



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

JUL 15 2009

Report Number: A-03-07-00034

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—Brandywine, Wilmington, 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-03-07-00034 in all correspondence.

Sincerely,

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

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

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

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PAYMENTS FOR
EPOGEN ADMINISTERED AT
FRESENIUS MEDICAL CARE –
BRANDYWINE,
WILMINGTON, DELAWARE**



Daniel R. Levinson
Inspector General

July 2009
A-03-07-00034

Office of Inspector General

<http://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people 65 years of age and older, people under 65 with certain disabilities, and people of all ages with end-stage renal disease (permanent kidney failure requiring a kidney transplant or dialysis). The Centers for Medicare & Medicaid Services administers the program.

Section 1881(a) of the Act establishes the benefits provided by Medicare Parts A and B for individuals who have been determined to have end-stage renal disease as provided in section 226A of the Act. Benefits include injections of Epogen, usually administered during dialysis. Individuals diagnosed with end-stage renal disease often suffer from anemia, and Epogen lessens the effects of anemia for those patients. Epogen doses are generally adjusted by a physician based on a review of the patient's medical record. For facilities that use a preestablished dosing algorithm, a nurse may also adjust the Epogen dose to maintain an optimal hematocrit (red blood cell) level.

As a basis for payment, section 1833(e) of the Act states: "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due" Federal regulations (42 CFR § 424.5(a)(6)) require providers to furnish sufficient information, upon request, to determine whether payment is due and, if so, the amount to be paid.

Fresenius Medical Care—Brandywine (Brandywine), located in Wilmington, Delaware, is one of more than 1,500 renal dialysis facilities operated by Fresenius Medical Care North America. Brandywine provides treatment for end-stage renal disease using 25 renal dialysis stations. It received payments totaling \$5,716,762 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$1,728,381 was for the administration of Epogen. During our audit period, Brandywine did not use dosing algorithms.

OBJECTIVE

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

SUMMARY OF FINDING

For 77 of the 100 sampled claims, Brandywine administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Brandywine's medical records. However, Brandywine did not meet the Medicare payment requirements for some dates of service for 23 claims (two of the claims had multiple errors). In those instances, we identified discrepancies in Brandywine'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 Brandywine, and paid by Medicare.

- For eight claims with errors totaling \$1,340, Brandywine’s medical and billing records reflected that more units of Epogen were administered to patients, billed by Brandywine, and paid by Medicare than were ordered by the patients’ attending physicians, resulting in overpayments.
- For 10 claims, Brandywine’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 Brandywine, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.
- For seven claims, Brandywine’s medical records reflected errors in documenting the ordering and administration of Epogen but not discrepancies in the quantities of Epogen ordered, administered, billed, or paid. For purposes of this report, we considered these errors procedural because they did not result in overpayments.

The errors related to these 23 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, nurses did not always administer the ordered units of Epogen printed on treatment sheets, and some Brandywine medical records did not identify the ordered or administered units of Epogen. As a result, for eight claims, Brandywine received \$1,340 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 Brandywine:

- refund the \$1,340 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 Brandywine, 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 \$1,340 in overpayments and that the nursing staff will undergo a training program to improve compliance with policies and procedures relating to the ordering and administration of Epogen. Fresenius also brought to our attention a technical correction regarding its algorithm policy that we have amended in the report.

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INTRODUCTION

BACKGROUND

Medicare

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people 65 years of age and older, people under 65 with certain disabilities, and people of all ages with end-stage renal disease (permanent kidney failure requiring a kidney transplant or dialysis). The Centers for Medicare & Medicaid Services (CMS) administers the program.

Epogen Therapy for End-Stage Renal Disease Patients

Section 1881(a) of the Act establishes the benefits provided by Medicare Parts A and B for individuals who have been determined to have end-stage renal disease as provided in section 226A of the Act. Benefits include injections of Epogen, usually administered during dialysis.¹

Individuals diagnosed with end-stage renal disease often suffer from anemia, and Epogen lessens the effects of anemia for those patients. The initial dose of Epogen is based on an individual's weight and hematocrit level, a measure of the percentage of red blood cells in the blood. The target hematocrit level for dialysis patients receiving Epogen therapy is 30 to 36 percent, which represents a hemoglobin level of 10 to 12 grams per deciliter.² For dialysis patients, hematocrit levels above 36 percent can lead to increased risk of cardiovascular complications and death.³

Epogen doses are generally adjusted by a physician based on a review of the patient's medical record. Some facilities may also use a preestablished dosing algorithm. An algorithm is a formula established by attending physicians. It requires the nurse on duty to gather information from the patient's medical record and determine the correct dose of Epogen to maintain an optimal hematocrit level. Based on the algorithm, a nurse may decrease, increase, or maintain the Epogen dose or temporarily suspend the dose for one or more treatments. Fresenius Medical Care—Brandywine (Brandywine) did not use dosing algorithms.

