent. The nurse then determines whether to start the Epogen dose at 2,000 units or 25 percent lower than the previous dose. However, for one patient the Wynnewood medical record reflected that instead of suspending the Epogen dose of 6,800 units, a nurse lowered it to 5,700 units. For the other patient, the medical record reflected that the nurse suspended the Epogen dose of 25,800 units for 1 week then started the Epogen at 19,800 units.
- For one claim, the algorithm directed that the dose of Epogen remain at 5,500 units; however, the patient's medical record reflected that the nurse increased the dose to 6,600 units.
- For two claims, the algorithm directed that the doses of Epogen be increased (from 18,700 to 22,700 units and from 23,200 to 25,200 units); however, the patients' medical records reflected that nurses administered higher doses (27,700 and 25,800 units, respectively) than identified by the Wynnewood algorithm.

Attending physicians electronically signed these order changes 6, 7, 35, 76, and 405 days after the effective date of the changes but none of the patients' medical records reflected why the dose differed from the Wynnewood algorithm.

### **Claim Not Correctly Billed**

For one claim with dates of service during April 2006, the patient had a hematocrit level lower than 39 percent at the end of the preceding month; however, Wynnewood reported a hematocrit higher than 39 percent. Beginning January 1, 2006, the hematocrit reading reported should be the patient's most recent reading taken before the start of the billing period.<sup>6</sup> Also, beginning April 1, 2006, CMS 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 payment for Epogen by 25 percent.

---

<sup>6</sup>Prior to January 1, 2006, the hematocrit reading reported was the reading reported prior to the last Epogen dose administered during the billing period.

Wynnewood administered and billed for the units of Epogen ordered by the attending physician, as documented in Wynnewood's medical and billing records but incorrectly identified the hematocrit as 40.5 percent instead of 36.3 percent. Consequently, CMS reduced the payment for Epogen from \$197.13 to \$147.78. As a result, Wynnewood was underpaid \$49.35.

For one claim with dates of service in April 2004, the attending physician ordered and the patient received 40,000 units of Epogen for self-administration during May 2004 home dialysis treatments. However, while the attending physician ordered and the patient received 40,000 units, Wynnewood billed and was paid by Medicare for only 4,000 units of Epogen. As a result, Wynnewood was underpaid \$288 for 36,000 units of Epogen.

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

For one claim, Wynnewood's medical records included an attending physician's order to administer 8,800 units of Epogen, but on one date of service during the month reviewed the patient only received 8,000 units. Wynnewood administered, billed, and was paid for fewer units than ordered.

### **Patient's Medical Record Not Clearly Documented**

For one claim, the patient's medical record was not updated on the date of service to reflect all services performed because the computer system was down. Although manual records documented the dialysis services performed it did not document the administration of Epogen. When the system was restored, summary information was posted to the Wynnewood System and the manual records were filed away. During the patient's next treatment, the nurse made a statement in the Wynnewood System that "the dose of Epogen was doubled because the computer system was down" during the previous treatment. We were unable to determine whether 6,600 units of Epogen were administered during each treatments or whether 13,200 units of Epogen were administered during the second treatment.

### **WYNNEWOOD POLICIES AND PROCEDURES NOT ALWAYS FOLLOWED**

To assist in its facilities' efforts to comply with requirements under Federal law and States' respective Nurse Practice Acts, Wynnewood operated under the Renal Care Group policies and procedures and the Wynnewood System that requires the use of electronic signatures. Although acquired by Fresenius in March 2006, Wynnewood continues to operate under those policies and procedures, including the Renal Care Group Manual.

- The Wynnewood System documents patient treatment. Each user of the system is assigned a unique login and password that (1) authenticates the user's security level and (2) allows the user access to those areas necessary to perform their assigned duties. The Wynnewood System dates and time stamps each event completed by the physician and the nurse and prevents the record from being changed.
- Nurses provide treatment to patients based on the instructions recorded in the Wynnewood System. The "Routine Medication Summary" of the medical record

displays the medications to be administered during dialysis and identifies each new or changed order since the last treatment. After each service or medication is provided, the nurse records in the Wynnewood System that the service or medication was provided in accordance with the medication summary instructions.

- Physicians enter and approve medical orders, including changes in the dose of Epogen, in the Wynnewood System. Also, physicians can change a patient's orders by telephone; however, when the nurse enters the change into the Wynnewood System the physician order is flagged until signed by the ordering physician. Changes made by nurses based on an algorithm are also flagged until signed by the attending physician.

Although Wynnewood had controls in place as specified in the Renal Care Group Manual, based on our review, Wynnewood personnel did not always follow all of these procedures. Nurses did not always administer the Epogen dose reflected in the Routine Medication Summary of the Wynnewood System, nurses did not always compute Epogen doses based on the algorithm ordered for the patient, and physicians did not verify or approve order changes, including changes in the Epogen dose, in a timely manner. Also, Wynnewood submitted bills for Epogen to Medicare with incorrect billing information.

## **RECOMMENDATIONS**

We recommend that Wynnewood:

- refund the \$371 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 Wynnewood, and paid by Medicare.

## **FRESENIUS COMMENTS**

In comments on our draft report, Fresenius stated that it will refund the \$371 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.

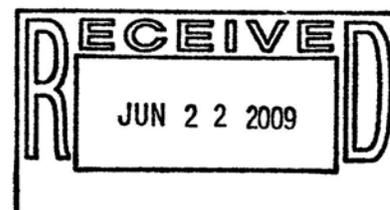
# **APPENDIX**



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-03-07-00029, Payments for Epogen Administered at Fresenius Medical Care-Wynnewood, Wynnewood, Pennsylvania

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 \$83,910.30 in claims reviewed, \$371 was identified by the audit as not eligible for Medicare reimbursement – reflecting 0.442% 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 Wynnewood, 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

**Fresenius Medical Care North America**

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

- 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 \$371 in overpayments"

**Fresenius Corrective Action Taken or Planned:**

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

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

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

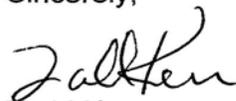
At Fresenius Medical Care clinics, while the facility Medical Director and Governing Body review and approve algorithms ordered by staff physicians, it is the staff physician (and not the medical director) who establishes the algorithm for the staff physician's patients. While often all physicians at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

**Fresenius Medical Care North America**

---

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

Sincerely,



Todd Kerr

Senior Vice President and Chief Compliance Officer

Fresenius Medical Care North America

920 Winter St.

Waltham, MA 02451