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JUN 24 2009

Report Number: A-03-07-00030

Ms. Elizabeth D. Hills
Corporate Compliance Officer
Lancaster General Hospital
555 North Duke Street
Lancaster, Pennsylvania 17604-3555

Dear Ms. Hills:

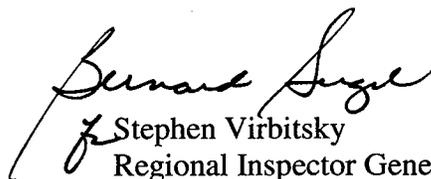
Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Payments for Epogen Administered at Lancaster General Hospital Dialysis Center, Lancaster, Pennsylvania." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

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

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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-03-07-00030 in all correspondence.

Sincerely,


Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

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Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PAYMENTS FOR
EPOGEN ADMINISTERED AT
LANCASTER GENERAL HOSPITAL
DIALYSIS CENTER,
LANCASTER, PENNSYLVANIA**



Daniel R. Levinson
Inspector General

June 2009
A-03-07-00030

Office of Inspector General

<http://oig.hhs.gov>

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

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

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

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

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

Lancaster General Hospital Dialysis Center (the Dialysis Center) is an outpatient department of Lancaster General Hospital located in Lancaster, Pennsylvania. The Dialysis Center provides treatment for end-stage renal disease using 30 renal dialysis stations. It received payments totaling \$9,233,388 for Medicare service provided from January 1, 2004, through June 30, 2006. Of this amount, \$1,858,753 was for the administration of Epogen. During our audit period, the Dialysis Center used a dosing algorithm to adjust patient Epogen doses.

OBJECTIVE

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

SUMMARY OF FINDINGS

For 97 of the 100 sampled claims, the Dialysis Center administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in the Dialysis Center's medical records. However, the Dialysis Center did not meet the Medicare payment requirements for some dates of service for three claims. In those instances, we identified discrepancies in the Dialysis 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 the Dialysis Center, and paid by Medicare.

- For two claims with errors totaling \$32, the Dialysis Center's medical and billing records reflected that more units of Epogen were administered to patients, billed by the Dialysis Center, and paid by Medicare than were ordered by the patients' attending physicians, resulting in overpayments.
- For one claim, the Dialysis Center's medical and billing records reflected discrepancies between the units of Epogen ordered by the patient's attending physician and administered to the patient, billed by the Dialysis Center, and paid by Medicare. For purposes of this report, we considered this error procedural because it did not result in an overpayment.

The errors related to these three claims occurred because administering nurses did not follow the Dialysis Center Manual for administering medication and updating medication orders into the Dialysis Center System. When physicians' orders are not followed, quality of care may be affected. Also, the Dialysis Center did not always bill for the quantity of Epogen administered.

RECOMMENDATION

We recommend that the Dialysis Center 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 the Dialysis Center, and paid by Medicare.

LANCASTER GENERAL HOSPITAL COMMENTS

In comments on our draft report (see Appendix), Lancaster General Hospital agreed with our findings and stated that it has instituted several changes in procedures including a verification process to ensure that policies are followed and medications are properly recorded and billed.

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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. The 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. Lancaster General Hospital Dialysis Center (the Dialysis Center) used an algorithm to determine the dose of Epogen to administer to its patients.

¹Epogen is an "erythropoiesis-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/2007/103234s5122lbl.pdf>. Accessed on April 23, 2009.

Medicare Requirements and Payments for End-Stage Renal Disease Services

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

CMS’s “Medicare Claims Processing Manual,” Pub. No. 100-04, chapter 8, section 10.1, specifies that renal dialysis facilities receive a composite rate for outpatient maintenance dialysis services. The composite rate is a comprehensive payment for dialysis services except for bad debts, physicians’ patient care services, separately billable laboratory services, and separately billable drugs, including Epogen. CMS contracts with fiscal 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.

Lancaster General Hospital Dialysis Center

The Dialysis Center, located in Lancaster, Pennsylvania, is an outpatient department of Lancaster General Hospital (the Hospital). The Dialysis Center provides treatment for end-stage renal disease at 30 renal dialysis stations. It received payments totaling \$9,233,388 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$1,858,753 was for the administration of Epogen.

