



Office of Audit Services, Region III
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AUG 14 2009

Report Number: A-03-07-00032

Ms. Tracey Mooney
Chief Financial Officer
Independent Dialysis Foundation
840 Hollins Street
Baltimore, Maryland 21201

Dear Ms. Mooney:

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 Independent Dialysis Foundation—Parkview Center, Baltimore, Maryland." 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-03-07-00032 in all correspondence.

Sincerely,

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

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

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

**OFFICE OF
INSPECTOR GENERAL**

**PAYMENTS FOR
EPOGEN ADMINISTERED AT
INDEPENDENT DIALYSIS
FOUNDATION—
PARKVIEW CENTER,
BALTIMORE, MARYLAND**



Daniel R. Levinson
Inspector General

August 2009
A-03-07-00032

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 who have 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.

Independent Dialysis Foundation—Parkview Center (Parkview Center) is an outpatient dialysis treatment facility, located in Baltimore, Maryland. Parkview Center provides treatment for end-stage renal disease using 36 renal dialysis stations. It received payments totaling \$7,699,964 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$2,524,829 was for the administration of Epogen. During our audit period, Parkview Center used dosing algorithms to adjust patient Epogen doses.

OBJECTIVE

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

SUMMARY OF FINDING

For 97 of the 100 sampled claims, Parkview Center administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Parkview Center's medical records. However, Parkview Center did not meet the Medicare payment requirements for some dates of service for three claims. In those instances, we identified discrepancies in Parkview Center'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 Parkview Center, and paid by Medicare. In addition, for 46 of the 100 claims (11 of the claims had two errors and one claim had three errors), Parkview Center medical and billing records reflected errors that we considered procedural because they did not result in overpayments.

- For three claims with errors totaling \$106, Parkview Center billed and Medicare paid for more units of Epogen than were ordered by the attending physicians.
- For 9 of the 46 claims, Parkview Center'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 Parkview Center, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.
- For 23 of the 46 claims, Parkview Center'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.
- For 27 of the 46 claims, Parkview Center's medical records reflected errors in the hematocrit levels reported with the claims. For purposes of this report, we considered these errors procedural because they did not result in overpayments.

Although Parkview Center had controls in place, based on our review, Parkview Center personnel did not always follow those procedures. The errors related to the three claims that resulted in overpayments occurred because nurses did not always follow Parkview Center policy and procedures for ensuring that attending physicians' orders changing the dose of Epogen were identified and entered into the Parkview Center System accurately and in a timely manner. As a result, Parkview Center received \$106 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 Parkview Center:

- refund the \$106 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 Parkview Center, and paid by Medicare.

INDEPENDENT DIALYSIS FOUNDATION COMMENTS

In comments on our draft report (see Appendix), Independent Dialysis Foundation stated that it will contact the intermediary about refunding the \$106 in overpayments, the nursing staff will undergo a training program to improve compliance with policies and procedures related to documenting patient care services provided, and physicians were instructed on the correct process to follow for changing medication orders.

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INDEPENDENT DIALYSIS FOUNDATION COMMENTS

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 the facility Medical Director and ordered by the physician. 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. Independent Dialysis Foundation—Parkview Center (Parkview Center) used dosing algorithms to adjust patient Epogen doses.

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.

Independent Dialysis Foundation—Parkview Center

Independent Dialysis Foundation, located in Baltimore, Maryland, is a not-for-profit organization affiliated with the University of Maryland that provides renal dialysis services to patients at nine renal dialysis facilities located in Maryland. Parkview Center, located in Baltimore, Maryland, provides treatment for end-stage renal disease at 36 renal dialysis stations. It received payments totaling \$7,699,964 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$2,524,829 was for the administration of Epogen.

