



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

October 8, 2009

Report Number: A-03-07-00028

Mr. John Frierson  
Director, Patient Financial Services  
University of Virginia Medical Center  
835 West Main Street  
Charlottesville, Virginia 22908

Dear Mr. Frierson:

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 University of Virginia Medical Center—Lynchburg Dialysis, Lynchburg, Virginia." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted 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-03-07-00028 in all correspondence.

Sincerely,

/Stephen Virbitsky/  
Regional Inspector General  
for Audit Services

Enclosure

**Direct Reply to HHS Action Official:**

Nanette Foster Reilly, Consortium Administrator  
Consortium for Financial Management & Fee for Service Operations (CFMFFSO)  
Centers for Medicare & Medicaid Services  
601 East 12<sup>th</sup> Street, Room 235  
Kansas City, Missouri 64106

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**PAYMENTS FOR  
EPOGEN ADMINISTERED AT  
UNIVERSITY OF VIRGINIA  
MEDICAL CENTER—  
LYNCHBURG DIALYSIS,  
LYNCHBURG, VIRGINIA**



Daniel R. Levinson  
Inspector General

October 2009  
A-03-07-00028

# *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>

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

## **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.

University of Virginia Medical Center—Lynchburg Dialysis (Lynchburg Dialysis), located in Lynchburg, Virginia, is one of eight outpatient dialysis facilities operated by the University of Virginia Medical Center. Lynchburg Dialysis provides treatment for end-stage renal disease using 43 renal dialysis and 2 home training stations. It received payments totaling \$11,115,806 for Medicare services provided from November 8, 2004, through June 30, 2006. Of this amount, \$2,444,366 was for the administration of Epogen. During our audit period, Lynchburg Dialysis used dosing algorithms to adjust patient Epogen doses.

### **OBJECTIVE**

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

### **SUMMARY OF FINDINGS**

For 99 of the 100 sampled claims, Lynchburg Dialysis administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Lynchburg Dialysis' medical records. However, Lynchburg Dialysis did not meet Medicare payment requirements for some dates of service for one claim. In that instance, we identified discrepancies in Lynchburg Dialysis' medical and billing records between the units of Epogen ordered by the patient's attending physicians and the units administered to the patients, billed by

Lynchburg Dialysis, and paid by Medicare. In addition, for 33 of the 100 claims (4 claims had two errors) Lynchburg Dialysis medical and billing records reflected errors that we considered procedural because they did not result in overpayments.

- For one claim with errors totaling \$120, Lynchburg Dialysis' medical and billing records reflected that, in total 15,000 units of Epogen were administered to a patient, billed by Lynchburg Dialysis, and paid by Medicare for three dates of service before November 8, 2004, the effective date of Lynchburg Dialysis' eligibility for participation in Medicare.
- For 9 of the 33 claims, Lynchburg Dialysis' medical and billing records reflected discrepancies between the units of Epogen ordered by the patients' attending physicians and the units administered to patients, billed by Lynchburg Dialysis, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.
- For 27 of the 33 claims, Lynchburg Dialysis' billing 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 Lynchburg Dialysis had controls in place, based on our review, Lynchburg Dialysis personnel did not always follow all of those procedures. The errors related to the one claim that resulted in overpayments occurred because the first three treatments occurred before Lynchburg Dialysis was eligible for participation with Medicare. As a result, Lynchburg Dialysis received \$120 in overpayments and patients did not always receive the amounts of Epogen ordered by attending physicians. When physicians' orders are not followed, quality of care may be affected.

## **RECOMMENDATIONS**

We recommend that Lynchburg Dialysis:

- refund the \$120 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 Lynchburg Dialysis, and paid by Medicare.

## **UNIVERSITY OF VIRGINIA MEDICAL CENTER COMMENTS**

In written comments (Appendix) on our draft report, the University of Virginia Medical Center concurred with our recommendations. The University of Virginia Medical Center stated that it had contacted the fiscal intermediary and refunded the \$120 in overpayments. In addition, it had updated its protocol guidelines for hemodialysis to remedy the issue of discrepancies between the physicians' orders and units of Epogen administered.