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

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

³After our audit period, the Food and Drug Administration issued a black box label warning for Epogen that "erythropoiesis-stimulating agents (ESAs) increased the risk for death and for serious cardiovascular events when administered to target a hemoglobin of greater than 12 [grams per deciliter]..." Food and Drug Administration, "Epogen Label," March 9, 2007. Available online at <http://www.fda.gov/cder/foi/label/2007/103234s51221bl.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 intermediaries⁴ to process and pay Medicare Part B claims for Epogen administered by renal dialysis facilities. Generally, for each patient, providers submit one bill per month, which includes the charges for up to 14 dialysis treatments, separately billable laboratory services, and separately billable drugs, including Epogen. Providers submitted claims that identified the total units of Epogen administered to each patient during the billing period, not the dose of Epogen administered during each treatment. Payments for Epogen are subject to Medicare Part B deductible and coinsurance requirements.

Fresenius Medical Care—Brandywine

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.

Brandywine, located in Wilmington, Delaware, is one of more than 1,500 renal dialysis facilities operated by Fresenius. Brandywine provides treatment for end-stage renal disease at 25 renal dialysis stations. It received payments totaling \$5,716,762 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$1,728,381 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).

⁴During the audit period, the Medicare Part B claims we reviewed were processed and paid by fiscal intermediaries. The Medicare Modernization Act of 2003, P. L. No. 108-173, which became effective on October 1, 2005, amended certain sections of the Act, including section 1842(a), to require that Medicare administrative contractors replace carriers and fiscal intermediaries by October 2011.

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

Scope

Our review covered 2,424 monthly claims totaling \$1,728,381 for Epogen administered by Brandywine from January 1, 2004, through June 30, 2006.

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

We performed fieldwork at Brandywine in Wilmington, 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 Brandywine's policies and procedures and the Fresenius Manual;
- reviewed Brandywine's policies and procedures, including the Fresenius Manual, and its medical recordkeeping and billing practices;
- interviewed Fresenius and Brandywine 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 Brandywine from January 1, 2004, through June 30, 2006, and:
 - selected from the sampling frame a simple random sample of 100 claims for Epogen totaling \$75,078 and
 - for each sampled claim, compared the units of Epogen ordered by the Brandywine attending physician, administered to the patient, billed by Brandywine, and paid by Medicare to determine whether such units, as reflected in Brandywine’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 77 of the 100 sampled claims, Brandywine administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Brandywine’s medical records. However, Brandywine did not meet the Medicare payment requirements for some dates of service for 23 claims (two of the claims had multiple errors). In those instances, we identified discrepancies in Brandywine’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 Brandywine, and paid by Medicare.

- For eight claims with errors totaling \$1,340, Brandywine’s medical and billing records reflected that more units of Epogen were administered to patients, billed by Brandywine, and paid by Medicare than were ordered by the patients’ attending physicians, resulting in overpayments.
- For 10 claims, Brandywine’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 Brandywine, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.
- For seven claims, Brandywine’s medical records reflected errors in documenting the ordering and administration of Epogen but not discrepancies in the quantities of Epogen ordered, administered, billed, or paid. For purposes of this report, we considered these errors procedural because they did not result in overpayments.

The errors related to these 23 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, nurses did not always administer the ordered units of Epogen printed on treatment sheets, and some Brandywine medical records did not identify the ordered or administered units of Epogen. As a result, for eight claims, Brandywine received \$1,340 in overpayments and patients did not always receive the amounts of Epogen ordered by attending physicians. When attending physicians' orders are not followed, quality of care may be affected.

FEDERAL REQUIREMENTS

Medical Recordkeeping

As a condition for coverage during our audit period, renal dialysis facilities were required to centralize all clinical information in each patient's medical record in accordance with accepted professional standards and practices (42 CFR § 405.2139).⁵ The medical records were required to be "completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information." Subsection (a) of 42 CFR § 405.2139 further stated that medical records must contain certain general categories of information, including "diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings"

Medicare Payment Procedures

As a basis for payment, section 1833(e) of the Act states that "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period."