Parkview Center Procedures for Administering Epogen and Medical Information System

Parkview Center’s procedures regarding “intravenous Erythropoietin infusion” (Epogen) are limited; however, the procedures state that the patient’s medical record should be checked before dialysis treatment for allergies and to verify physician’s orders for current Epogen dose, route, and frequency. All medication should be labeled with the patient’s name, name of medication, the dose, route, date, and initials of the individual preparing the dose. Also, the administering nurse should document the time, dose, route, and how the medication was tolerated on the treatment sheet and the administering nurse should sign the treatment sheet once dialysis treatment has been administered. Parkview Center uses the Clinical Vision Version 4 (Parkview Center System), which is a medical information system that documents all procedures and medications prescribed for and provided to patients.

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.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

Our review covered 4,178 monthly claims totaling \$2,524,829 for Epogen administered by Parkview Center from January 1, 2004, through June 30, 2006.

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

We performed fieldwork at Parkview Center in Baltimore, Maryland.

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 Parkview Center's policies and procedures for intravenous Erythropoietin infusion;
- reviewed Parkview Center's policies and procedures, including its medical recordkeeping and billing practices;
- interviewed Parkview Center 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 Parkview Center from January 1, 2004, through June 30, 2006, and:
 - selected from the sampling frame a simple random sample of 100 claims for Epogen totaling \$64,606 and
 - for each sampled claim, compared the units of Epogen ordered by the Parkview Center attending physician, administered to patients, billed by Parkview Center, and

paid by Medicare to determine whether such units, as reflected in Parkview Center'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 97 of the 100 sampled claims, Parkview Center administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Parkview Center's medical records. However, Parkview Center did not meet the Medicare payment requirements for some dates of service for three claims. In those instances, we identified discrepancies in Parkview Center'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 Parkview Center, and paid by Medicare. In addition, for 46 of the 100 claims (11 of the claims had two errors and one claim had three errors), Parkview Center medical and billing records reflected errors that we considered procedural because they did not result in overpayments.

- For three claims with errors totaling \$106, Parkview Center billed and Medicare paid for more units of Epogen than were ordered by the attending physicians.
- For 9 of the 46 claims, Parkview Center'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 Parkview Center, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.
- For 23 of the 46 claims, Parkview Center'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.
- For 27 of the 46 claims, Parkview Center's medical records reflected errors in the hematocrit levels reported with the claims. For purposes of this report, we considered these errors procedural because they did not result in overpayments.

Although Parkview Center had controls in place, based on our review, Parkview Center personnel did not always follow those procedures. The errors related to the three claims that resulted in overpayments occurred because nurses did not always follow Parkview Center policy and procedures for ensuring that attending physicians' orders changing the dose of Epogen were identified and entered into the Parkview Center System accurately and in a timely manner. As a result, Parkview Center received \$106 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 "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.

CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, chapter 8, section 60.4, requires that renal dialysis facilities report the patient's hematocrit level for claims that include administered Epogen. Prior to January 1, 2006, the hematocrit level reported should be the level taken prior to the last dose of Epogen administered during the billing period. Beginning January 1, 2006, the hematocrit level reported should be the patient's most recent level taken before the start of the billing period.

CLAIMS FOR EPOGEN NOT CONSISTENT WITH PHYSICIANS' ORDERS

For each sample claim, we compared Parkview Center'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 Parkview Center, and (4) paid by Medicare. For three claims with questioned amounts totaling \$106, there were discrepancies in Parkview Center's medical and billing records between the units of Epogen ordered by the attending physician and the units of Epogen administered and billed by Parkview Center, and paid by Medicare. For two claims the patient received fewer units of Epogen than ordered, billed, and paid. For one claim

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

Parkview Center administered, billed, and Medicare paid for more units of Epogen than ordered by the attending physician, as documented in Parkview Center's medical and billing records.

More Units of Epogen Ordered, Billed and Paid Than Administered

For two claims covering two patients, Parkview Center's medical records contained attending physicians' orders that increased the units of Epogen prescribed, but an assigned staff member did not record the changes in the Parkview Center System. Consequently, the Parkview Center System printed treatment sheets showing the original units ordered, which were administered to the patients. However, Parkview Center billed and Medicare paid for the higher units of Epogen ordered by the attending physician.

