



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203
(617) 565-2684

September 25, 2002

CIN: A-01-02-00502

Dr. Jeffrey Hymes
Chief Executive Officer
National Nephrology Associates Corporate Office
230 Great Circle Road, Suite 218
Nashville, Tennessee 37228

Dear Dr. Hymes:

Enclosed are two copies of the U.S. Department of Health and Human Services, Office of Inspector General (OIG), Office of Audit Services' (OAS) report entitled "Review of EPOGEN Internal Control Procedures at Massachusetts Renex Dialysis Clinics for Calendar Year 1999." A copy of this report will be forwarded to the action official noted on page 2 for her review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official named on page 2. We request that you respond to the HHS action 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.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG, OAS reports issued to the Department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act which the Department chooses to exercise. (See 45 CFR Part 5.)

To facilitate identification, please refer to Common Identification Number A-01-02-00502 in all correspondence relating to this report.

Sincerely,

A handwritten signature in cursive script that reads "Michael J. Armstrong".

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosures - as stated

cc: w/enclosure - Lynda Silva, Acting Regional Administrator, CMS
- Martha McCrary, Director of Medicare Claims Operations, BC/BS of Georgia

Page 2 - Dr. Jeffrey Hymes

Direct Reply to HHS Action Official:

Ms. Lynda Silva
Acting Regional Administrator
Centers for Medicare and Medicaid Services - Region I
U.S. Department of Health and Human Services
Room 2325
JFK Federal Building
Boston, Massachusetts 02203-0003

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF EPOGEN INTERNAL
CONTROL PROCEDURES AT
MASSACHUSETTS RENEX DIALYSIS
CLINICS FOR
CALENDAR YEAR 1999**



JANET REHNQUIST
Inspector General

September 2002
A-01-02-00502

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 OIG's Office of Audit Services (OAS) provides all 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 in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the department.

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Office of Investigations

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees state Medicaid fraud control units, which investigate and prosecute fraud and patient abuse in the Medicaid program.

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 in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

EXECUTIVE SUMMARY

Background

Health Insurance for the Aged and Disabled (Medicare), Title XVIII of the Social Security Act, as amended, is a broad program of health insurance that is administered by the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration. Medicare includes coverage for eligible persons suffering from kidney failure under its End Stage Renal Disease (ESRD) program. One type of coverage includes the use of EPOGEN (EPO), which is used as a substitute for the protein erythropoietin. The EPO stimulates the production and development of red blood cells. Low levels of erythropoietin often result in anemia, with symptoms including rapid heartbeat, chest pain, fatigue, and limitations in performance of daily activities.

The ESRD facilities are reimbursed by Medicare based on the number of EPO units administered to each ESRD patient. Medicare is responsible for paying \$8 per 1,000 units of EPO.

Renex Medical Care (Renex) is an affiliate of National Nephrology Association, which operates a network of dialysis clinics and is a leading administrator of dialysis services. In Massachusetts, there were 2 Renex providers that submitted claims that contained services for EPO equal to or greater than 90,000 billed and reimbursed units in calendar year 1999 to the fiscal intermediary Blue Cross Blue Shield (BCBS) of Florida. Renex currently submits their Medicare claims to the fiscal intermediary BCBS of Georgia.

Objective

The objective of our review was to determine if Massachusetts Renex providers have established adequate internal controls and procedures to ensure that claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations.

Summary of Findings

We employed a one hundred percent review of 296 Renex claims and the value of the selected claims EPO amounts totaled \$327,540. We reviewed the billing and medical records for the 296 claims to determine whether the billed and reimbursed EPO services were supported by the medical records. As a basis for a Medicare payment, federal regulations require that the provider, supplier or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due. As part of our review, we requested, obtained and reviewed beneficiaries' records for (1) written physician orders prescribing the number of units of EPO to be administered per patient treatment, (2) dialysis treatment records to determine the amount of EPO administered per treatment, and (3) CMS' common working file records to determine the number of units billed to the Medicare program. We identified portions of 85 claims totaling \$6,016 not eligible for Medicare reimbursement.

Recommendations

We recommend that Renex:

- (1) continue to strengthen its internal controls and procedures to ensure that the claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations.
- (2) reimburse the Medicare Program in the amount of \$6,016 for billings that contained reconciliation inconsistencies between the number of units of EPO prescribed in the written physician order, administered by the facility to the patient, and billed to the Medicare program.

We will provide the CMS and BCBS of Georgia with the results of our review for appropriate consideration and corrective action.

Auditee Response

In its comments to our draft report, Renex officials concurred with our findings and recommendations.

See APPENDIX for complete text of Auditee comments.