Federal regulations (42 CFR § 424.5(a)(6)) require providers to furnish sufficient information, upon request, to determine whether payment is due and, if so, the amount to be paid.

CLAIMS FOR EPOGEN NOT CONSISTENT WITH PHYSICIANS' ORDERS

For each sample claim, we compared Brandywine'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 Brandywine, and (4) paid by Medicare. For eight claims (two claims had two overpayment errors), Brandywine billed and Medicare paid for 168,000 units more of Epogen, with questioned amounts totaling \$1,340, than was ordered because there were discrepancies in Brandywine's medical and billing records between the units of Epogen ordered by the attending physician and the units of Epogen administered, billed by Brandywine, and paid by Medicare.

For eight claims (two claims had two errors) covering seven patients, Brandywine's medical records contained attending physicians' orders that decreased the units or frequency of Epogen prescribed, but an assigned staff member did not accurately record the changes in the Fresenius

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

System. For five claims, the assigned staff member did not record the changed dose of Epogen prescribed; consequently, the Fresenius System printed treatment sheets showing the incorrect number of units, which were administered to patients, billed by Brandywine, and paid by Medicare. For four claims, the printed treatment sheet correctly reflected the physicians' orders to administer Epogen during one or two of the patients' treatments each week; however, nurses administered Epogen on more days than was ordered. Brandywine administered, billed, and was paid for 156,000 units more of Epogen, totaling \$1,244, than was ordered, and Brandywine billed and was paid for 12,000 units more of Epogen, totaling \$96, than was ordered and administered.

- For four claims covering three patients, Brandywine's medical records contained attending physicians' orders that decreased the units of Epogen prescribed, but an assigned staff member did not record the change for two claims and incorrectly recorded the change for two claims in the Fresenius System. Consequently, the Fresenius System printed treatment sheets with incorrect units of Epogen, which were administered to the patients, billed by Brandywine, and paid by Medicare for one or more dates of service. In total, these three patients received, Brandywine billed, and Medicare paid for 37,000 units more of Epogen, totaling \$294, than was ordered.
- For two claims covering two patients, Brandywine's medical records contained attending physicians' orders to administer Epogen during one or two of the patient's three weekly dialysis treatments. During the month reviewed, two patients received the prescribed units of Epogen more frequently than ordered. In total, these two patients received, Brandywine billed, and Medicare paid for 30,000 units more of Epogen, totaling \$240, than was ordered.
- For one claim with multiple errors, Brandywine's medical records contained attending physicians' orders that decreased the units of Epogen prescribed. In April 2005, the physician order in the Brandywine medical records reflected an order for Epogen of 2,000 units once a week on Monday. On May 11, 2005, the physician order was changed to 1,000 units once a week on Monday. Nurses did not administer the Epogen as reflected on the patient's treatment sheet or did not update the Fresenius System to reflect the change in the physician's order. Brandywine administered a total of 6,000 units of Epogen on 3 days that the physician did not order Epogen and administered a total of 3,000 units more of Epogen than was ordered on 3 other days during May 2005. As a result, Brandywine administered and billed, and Medicare paid for 9,000 units more of Epogen, totaling \$70, than was ordered by the attending physician.
- For one claim with multiple errors, Brandywine billed and Medicare paid for units of Epogen in excess of the units of Epogen reflected on the patient's treatment sheets. Because Brandywine medical records did not include the attending physicians' orders for July 2004, 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 Brandywine.
 - From July 5 through July 19, 2004, the patient's treatment sheets reflected a printed order to administer 40,000 units of Epogen during two of the three weekly dialysis

treatments; however, the two days were not identified. Nurses administered 40,000 units of Epogen during the seven dialysis treatments from July 5 through July 19 instead of five treatments. As a result, the patient received 80,000 units more of Epogen, totaling \$640, than was ordered.

- For July 19, the Brandywine treatment sheet reflected that Brandywine ordered and administered 40,000 units of Epogen but Brandywine billed and Medicare paid for 52,000 units of Epogen.⁶ Medicare paid Brandywine for 12,000 units more of Epogen, totaling \$96, than was ordered and administered.

CLAIMS WITH PROCEDURAL ERRORS THAT RESULTED IN DISCREPANCIES

For 10 claims, Brandywine'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 Brandywine, 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 five of these claims, patients received lower doses than ordered. For five claims, Brandywine did not bill for one date of service for each claim.