Lancaster General Hospital Dialysis Center Policies and Procedures

To assist in its efforts to comply with requirements under Federal and State law, the Dialysis Center maintained an automated medical record system (Dialysis Center System). The Hospital established a medical record policy and documentation procedures in its “Designated Record Set/Legal Medical Record.” Specific policies relating to the documentation of physician orders and the administration of medications are included in the Hospital’s “Department of Pharmacy Policy and Procedure Manual” (Dialysis Center Manual).⁵

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.

⁵The Dialysis Center, an outpatient department of the Hospital, is subject to the Hospital’s policies and procedures.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

Our review covered 4,433 monthly claims totaling \$1,858,753 for Epogen administered by the Dialysis Center from January 1, 2004, through June 30, 2006.

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

We performed fieldwork at the Dialysis Center's compliance office in Lancaster, Pennsylvania.

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 the Hospital's policies and procedures;
- reviewed the Hospital's policies and procedures, including its medical recordkeeping and billing practices;
- interviewed Hospital and Dialysis 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 the Dialysis 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 \$35,911 and
 - for each sampled claim, compared the units of Epogen ordered by the Dialysis Center attending physician, administered to the patient, billed by the Dialysis Center, and

paid by Medicare to determine whether such units, as reflected in the Dialysis 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 RECOMMENDATION

For 97 of the 100 sampled claims, the Dialysis Center administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in the Dialysis Center's medical records. However, the Dialysis Center did not meet the Medicare payment requirements for some dates of service for three claims. In those instances, we identified discrepancies in the Dialysis 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 the Dialysis Center, and paid by Medicare.

- For two claims with errors totaling \$32, the Dialysis Center's medical and billing records reflected that more units of Epogen were administered to patients, billed by the Dialysis Center, and paid by Medicare than were ordered by the patients' attending physicians, resulting in overpayments.
- For one claim, the Dialysis Center's medical and billing records reflected discrepancies between the units of Epogen ordered by the patient's attending physician and administered to the patient, billed by the Dialysis Center, and paid by Medicare. For purposes of this report, we considered this error procedural because it did not result in an overpayment.

The errors related to these three claims occurred because administering nurses did not follow the Dialysis Center Manual for administering medication and updating medication orders into the Dialysis Center System. When physicians' orders are not followed, quality of care may be affected. Also, the Dialysis Center did not always bill for the quantity of Epogen administered.

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).⁶ 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

⁶This condition for coverage was amended effective October 14, 2008. The amended condition for coverage is now at 42 CFR § 494.170.

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 the Dialysis 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 the Dialysis Center, and (4) paid by Medicare. For two claims with questioned amounts totaling \$32, there were discrepancies in the Dialysis Center’s medical and billing records between the units of Epogen ordered by the attending physician and the units of Epogen administered, billed by the Dialysis Center, and paid by Medicare. The Dialysis Center administered, billed, and was paid for higher doses than ordered by the attending physician, as documented in the Dialysis Center’s medical and billing records.

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

For two claims covering two patients, the Dialysis Center’s medical records contained attending physicians’ orders that reduced the units of Epogen prescribed, but the nurse administered more Epogen than was ordered.

- For one claim, the attending physician’s order decreased the units of Epogen prescribed for one patient from 3,000 to 2,000 units; however, the nurse administered both doses, totaling 5,000 units, for that date of service.⁷ As a result, the patient received, the Dialysis Center billed, and Medicare paid for 3,000 more units of Epogen, totaling \$24, than was ordered.
- For one claim, the attending physician’s order decreased the units prescribed for one patient from 2,000 to 1,000 units. Both the previous and the new order required the administration of the prescribed Epogen on the first Thursday of the month. On September 1, 2005, the first Thursday, a nurse administered 1,000 units of Epogen. However, on Saturday, September 10, the nurse administered an additional 1,000 units of

⁷The “Medication Summary” on the treatment screen showed the same date to end the previous order and begin the new order, possibly resulting in the administration of both doses. We noted that the start date of the current dose is always the same as the ending date of the previous dose.

Epogen to the patient. As a result, the patient received, the Dialysis Center billed, and Medicare paid for 1,000 units more units of Epogen, totaling \$8, than was ordered.