- For one claim the attending physician's order, dated June 28, 2005, increased the prescribed Epogen dose from 10,000 to 12,500 units. However, the treatment sheet for June 29 reflected the original dose of 10,000 units, which the nurse administered to the patient. Parkview Center billed and Medicare paid for 12,500 units reflected in the attending physician's order. Parkview Center billed and Medicare paid for 2,500 more units, totaling \$20, than were administered.
- For one claim the attending physician's order, dated January 24, 2006, increased the prescribed Epogen dose from 7,500 to 9,000 units. However, the treatment sheet for January 25 reflected the original dose of 7,500 units, which the nurse administered to the patient. Parkview Center billed and Medicare paid for 9,000 units reflected in the attending physician's order. Parkview Center billed and Medicare paid for 1,500 more units of Epogen, totaling \$11, than were administered.

The Parkview Center billing department did not reconcile differences between the service administration report, which reflects the units of Epogen ordered and administered, and the accounting system records. If a difference is identified, billing personnel review the patient treatment sheet to determine the correct units of Epogen administered. As a result, Parkview Center billed and Medicare paid for 4,000 more units of Epogen, totaling \$31, than were administered.

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

For one claim, Parkview Center's medical records included the attending physician's order to decrease the units of Epogen from 15,000 to 13,000 units, but an assigned staff member did not record the change in the Parkview Center System. Consequently, the Parkview Center System printed treatment sheets showing the original units ordered, which were administered to the patient for five treatments after the lower dose was prescribed by the attending physician. As a result, Parkview Center administered and billed, and Medicare paid for 10,000 more units of Epogen, totaling \$75, than were ordered.

CLAIMS WITH PROCEDURAL ERRORS THAT RESULTED IN DISCREPANCIES

For nine claims, Parkview Center'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 Parkview Center, 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 four of these claims patients received fewer units of Epogen than ordered. For three claims, Parkview Center did not bill for the units of Epogen that were ordered and administered. For two claims patients received more units of Epogen than ordered by attending physicians.

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

For four claims, Parkview Center's medical records included attending physicians' orders to change the units of Epogen. For three of these claims, physicians' orders increased the units of Epogen but an assigned staff member did not enter the changes in the Parkview Center System on a timely basis. For one of these claims, the physician order decreased the units of Epogen from 5,000 to 4,500 units but an assigned staff member entered the change in the Parkview Center System as 4,000 units. As a result, the ordered amounts did not appear on the treatment sheets. Nurses continued to administer the fewer units of Epogen for two to eight treatments. Parkview Center administered, billed, and was paid for fewer units of Epogen than ordered.

Claims Not Correctly Billed

For three claims, Parkview Center medical records reflected that three patients received the dose of Epogen (500, 6,500, and 10,000 units) prescribed by attending physicians. However, Parkview Center did not bill for the 500 and 6,500 unit doses and only billed for 7,500 of the 10,000 unit dose. As a result, Medicare did not pay for 9,500 units, totaling \$73, that were administered but not billed by Parkview Center.

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

For two claims, Parkview Center's medical records included attending physicians' orders to suspend or decrease the frequency of Epogen doses but the changes were not entered into the Parkview Center System correctly or on a timely basis. Consequently, the ordered amounts did not appear on the treatment sheets. Nurses administered a total of 21,000 more units of Epogen than ordered for one or two treatments during the months reviewed. However, Parkview Center billed and Medicare paid for the units of Epogen ordered by the attending physicians.

CLAIMS WITH PROCEDURAL ERRORS THAT DID NOT RESULT IN DISCREPANCIES

Parkview Center's intravenous Erythropoietin infusion procedures state that the patient's medical record should be checked before dialysis treatment to verify the physician's orders for the current Epogen dose, route, and frequency and that all medication should be labeled with the patient's name, name of medication, dose, route, date, and the initials of the individual preparing the dose.