**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
University of Virginia Medical Center—Lynchburg Dialysis.....	2
Policy and Procedures 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>CLAIM FOR EPOGEN BEFORE MEDICARE ELIGIBILITY</b> .....	5
<b>CLAIMS WITH PROCEDURAL ERRORS THAT RESULTED IN DISCREPANCIES</b> .....	6
Fewer Units of Epogen Billed and Paid Than Ordered and Administered.....	6
More Units of Epogen Administered Than Ordered, Billed, and Paid.....	6
<b>CLAIMS WITH INCORRECT HEMATOCRIT LEVELS</b> .....	6
<b>LYNCHBURG DIALYSIS POLICY AND PROCEDURES NOT ALWAYS FOLLOWED</b> .....	7
<b>RECOMMENDATIONS</b> .....	8
<b>UNIVERSITY OF VIRGINIA MEDICAL CENTER COMMENTS</b> .....	8
<b>APPENDIX</b>	
<b>UNIVERSITY OF VIRGINIA MEDICAL CENTER 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 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. University of Virginia Medical Center—Lynchburg Dialysis (Lynchburg Dialysis) used dosing algorithms to adjust patient Epogen doses.

---

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

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

<sup>3</sup>After our audit period, the Food and Drug Administration issued a black box label warning for Epogen that "erythropoiesis-stimulating agents (ESAs) increased the risk for death and for serious cardiovascular events when administered to target a hemoglobin of greater than 12 [grams per deciliter]..." Food and Drug Administration, "Epogen Label," March 9, 2007. Available online at <http://www.fda.gov/cder/foi/label/2007/103234s51221bl.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 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.

### **University of Virginia Medical Center—Lynchburg Dialysis**

Lynchburg Dialysis, located in Lynchburg, Virginia, is one of eight outpatient dialysis facilities operated by University of Virginia Medical Center. Lynchburg Dialysis provides treatment for end-stage renal disease at 43 dialysis stations and 2 home training stations. It received payments totaling \$11,115,806 for Medicare service provided from November 8, 2004, through June 30, 2006. Of this amount, \$2,444,366 was for the administration of Epogen.

### **Policy and Procedures Manual and Medical Information System**

To assist in its facilities’ efforts to comply with requirements under Federal and State law, Lynchburg Dialysis established a medical record policy and documentation procedures regarding Epogen administration. Lynchburg Dialysis policy requires a physician, nurse practitioner, or physician assistant to order and adjust the Epogen dose as necessary. In addition, the anemia manager may adjust the Epogen dose in accordance with the preestablished dosing algorithm. Lynchburg Dialysis maintains an automated medical records application (Lynchburg System) that provides a process for prescribers to initiate and update medication orders and inform nurses of the ordered medications to administer during dialysis treatment. The Lynchburg System documents the treatments, laboratory services, medications, and other services administered to

---

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

the patient during the dialysis session. Also, the Lynchburg System verifies the quantity ordered to the quantity administered and submits that quantity to the billing department to produce bills.

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

### **Objective**

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

### **Scope**

Our review covered 4,866 monthly claims totaling \$2,444,366 for Epogen administered by Lynchburg Dialysis from November 8, 2004, through June 30, 2006.

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

We performed fieldwork at the University of Virginia Medical Center in Charlottesville, Virginia.

### **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 Lynchburg Dialysis' policies and procedures;
- reviewed Lynchburg Dialysis' policies and procedures, including its medical recordkeeping and billing practices;
- interviewed Lynchburg Dialysis 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 Lynchburg Dialysis from November 8, 2004, through June 30, 2006, and:

- selected from the sampling frame a simple random sample of 100 claims for Epogen totaling \$49,898 and
- for each sampled claim, compared the units of Epogen ordered by the Lynchburg Dialysis attending physician, administered to patients, billed by Lynchburg Dialysis, and paid by Medicare to determine whether such units, as reflected in Lynchburg Dialysis' 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 99 of the 100 sampled claims, Lynchburg Dialysis administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Lynchburg Dialysis' medical records. However, Lynchburg Dialysis did not meet Medicare payment requirements for some dates of service for one claim. In that instance, we identified discrepancies in Lynchburg Dialysis' medical and billing records between the units of Epogen ordered by the patient's attending physicians and the units administered to the patients, billed by Lynchburg Dialysis, and paid by Medicare. In addition, for 33 of the 100 claims (4 claims had two errors) Lynchburg Dialysis medical and billing records reflected errors that we considered procedural because they did not result in overpayments.