CLAIM WITH A PROCEDURAL ERROR THAT RESULTED IN A DISCREPANCY

For one claim, the Dialysis Center's medical and billing records reflected a discrepancy between the units of Epogen ordered by the patient's attending physician and the units administered to the patient, billed by the Dialysis Center, and paid by Medicare for 13 dates of service during the month reviewed that did not result in an overpayment and is, for purposes of this report, considered a procedural error. The Dialysis Center's medical record showed that a physician ordered and the Dialysis Center administered a total of 90,000 units of Epogen during 13 dialysis treatments for the month of September 2004. However, the Dialysis Center billed and Medicare paid for only 60,000 units of Epogen. The Dialysis Center could not explain why the full quantity administered during September 2004 was not billed to Medicare.

DIALYSIS CENTER POLICIES AND PROCEDURES NOT ALWAYS FOLLOWED

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

To assist in the Dialysis Center's efforts to comply with requirements under Federal law and States' respective Nurse Practice Acts, the Dialysis Center maintained the Dialysis Center System. The Dialysis Center Manual identified policies and procedures that required that medication dose changes were recorded in the Dialysis Center System and subsequently entered by a nurse into the "All Medications Summary" of the Dialysis Center System. Nurses refer to the "All Medications Summary" to determine the dose of each medication, including Epogen, to administer.

The Hospital's "Rules Governing the Safe Use of Drugs and Biologicals," (Policy 2:6, rev. # 4) required a physician's order for the administration of medications. Nurses administering medications must verify the medication to be administered with a physician's order, positively identify the patient prior to administering the medication, and document the medication administration in the patient's medical record.

Although the Dialysis Center had controls in place as specified in the Dialysis Center Manual, based on our review, the Dialysis Center personnel did not always follow all of these procedures. Attending physician orders changing the dose of Epogen were not always followed by the administering nurses and were not always updated in the Dialysis Center System. When the attending physician changes the units of Epogen to administer, nurses should administer the quantity ordered for that day and not administer previously ordered units of Epogen. When attending physicians' orders are not followed, quality of care may be affected.

Also, the Dialysis Center did not always bill for the units of Epogen administered.

RECOMMENDATION

We recommend that the Dialysis Center 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 the Dialysis Center, and paid by Medicare.

LANCASTER GENERAL HOSPITAL COMMENTS

In comments on our draft report, Lancaster General Hospital agreed with our findings and stated that it has instituted several changes in procedures including a verification process to ensure that policies are followed and medications are properly recorded and billed. Lancaster General Hospital's comments are included in the Appendix.

APPENDIX



555 N. Duke Street
Lancaster, PA 17604

DELIVERED VIA ENCRYPTED EMAIL

June 19, 2009

Mr. Bernard Siegel
Audit Manager
Office of Inspector General
Office of Audit Services
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

Dear Mr. Siegel:

This letter is Lancaster General Hospital's (LGH's) response to the Office of Inspector General's (OIG's) Office of Audit Services (OAS) draft report entitled "Payments for Epogen Administered at Lancaster General Hospital Dialysis Center, Lancaster, Pennsylvania."

We have reviewed the draft report and agree with the OIG's findings. Since the time the three errors were made (2004 – 2006), the LGH Dialysis Center has instituted several changes in procedures including a verification process to ensure that policies are followed and medications are properly recorded and billed. Specifically;

- The same nurse that dispenses a medication also administers the medication. A second nurse verifies that the correct medication was administered and documented.
- A formal hand off procedure was developed and implemented to standardize report from one shift of nurses to the next. Included in the shift change is a review of the medications.

LGH is committed to conducting its business in compliance with Medicare rules. As such, LGH's comprehensive Compliance Program complies with the OIG's Compliance Program Guidance for Hospitals. Integral to the LGH Compliance Program is an internal auditing system that monitors, identifies, and corrects billing errors. When billing errors are identified, corrected claims are submitted and overpayments refunded to Medicare and the beneficiary, as appropriate.

We appreciate the opportunity to review the draft report. If you have any questions regarding this response, please contact me at 717-544-5866

Sincerely,


Elizabeth D. Hills, MJ, RHIA, CHC, CPC
Compliance Officer
Lancaster General Health