Also, the administering nurse should document the time, dose, route, and how the medication was tolerated on the treatment sheet and the administering nurse should sign the treatment sheet once dialysis treatment has been administered.

CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, chapter 8, section 60.4, requires that renal dialysis facilities report the patient's hematocrit level for claims that include administered Epogen. Prior to January 1, 2006, the hematocrit level reported should be the level taken prior to the last dose of Epogen administered during the billing period. Beginning January 1, 2006, the hematocrit level reported should be the patient's most recent level taken before the start of the billing period.

For 23 claims Parkview Center's medical records reflected errors in documenting the ordering and administration of Epogen for one or more dates of service for the months reviewed but not discrepancies in the quantities of Epogen ordered, administered, billed, or paid.

- For 17 claims the patients' treatment sheets were not signed or initialed by the administering nurses.
- For six claims the patients' medical records did not include either a copy of the treatment sheets or the attending physician's order for Epogen services.

For 27 claims, the hematocrit level included on the claims was not correct.

Unsigned Treatment Sheets

For 17 claims Parkview Center's medical records lacked the signature/initials of the administering nurse, as required by Parkview Center's internal policy and procedures for administering intravenous Erythropoietin infusions. Based on other medical record documents, we verified that nurses administered the units of Epogen consistent with the patients' attending physicians' orders, but 19 treatment sheets during the months reviewed, were not signed or initialed by the administering nurses. Parkview Center administered and billed and Medicare paid for the units of Epogen ordered by the attending physician.

Missing Treatment Sheets and Physician Orders

For six claims Parkview Center's medical records were missing patients' treatment sheets or the attending physician's order for one or more dates of service.

- For four claims, treatment sheets were missing for one date of service during the months reviewed.
- For one claim, the patient's treatment sheets for the entire month reviewed were not available and, according to Parkview Center personnel, destroyed by accident.
- For one claim, the attending physician's order for Epogen for the month reviewed was not available and, according to Parkview Center personnel, destroyed by accident.

For these six claims, based on Parkview Center's service administration report, we verified that the units of Epogen administered and billed by Parkview Center and paid by Medicare agreed with the units ordered by attending physicians.

Claims with Incorrect Hematocrit Levels

For 27 claims, Parkview Center's billing records reflected a hematocrit level that was different than the hematocrit level reflected in the patients' medical records.

- For calendar years 2004 and 2005, Parkview Center should have reported the last hematocrit level during the billing period on the claim. The hematocrit levels submitted on six claims were not correct.
- For calendar year 2006, Parkview Center should have reported the last hematocrit level before the start of the billing period on the claim. The hematocrit levels on 21 claims were not correct.

Although the hematocrit levels for the 27 claims were not correct, the amount Medicare paid for those claims did not result in overpayments.

PARKVIEW CENTER'S POLICY AND PROCEDURES NOT ALWAYS FOLLOWED

Parkview Center personnel stated that they did not have an extensive set of written policy and procedures for the administration of renal dialysis treatment, including the administration of Epogen, other medications, and other related procedures. Parkview Center's policy on the administration of medication is limited but identifies the key steps to ensure that a patient receives the medication, including Epogen, according to the attending physicians' orders.

Parkview Center personnel stated that they follow "standard industry procedures" in providing services to their patients and in the documentation of related medical records. These policies and procedures include processes to record the results of each treatment and changes to existing treatments, including the dose of Epogen administered, and billing procedures in the Parkview Center System.

- All changes to the prescribed Epogen dose are recorded in the patient's medical record. This includes written physician orders, verbal orders provided telephonically, and changes based on a preestablished algorithm. Changes should be identified and entered into the Parkview Center System to ensure that the Epogen dose reflected on the treatment sheet is accurate.
- Administering nurses and patient care technicians administer dialysis treatment to patients, including administering Epogen, and record each service provided on the patient's treatment sheet. The administering nurse or patient care technician must document that each service was provided by signing or initialing each service on the treatment sheet and documenting any deviations from the existing attending physician orders. After all services have been provided, information from the treatment sheet is

entered in the Parkview Center System. Periodically, Parkview Center converts old medical records, including attending physician orders, treatment sheets, and laboratory tests into an electronic format and destroys the paper copies.