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

For five claims, Brandywine'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. For three claims, nurses continued to administer the lower amounts for two to five treatments during the month reviewed for three patients. However, for the remaining two claims, nurses administered fewer units than the attending physician ordered for the months reviewed. The attending physician increased the Epogen doses 1 to 2 months before the months reviewed. Brandywine administered, billed, and was paid for fewer units of Epogen than ordered.

Epogen Not Billed by Brandywine

For five claims, the Brandywine medical records included attending physicians' orders to administer Epogen to five patients. For one date of service during the month reviewed, the patient received the prescribed dose of Epogen but Brandywine did not bill and Medicare did not pay for the units of Epogen ordered and administered. In total, Brandywine did not bill for 27,800 units of Epogen, totaling \$215, that were ordered and administered.

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."

⁶From July 21 through July 30, 2004, the patient's treatment sheets reflected a printed order to administer 52,000 units of Epogen during each dialysis treatment.

(24 Del. C. § 1902(a)). To assist facilities in documenting compliance with Federal and State requirements, the Fresenius Manual requires an order for all new medications or whenever a medication dose changes, along with the signature of the ordering physician. Nurses are responsible for ensuring that all medications provided to patients have accurately documented physician orders. Administering nurses are required to sign or initial on the treatment sheet to show that a medication, including Epogen, has been administered.

For seven claims, the Brandywine medical records reflected errors in documenting the ordering and administration of Epogen. However, Brandywine billed for and was reimbursed for the units ordered or administered.

- For three of these claims, the treatment sheet for one date of service was not in the Brandywine medical record. Brandywine billed and Medicare paid for the units of Epogen prescribed by the attending physicians order for the period reviewed.
- For two of these claims, the attending physicians' orders for the months reviewed were not in the medical record. Although the physicians' orders were missing for the month reviewed, the medical record included inpatient documents that reflected the patient received Epogen while in the hospital. Brandywine billed and Medicare paid for the units of Epogen reflected on the dialysis treatment sheets.
- For one of these claims, the patient's medical record lacked the signature/initials of the administering nurse, as required by Brandywine's internal policies, including those in the Fresenius Manual. The administering nurse administered the units of Epogen consistent with the patient's attending physician's order, but did not sign or initial the treatment sheet to document the administration of Epogen for one date of service.
- For one of these claims, the patient's medical record did not include a physician order covering four dates of service following an inpatient hospital stay. During the inpatient stay, the patient received 15,000 units of Epogen with each dialysis treatment. Following the hospital stay, the Brandywine dialysis treatment sheets reflected that Brandywine administered and billed, and Medicare paid for 15,000 units of Epogen for each of four dates of service.

FRESENIUS POLICY AND PROCEDURES NOT ALWAYS FOLLOWED

To assist in its facilities' efforts to comply with requirements under Federal law and the 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.⁷

- 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 Brandywine had controls in place as specified in the Fresenius Manual, based on our review, Brandywine 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. Administering nurses did not always administer units of Epogen in accordance with the ordered dose printed on patient treatment sheets resulting in patients receiving doses of Epogen that were not ordered by a physician.

Also, entries on the treatment sheet were not always initialed or signed, and in one case the amount billed by Brandywine was greater than the units of Epogen ordered and administered.

RECOMMENDATIONS

We recommend that Brandywine:

- refund the \$1,340 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 Brandywine, and paid by Medicare.

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

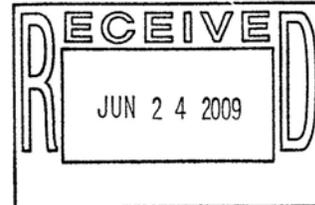
FRESENIUS COMMENTS

In comments on our draft report, Fresenius stated that it will contact the intermediary about refunding the \$1,340 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-03-07-00034, Payments for Epogen Administered at
Fresenius Medical Care-Brandywine, Wilmington DE

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 \$75,078.00 in claims reviewed, \$1,340 was identified by the audit as not eligible for Medicare reimbursement – reflecting 1.73% 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 Brandywine, 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:

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- 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 \$1,340 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:

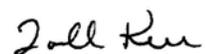
"Some facilities may also use a preestablished dosing algorithm. The algorithm is a formula established by the facility Medical Director and ordered by the physician."

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

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Sincerely,

A handwritten signature in black ink that reads "Todd Kerr". The signature is written in a cursive, slightly slanted style.

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

Fresenius Medical Care North America

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