- For one claim with errors totaling \$120, Lynchburg Dialysis' medical and billing records reflected that, in total 15,000 units of Epogen were administered to a patient, billed by Lynchburg Dialysis, and paid by Medicare for three dates of service before November 8, 2004, the effective date of Lynchburg Dialysis' eligibility for participation in Medicare.
- For 9 of the 33 claims, Lynchburg Dialysis' medical and billing records reflected discrepancies between the units of Epogen ordered by the patients' attending physicians and the units administered to patients, billed by Lynchburg Dialysis, and paid by Medicare. For purposes of this report, we considered these errors procedural because they did not result in overpayments.
- For 27 of the 33 claims, Lynchburg Dialysis' billing 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 Lynchburg Dialysis had controls in place, based on our review, Lynchburg Dialysis personnel did not always follow all of those procedures. The errors related to the one claim that resulted in overpayments occurred because the first three treatments occurred before Lynchburg Dialysis was eligible for participation with Medicare. As a result, Lynchburg Dialysis received

\$120 in overpayments and patients did not always receive the amounts of Epogen ordered by attending physicians. When physicians' orders are not followed, quality of care may be affected.

## **FEDERAL REQUIREMENTS**

### **Medical Recordkeeping**

As a condition for coverage during our audit period, renal dialysis facilities were required to centralize all clinical information in each patient's medical record in accordance with accepted professional standards and practices (42 CFR § 405.2139).<sup>5</sup> The medical records were required to be "completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information." Subsection (a) of 42 CFR § 405.2139 further stated 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.

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 reading for claims that include administered Epogen. Prior to January 1, 2006, the hematocrit reading reported should be the reading taken prior to the last dose of Epogen administered during the billing period. Beginning January 1, 2006, the hematocrit reading reported should be the patient's most recent reading taken before the start of the billing period.

## **CLAIM FOR EPOGEN BEFORE MEDICARE ELIGIBILITY**

For each sample claim, we compared Lynchburg Dialysis' 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 Lynchburg Dialysis, and (4) paid by Medicare. For one claim with errors totaling \$120, Lynchburg Dialysis billed for 15,000 units of Epogen before it was eligible for participation in Medicare.

On November 24, 2004, CMS notified the University of Virginia Health System that, effective November 8, 2004, Lynchburg Dialysis was approved to operate as a satellite facility of 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.

University of Virginia Medical Center and eligible for participation in Medicare. For one claim in our sample, Lynchburg Dialysis billed for three dialysis treatments, including a total of 15,000 units of Epogen totaling \$120, for treatments that occurred before November 8, 2004, the date Lynchburg Dialysis became eligible for participation in Medicare.

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

For nine claims, Lynchburg Dialysis' 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 Lynchburg Dialysis, 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 eight of these claims, Lynchburg Dialysis did not bill for units of Epogen that were ordered and administered. For one claim, the patient received a higher dose of Epogen than ordered.

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

For eight claims, Lynchburg Dialysis' medical records included attending physician orders to administer Epogen to eight patients. The eight patients received the prescribed doses of Epogen during the months reviewed, but Lynchburg Dialysis did not bill and Medicare did not pay for all of the units of Epogen ordered and administered. In total, Lynchburg Dialysis did not bill for 313,000 units of Epogen, totaling \$2,420, that were ordered and administered. The billing errors occurred because the staff responsible for billing did not include the total units of Epogen that were ordered and administered in Value Code 68, the field on the Medicare claim form that includes the units of Epogen administered and is the basis for Medicare payment for Epogen. Lynchburg Dialysis reported units of Epogen administered in the description field of the Medicare claim form but that field does not effect Medicare payment.

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

For one claim, Lynchburg Dialysis' medical records included the attending physician's order, dated March 29, 2005, to administer 10,000 units with dialysis treatments on Tuesday, Thursday, and Saturday. On Wednesday March 30, a nurse administered 10,000 units of Epogen to the patient even though the attending physician did not order Epogen for that day. However, Lynchburg Dialysis did not bill for the 10,000 units administered on March 30, and Medicare only paid for the units of Epogen ordered by the attending physician.

### **CLAIMS WITH INCORRECT HEMATOCRIT LEVELS**

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 27 claims, Lynchburg Dialysis' 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, Lynchburg Dialysis should have reported the last hematocrit level during the billing period on the claim. The hematocrit levels submitted on nine claims were not correct.
- For calendar year 2006, Lynchburg Dialysis should have reported the last hematocrit level before the start of the billing period on the claim. The hematocrit levels on 18 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.

