



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-03-07-00031

Ms. Judy Thomas
Executive Director of renal Services
Bon Secours Baltimore Hospital
2000 W. Baltimore Street
Baltimore, Maryland 21223

Dear Ms. Thomas:

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 Bon Secours Baltimore Hospital Renal Dialysis 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.

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, 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-03-07-00031 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 12th Street, Room 235
Kansas City, Missouri 64106
rokcmora@cms.hhs.gov

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PAYMENTS FOR
EPOGEN ADMINISTERED AT
BON SECOURS
BALTIMORE HOSPITAL
RENAL DIALYSIS CENTER,
BALTIMORE, MARYLAND**



Daniel R. Levinson
Inspector General

October 2009
A-03-07-00031

Office of Inspector General

<http://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

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

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

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

Bon Secours Baltimore Hospital Renal Dialysis Center (Bon Secours), located in Baltimore, Maryland, is a hospital-based renal dialysis facility operated by Bon Secours Baltimore Hospital. Bon Secours provides treatment for end-stage renal disease using 37 renal dialysis stations. It received payments totaling \$15,847,589 for Medicare service provided from January 1, 2004, through June 30, 2006. Of this amount, \$2,520,544 was for the administration of Epogen. During our audit period, Bon Secours used dosing algorithms to adjust patient Epogen doses.

OBJECTIVE

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

SUMMARY OF FINDING

For 95 of the 100 sampled claims, Bon Secours administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Bon Secours' medical records. However, Bon Secours did not meet the Medicare payment requirements for some dates of service for five claims. In those instances, we identified discrepancies in Bon Secours' medical and billing records between the units of Epogen ordered by the patients' attending physicians and the units administered to the patients, billed by Bon Secours, and paid by Medicare. In addition, for 76 of the 100 claims (10 of the claims had two

errors) Bon Secours medical and billing records reflected errors that we considered procedural because they did not result in overpayments.

- For five claims with errors totaling \$89, Bon Secours billed and Medicare paid for more units of Epogen than were ordered by the attending physicians.
- For 13 of the 76 claims, Bon Secours' 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 73 of the 76 claims, Bon Secours' billing records reflected errors in the hematocrit level reported with the claims. For purposes of this report, we considered these errors procedural because they did not result in overpayments.

Although Bon Secours had controls in place, based on our review, Bon Secours personnel did not always follow all of those procedures. The errors related to the five claims that resulted in overpayments occurred because an attending physician's order decreasing the dose of Epogen was not followed resulting in a patient receiving a larger Epogen dose than ordered for several treatments and Bon Secours did not correctly bill for units of Epogen administered. As a result, Bon Secours received \$89 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 Bon Secours:

- refund the \$89 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 Bon Secours, and paid by Medicare.

BON SECOURS COMMENTS

In written comments (Appendix) on our draft report, Bon Secours concurred with our recommendations. Bon Secours stated that it will contact the fiscal intermediary about refunding the \$89 in overpayments and that its monthly chart audits will ensure compliance with its policies and procedures.

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BON SECOURS 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. Bon Secours Baltimore Hospital Renal Dialysis Center (Bon Secours) used dosing algorithms to adjust patient Epogen doses.

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 hemoglobin of greater than 12 [grams per deciliter] . . ." Food and Drug Administration, "Epogen Label," March 9, 2007. Available at <http://www.fda.gov/cder/foi/label/2007/103234s5122lbl.pdf>. Accessed on April 24, 2009.

Medicare Requirements and Payment 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.

Bon Secours Baltimore Hospital Renal Dialysis Center

Bon Secours, located in Baltimore, Maryland, is a hospital-based renal dialysis facility operated by Bon Secours Baltimore Hospital. Bon Secours provides treatment for end-stage renal disease using 37 renal dialysis stations. It received payments totaling \$15,847,589 for Medicare services provided from January 1, 2004, through June 30, 2006. Of this amount, \$2,520,544 was for the administration of Epogen.

Bon Secours Medical Information System and Procedures for Administering Epogen

Bon Secours uses an electronic medical information recordkeeping system (Bon Secours System) that documents all procedures and medications ordered and administered to patients. Bon Secours’ written guidance for administering Epogen is limited. The guidance states that the patient’s hemoglobin level will be reviewed weekly and the anemia management team determines the Epogen dose using the physician-approved dosing algorithm. A nurse enters changes in the Epogen dose into the Bon Secours System and the new Epogen dose is reflected on the next dialysis treatment sheet. The physician signs the Epogen dose order change during the next visit to the facility. Before entering Epogen dose changes in the Bon Secours System that are not in accordance with the physician-approved dosing algorithm, the ordering physician must approve the change. The nurse who administers the Epogen dose must document the time administered and how well the patient tolerated the Epogen on the treatment sheet.