INTRODUCTION

BACKGROUND

Health Insurance for the Aged and Disabled (Medicare), Title XVIII of the Social Security Act, as amended, is a broad program of health insurance that is administered by the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration. Medicare includes coverage for eligible persons suffering from kidney failure under its End Stage Renal Disease (ESRD) program.

The Food and Drug Administration approved the generic drug epoetin commonly known as EPO on June 1, 1989. The drug EPO is used as a substitute for the protein erythropoietin, which is secreted by the kidneys and stimulates the production and development of red blood cells. Low levels of erythropoietin often result in anemia with symptoms including rapid heartbeat, chest pain, fatigue, and limitations in performance of daily activities. Prior to the development of EPO, ESRD beneficiaries with low levels of erythropoietin required frequent blood transfusions, an expensive procedure that could have introduced significant medical risk.

The CMS authorized Medicare contractors to pay for EPO as of June 1, 1989. The EPO, when provided to a patient determined to have ESRD, shall not be included as a dialysis service for purposes of payment under any prospective payment amount or comprehensive fee, and payment shall be made separately in the amount equal to \$10 per 1,000 units of EPO (rounded to the nearest 100 units). Medicare is responsible for paying \$8 per 1,000 units of EPO, as the Medicare payment amount is subject to the Medicare Part B deductible and coinsurance.

Renex Medical Care (Renex) is an affiliate of National Nephrology Association, which operates a network of dialysis clinics and is a leading administrator of dialysis services. In Massachusetts, there were 2 Renex providers that submitted claims that contained services for EPO equal to or greater than 90,000 billed and reimbursed units in calendar year 1999 to the fiscal intermediary Blue Cross Blue Shield (BCBS) of Florida. Renex currently submits their Medicare claims to the fiscal intermediary BCBS of Georgia.

OBJECTIVE, SCOPE AND METHODOLOGY

Our review was conducted in accordance with generally accepted government auditing standards. The objective of our review was to determine if Massachusetts Renex providers have established adequate internal controls and procedures to ensure that claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations.

We limited consideration of the internal control structure to those controls concerning claims submission because the objective of our review did not require an understanding or assessment of the complete internal control structure of Renex. We concluded, however, that our consideration of the internal control structure could be conducted more efficiently by expanding substantive audit tests, thereby placing limited reliance on the providers' internal control structure.

To accomplish our objective, we:

- ◆ researched applicable laws and regulations related to EPO.
- ◆ used CMS' National Claims History (NCH) to identify 296 Massachusetts Renex claims that contained services for EPO equal to or greater than 90,000 billed and reimbursed units. The 296 claims EPO amounts were valued at \$327,540, and were submitted by 2 Massachusetts Renex providers to the fiscal intermediary Blue Cross Blue Shield of Florida during calendar year 1999.
- ◆ performed a one hundred percent review of Medicare claims submitted by 2 Massachusetts Renex providers for services rendered during the period January 1, 1999 through December 31, 1999 that contained services equal to or greater than 90,000 billed and reimbursed units. The 2 providers submitted 296 claims in this category.
- ◆ reviewed the billing and medical records for the 296 claims to determine whether the medical records supported the billed and reimbursed EPO services. The billed and reimbursed charges associated with the EPO claims were reviewed and discussed with the Office of Inspector General (OIG) and Renex medical review staff to determine whether claims complied with Medicare rules and regulations. Our audit did not include determining whether the beneficiary's medical condition warranted the need of EPO.
- ◆ interviewed the Massachusetts Renex providers' officials concerning internal controls pertaining to the submission of Medicare claims for EPO.

Our fieldwork was conducted from February 2002 to August 2002 at Renex in North Andover, Massachusetts and the Boston Regional OIG Office.

FINDINGS AND RECOMMENDATIONS

As part of our review, we requested, obtained and reviewed beneficiaries' records for (1) written physician orders prescribing the number of units of EPO to be administered per patient treatment, (2) dialysis treatment records to determine the amount of EPO administered per treatment, and (3) CMS' common working file records to determine the number of units billed to the Medicare program. Our assessment of Massachusetts Renex providers' internal controls and procedures identified a control weakness for ensuring that the claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations. As a result of reviewing the 296 claims with paid EPO services valued at \$327,540, we identified portions of 85 claims not eligible for Medicare reimbursement. The portions of the claims not eligible for Medicare reimbursement totaled \$6,016.

For ESRD providers, Title 42 Code of Federal Regulations Section 405.2139(a) provides "Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: ... diagnostic and therapeutic orders ..."