### **LYNCHBURG DIALYSIS POLICY AND PROCEDURES NOT ALWAYS FOLLOWED**

To assist in its efforts to comply with requirements under Federal law and States' respective Nurses Practice Act, Lynchburg Dialysis established a medical record policy and documentation procedures regarding Epogen administration. Lynchburg Dialysis maintains automated medical and billing records.

Lynchburg Dialysis policy requires a physician, nurse practitioner, or physician assistant to order and adjust the Epogen dose as necessary. In addition, the anemia manager may adjust the Epogen dose in accordance with the preestablished dosing algorithm. Lynchburg Dialysis maintains the Lynchburg System that provides a process for prescribers to initiate and update medication orders and inform nurses of the ordered medications to administer during dialysis treatment. The Lynchburg System documents the treatments, laboratory services, medications, and other services administered to the patient during the dialysis session. Also, the Lynchburg System verifies the quantity ordered to the quantity administered and submits that quantity to the billing department to produce bills.

Although Lynchburg Dialysis had controls in place as specified in the documented procedures, based on our review, Lynchburg Dialysis personnel did not always follow all of those procedures. Lynchburg Dialysis (1) billed for services that were provided before its eligibility for Medicare reimbursement, (2) administered Epogen on one date of service that was not ordered, (3) submitted bills to Medicare that did not identify the correct number of units of Epogen administered to patients, and (4) submitted bills to Medicare that did not identify the correct hematocrit levels for the patients.

## **RECOMMENDATIONS**

We recommend that Lynchburg Dialysis:

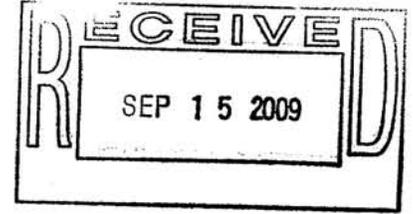
- refund the \$120 in overpayments and
- ensure that it follows policies and procedures that are consistent with Federal requirements in order to avoid discrepancies between the unit of Epogen ordered by patients' physicians and the units administered to the patient, billed Lynchburg Dialysis, and paid by Medicare.

## **UNIVERSITY OF VIRGINIA MEDICAL CENTER COMMENTS**

In written comments on our draft report, the University of Virginia Medical Center concurred with our recommendations. The University of Virginia Medical Center stated that it had contacted the fiscal intermediary and refunded the \$120 in overpayments. In addition, it had updated its protocol guidelines for hemodialysis to remedy the issue of discrepancies between the physicians' orders and units of Epogen administered. The University of Virginia Medical Center's comments are included in the appendix. We have excluded the enclosure accompanying the comments because it contained personally identifiable information.

# **APPENDIX**

**APPENDIX: UNIVERSITY OF VIRGINIA MEDICAL CENTER COMMENTS**



**Medical Center | Patient Financial Services**

September 11, 2009

Stephen Virbitsky  
Regional Inspector General for Audit Services  
Department of Health and Human Services  
Public Ledger Building, Suite 316  
150 S. Independence Mall West  
Philadelphia, PA 19106-3499

Re: Payments for Epogen - Report Number: A-03-07-00028

Dear Mr. Virbitsky:

Thank you for your letter dated August 14, 2009 enclosing the audit report on payments for Epogen administered in our Lynchburg dialysis unit. I have listed our responses below for the two recommendations in the report.

1. The claim that was overpaid by \$120 was corrected with National Government Services on 6/8/09. I have enclosed a print out from their claim system reflecting the correction, as well as print out of our account records documenting the retraction and repayment of the claim.
2. The protocol guidelines for hemodialysis have been updated to include the following change which has been approved by the physician director. This change should remediate the issue of discrepancies between the physicians' orders and units administered:

When a patient's dialysis schedule is altered for any reason resulting in a change of their routine dialysis day, all scheduled services regular dialysis, including ESA's, Vitamin D analogs, and parenteral iron will be administered on the off schedule day. The nurse will consult with the MD/NP/PA for guidelines regarding any ordered antibiotics or other medications.

Please let me know if you need any further information from our pertaining to the audit.

Sincerely,

A handwritten signature in black ink, appearing to read "John H. Frierson".

John H. Frierson  
Administrator, Patient Financial Services

Enclosure

PO Box 800750 | Charlottesville, VA 22908-0750 | 434.924.5376 | 800.523.4398 | Fx 434.982.2592