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

Scope

Our review covered 4,260 monthly claims totaling \$2,520,544 for Epogen administered by Bon Secours from January 1, 2004, through June 30, 2006.

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

We performed fieldwork at Bon Secours 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 Bon Secours' policies and procedures for Epogen administration;
- reviewed Bon Secours' policies and procedures, including its medical recordkeeping and billing practices;
- interviewed Bon Secours' 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 Bon Secours from January 1, 2004, through June 30, 2006, and:
 - selected from the sampling frame a simple random sample of 100 claims for Epogen totaling \$46,368 and
 - for each sampled claim, compared the units of Epogen ordered by the Bon Secours attending physician, administered to patients, billed by Bon Secours, and paid by

Medicare to determine whether such units, as reflected in Bon Secours' 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 95 of the 100 sampled claims, Bon Secours administered, billed, and was paid for units of Epogen that were consistent with the units ordered by attending physicians, as reflected in Bon Secours' medical records. However, Bon Secours did not meet the Medicare payment requirements for some dates of service for five claims. In those instances, we identified discrepancies in Bon Secours' medical and billing records between the units of Epogen ordered by the patients' attending physicians and the units administered to the patients, billed by Bon Secours, and paid by Medicare. In addition, for 76 of the 100 claims (10 of the claims had two errors) Bon Secours medical and billing records reflected errors that we considered procedural because they did not result in overpayments.

- For five claims with errors totaling \$89, Bon Secours billed and Medicare paid for more units of Epogen than were ordered by the attending physicians.
- For 13 of the 76 claims, Bon Secours' 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 73 of the 76 claims, Bon Secours' billing records reflected errors in the hematocrit level reported with the claims. For purposes of this report, we considered these errors procedural because they did not result in overpayments.

Although Bon Secours had controls in place, based on our review, Bon Secours personnel did not always follow all of those procedures. The errors related to the five claims that resulted in overpayments occurred because an attending physician's order decreasing the dose of Epogen was not followed resulting in a patient receiving a larger Epogen dose than ordered for several treatments and Bon Secours did not correctly bill for units of Epogen administered. As a result, Bon Secours received \$89 in overpayments and patients did not always receive the amounts of Epogen ordered by attending physicians. When attending physicians' orders are not followed, quality of care may be affected.

FEDERAL REQUIREMENTS

Medical Recordkeeping

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

Medicare Payment Procedures

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

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

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.

CLAIMS FOR EPOGEN NOT CONSISTENT WITH PHYSICIANS' ORDERS

For each sample claim, we compared Bon Secours' 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 Bon Secours, and (4) paid by Medicare. For five claims with questioned amounts totaling \$89, Bon Secours billed and Medicare paid for more units of Epogen than were ordered by the attending physicians.

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

For one claim, Bon Secours' medical records reflected an attending physician's order, dated November 19, 2004, to decrease the units of Epogen from 5,000 to 3,000 units. However, the administering nurse continued to administer 5,000 units of Epogen for four treatments following

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

the change ordered by the attending physician. Bon Secours administered and billed, and Medicare paid for 8,000 more units of Epogen, totaling \$64, than was ordered.

More Units of Epogen Billed and Paid Than Ordered and Administered

For four claims covering four patients, Bon Secours was paid for more units of Epogen than were administered during the month reviewed. In total, Bon Secours billed and Medicare paid for 3,350 more units of Epogen, totaling \$25, than was ordered and administered.

- For one claim, the attending physician ordered and Bon Secours administered 3,000 units of Epogen during the 13 dialysis treatments during June 2006. In total, Bon Secours administered 39,000 units of Epogen during the month; however, Bon Secours billed for 42,000 units of Epogen. As a result, Bon Secours billed and Medicare paid for 3,000 more units of Epogen, totaling \$22, than was ordered and administered.
- For three claims, the Bon Secours' medical records showed that three patients received doses of Epogen and Aranesp⁶ during the months reviewed. For the three claims, Bon Secours billed the units of Aranesp administered as units of Epogen. As a result, Bon Secours billed and Medicare paid for 350 more units of Epogen, totaling \$3, than was ordered and administered.