- Daily, Parkview Center accounting personnel compare the billed medications from the Parkview Center System with a service administration report of medications administered. Any differences are researched to ensure that the proper amounts are billed. The accounting system provides the total units of Epogen that are billed monthly. The billing system creates the bills that are submitted to Medicare for payment. Parkview Center uses its service administration reports as its audit report.

Although Parkview Center had controls in place as specified, based on our review, Parkview Center 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 Parkview Center System accurately or on a timely basis. Therefore, changes to the attending physicians' orders did not always appear on subsequent treatment sheets. Some Parkview Center medical records did not document the administration of Epogen because the administering nurse failed to sign/initial the patient treatment sheets. For six claims the medical records did not include the treatment sheet or physician order for Epogen for one of more treatments.

Also, Parkview Center did not always administer the correct units of Epogen or bill for the units of Epogen administered to patients and hematocrit levels submitted on claims for Medicare payment were not always accurate.

RECOMMENDATIONS

We recommend that Parkview Center:

- refund the \$106 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 Parkview Center, and paid by Medicare.

INDEPENDENT DIALYSIS FOUNDATION COMMENTS

In comments on our draft report, Independent Dialysis Foundation stated that it will contact the intermediary about refunding the \$106 in overpayments, the nursing staff will undergo a training program to improve compliance with policies and procedures related to documenting patient care services provided, and physicians were instructed on the correct process to follow for changing medication orders. Independent Dialysis Foundation's comments are included in the Appendix.

APPENDIX

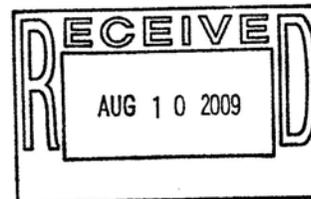
I N D E P E N D E N T D I A L Y S I S F O U N D A T I O N



Affiliated with the University of Maryland
840 Hollins Street • Baltimore, Maryland 21201

August 5, 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-03-07-00035, Payments for Epogen Administered at Independent Dialysis Foundation Parkview, Baltimore, Maryland

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 our Nurse Educator as part of ongoing claims audits and activities. Of the \$64,606 in claims reviewed, \$106 was identified by the audit as not eligible for Medicare reimbursement- reflecting 0.16% of the sampled claims. This payment error rate compares favorably to the most recent May 2008 3.7% CERT national paid claims.

In response to these audit findings Independent Dialysis Foundation (IDF) will take the following steps:

OIG Recommendation:

"Refund the \$106 in overpayments"

IDF Recommendation:

Based on the age of the claims, we will contact the intermediary to determine the process to repay overpayments.

OIG 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 patients' physicians and the units administered to the patient, billed by Parkview Center, and paid by Medicare."

IDF Recommendation:

While the payment error rate is very low, we recognize the need for the clinic 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 staff of regulations relating to documenting care furnished and the consequences of failing to conform to applicable IDF policies, with emphasis on signing and initializing services provided.

Consistent with the Part 494 Conditions of Coverage for the next 12 months the facilities Quality Assessment and Improvement Process will review a sampling of active medical records to monitor improved compliance with applicable IDF medical record documentation.

During the field work of this audit our attending physicians were advised that orders changing the dose of medications should be reflected in doctor's orders, and not treatment sheets, with a corresponding effective date to avoid timing errors that occurred in the sequence of the paper recording of the order and the effective date of medication orders.

Finally, I appreciate the professionalism that was displayed by the audit team and the efforts that were taken to understand our policies and procedures and assist us with improving our overall compliance.

Sincerely,



Tracey Mooney, CPA
Chief Financial Officer