As a basis for a Medicare payment, Title 42 Code of Federal Regulations (CFR) Section 424.5 (a)(6) provides:



In addition, the Hospital Manual Section 462 provides the following uniform instructions for completing Billing Form-1450:

“In order to be paid correctly and promptly, a bill must be completed accurately”.

We found the following examples in which Renex received Medicare reimbursement for EPO services that did not meet Medicare rules and regulations:

- ◆ Renex billed one claim for 130,000 units of EPO totaling \$1,040 and the treatment forms indicate that Renex staff administered 130,000 units of EPO to the patient; however, the physician’s order contained in the medical record only supported 104,000 units of EPO totaling \$832 to the patient. Therefore, we are questioning 26,000 units of EPO totaling \$208.
- ◆ Renex billed one claim for 146,000 units of EPO totaling \$1,168; however, the physician written orders prescribed 134,000 units of EPO and the treatment forms indicate the provider’s staff administered 134,000 units of EPO to the patient. Therefore, we are questioning 12,000 units of EPO totaling \$96, because the physician orders and treatment forms only support 134,000 units.
- ◆ Renex billed one claim for 96,000 units of EPO; however, the physician written orders prescribed 144,000 units of EPO and the treatment forms indicate the provider’s staff administered 144,000 units of EPO to the patient. Therefore, 48,000 units of EPO were underbilled the Medicare program.

We noted that Renex began to strengthen its internal controls since our audit period to ensure that future claims submitted for EPO will be supported and billed in accordance with Medicare rules and regulations.

RECOMMENDATIONS

We recommend that Renex:

- (1) continue to strengthen its internal controls and procedures to ensure that the claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations.
- (2) refund the Medicare program \$6,016 of unallowable Medicare costs to the fiscal intermediary BCBS of Georgia.

AUDITEE RESPONSE

In its comments to our draft report, Renex officials concurred with our findings and recommendations.

See APPENDIX for complete text of Auditee comments.

APPENDIX

September 19, 2002

Mr. Mike Armstrong
Regional Inspector General for Audit Services
Region I
John F. Kennedy Building
Boston, MA 02203

RE: CIN A-01-02-00502
"Review of EPOGEN Internal Control Procedures at Renex Dialysis Center for
Calendar Year 1999"

Dear Sir:

I am in receipt of your draft report captioned above, and appreciate the opportunity to respond to its recommendations.

The Renex Dialysis Company was acquired by National Nephrology Associates (NNA) in February of 2000. As a result, the period examined reflects control procedures that were in place prior to the Massachusetts Renex clinics coming under NNA management. As the report correctly states, since that time significant improvements in internal controls have been initiated.

Among the most significant changes adopted by NNA are the following:

1. Appointment of Anemia Managers in each clinic to supervise the use of Epogen
2. Adoption of a standard Epogen Administration Protocol by the company, upon the recommendation of the company's Medical Advisory Board.
3. The installation of a computerized medical record information system with the following capabilities:
 - a. Real time monitoring of hemoglobin results and cross referencing of these to the Epogen protocol guidelines.
 - i. Epogen placed on hold and restarted according to physician orders upon receipt of lab results
 - ii. Electronic order verification by physician upon changes in dosage
 - iii. Automatic updating of Epogen orders on daily flow sheets
 - b. Generation of Charge History Reports daily to cross check accuracy and agreement of ordered, administered, and charged medications.
 - c. Generation of reports including
 - i. Clinical outcomes
 - ii. Dosage "outliers"
 - iii. Unsigned physician orders

A real-time chair-side data entry system is being installed in NNA clinics. Features that further strengthen our internal controls include:

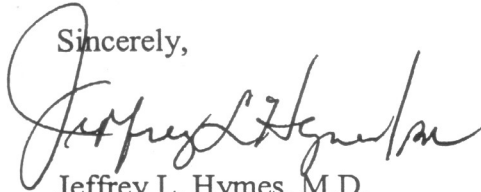
1. Treatment cannot be closed if there is a discrepancy in medication prescription and administration.
2. All discrepancies require explanation and employee signature.
3. Automatic generation of exception reports highlighting differences in prescribed or administered doses.

While we would have preferred to have had flawless performance by the Renex clinics, we are pleased at the finding of only a 1.8% financial discrepancy and plan to refund to the Medicare program \$6,016. We believe this to be consistent with human error. This confirms NNA's impression at the time of acquisition that the staff and physicians of the Renex clinics practice in an ethical and conscientious manner. We are confident that our improved controls will further reduce the error rate.

I would also like to compliment your staff on their conduct during this inspection. Our staff found them to be professional, helpful and well informed.

Thank you for the opportunity to respond to this review. Please let me know if you require additional information.

Sincerely,



Jeffrey L. Hymes, M.D.
President and Chief Medical Officer