CLAIMS WITH PROCEDURAL ERRORS THAT DID NOT RESULT IN DISCREPANCIES

Bon Secours' Epogen administration guidance states that the patient's hemoglobin level will be reviewed weekly and the anemia management team determines the Epogen dose using the physician-approved dosing algorithm. A nurse enters changes in the Epogen dose into the Bon Secours System and the new Epogen dose is reflected on the next dialysis treatment sheet. The physician signs the Epogen dose order change during the next visit to the facility. Before entering Epogen dose changes in the Bon Secours System that are not in accordance with the physician-approved dosing algorithm, the ordering physician must approve the change. The nurse who administers the Epogen dose must document the time administered and how well the patient tolerated the Epogen on the treatment sheet.

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. Before January 1, 2006, the hematocrit reading reported should be the reading taken before 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.

For 13 claims Bon Secours' 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

⁶Aranesp is a man-made form of human erythropoietin manufactured by Amgen, which stimulates the production of red blood cells.

discrepancies in the quantities of Epogen ordered, administered, billed, or paid. For 73 claims, the hematocrit level included on the claim was incorrect.

Unsigned Medical Record Documents

For 11 claims, the ordering physician did not electronically sign a verbal order changing the Epogen dose in accordance with Bon Secours guidance. The verbal order status in the Bon Secours System was “open,” indicating that the ordering physician did not sign the order. The nurse updated the Bon Secours System and administered the units of Epogen consistent with the attending physicians’ verbal orders. Bon Secours billed and Medicare paid for the units of Epogen ordered by the attending physician and administered to the patients.

Missing Treatment Sheets

For two claims, the patients’ medical records did not include the patient treatment sheets for one date of service for the month reviewed. Bon Secours billed and Medicare paid for the units of Epogen ordered by attending physicians and administered to the patients.

Claims with Incorrect Hematocrit Levels

For 73 claims, Bon Secours’ 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, the provider should have reported the last hematocrit level during the billing period. The hematocrit levels submitted on 53 claims were not correct.
- For calendar year 2006, the provider should have reported the last hematocrit level before the start of the billing period. The hematocrit levels submitted on 20 claims were not correct.

Although the hematocrit levels for the 73 claims were not correct; the amount Medicare paid for those claims did not result in overpayments.

BON SECOURS PROCEDURES NOT FOLLOWED

Although Bon Secours had controls in place, based on our review, Bon Secours personnel did not always follow all of those procedures. An attending physician’s order decreasing the dose of Epogen was not followed resulting in a patient receiving a larger Epogen dose than ordered for several treatments. Physicians did not electronically sign some Epogen dose changes in the Bon Secours System. Also, Bon Secours did not correctly bill for units of Epogen administered and hematocrit levels submitted on claims for Medicare payment were not always accurate.

RECOMMENDATIONS

We recommend that Bon Secours:

- refund the \$89 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 Bon Secours, and paid by Medicare.

BON SECOURS COMMENTS

In written comments on our draft report, Bon Secours concurred with our recommendations. Bon Secours stated that it will contact the fiscal intermediary about refunding the \$89 in overpayments and that its monthly chart audits will ensure compliance with its policies and procedures. Bon Secours' comments are included in the appendix.

APPENDIX



APPENDIX: BON SECOURS COMMENTS

BON SECOURS BALTIMORE HEALTH SYSTEM
2000 West Baltimore Street
Baltimore, Maryland 21223

September 7, 2009

Report Number: A-03-07-00031

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

Dear Mr. Virbitsky:

In response to report number noted above, "Payments for Epogen Administered at Bon Secours Baltimore Hospital Renal Dialysis Center, Baltimore, Maryland", attached please find our written comments. In summary, we concur with your recommendations, see enclosed for detail.

If you have any questions about this response, please do not hesitate to call or e-mail me at (410) 362-3396 (judy_thomas@bshsi.org), or contact Richard Jones, Chief Financial Officer, at (410) 362-4477 (Richard_jones@bshsi.org).

Sincerely,

/Judy A. Thomas/
Executive Director of Renal Services

Enclosure

Report Number: A-03-07-00031

Response to Recommendations

- Concur: Working with fiscal intermediary to refund \$89.
- Concur: Policy and Procedure stipulate medication orders be entered into the patient's electronic record within 24 hours. The orders are then electronically printed on the patients treatment record; thus, ensuring proper dose administration. The nurse indicates and signs off on medications given, which in turn is used for billing procedures. Monthly chart audits ensure compliance with said policies.