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

JUN 2 5 2002

CIN: A-01-01-00544

Mr. James Perry
President
Dialysis Clinic, Inc.
1633 Church Street
Suite 500
Nashville, Tennessee 37203

Dear Mr. Perry:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Services' (OAS) final report entitled "Review of Internal Control Procedures at Dialysis Clinic, Inc. Facilities Located at Boston and Somerville, Massachusetts for the Administration of Epogen for Calendar Year 1999." A copy of this report will be forwarded to the action official noted below for his/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 below. 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 (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-01-01-00544 in all correspondence relating to this report.

Sincerely yours,

Michael J. Armstrong

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosures – as stated

cc: Direct Reply to HHS Action Official:
Roger Perez
Acting Regional Administrator
John F. Kennedy Federal Building
Room 2325
Boston, Massachusetts 02203-0003

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF INTERNAL CONTROL PROCEDURES AT DIALYSIS CLINIC, INC. FACILITIES LOCATED AT BOSTON AND SOMERVILLE, MASSACHUSETTS FOR THE ADMINSTRATION OF EPOGEN FOR CALENDAR YEAR 1999

JANET REHNQUIST
Inspector General

June 2002
A-01-01-00544

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:

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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.

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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 Center for Medicare and Medicaid Services (CMS). Medicare includes coverage for eligible persons suffering from kidney failure under its End Stage Renal Disease (ESRD) program. The latest options in the treatment of kidney disease include transplantation, hemodialysis and peritoneal dialysis. Transplantation involves the placement of a healthy kidney inside your body to do the work of your own kidneys. Hemodialysis is performed at a clinic usually three times a week and involves the cleansing of the blood through a dialysis machine operated by trained personnel. Peritoneal dialysis is performed independently at home after completing a successful training program.

Objective

The objective of our review was to determine whether Dialysis Clinic, Inc., (DCI), headquartered in Nashville, Tennessee, has established adequate internal controls and procedures to ensure the claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations. Our review covered claims submitted by two DCI facilities, Boston and Somerville, Massachusetts, during Calendar Year 1999.

Summary of Findings

In 101 out of the 224 claims reviewed (45%), we found 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. As a result, we are questioning 92 claims that were either not documented in the medical record as being administered, or that the number of units administered exceed what the prescribed written physician order indicated Ninety-two claims resulted in over billings and the remaining 9 claims resulted in under billings. The 101 claims were

incorrectly billed because DCI had not established adequate internal controls and procedures. These claims were not supported and billed in accordance with Medicare rules and regulations.

Recommendations

We recommend that DCI:

Strengthen its procedures to ensure that the claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations.[1] We will provide the interested parties with the results of our review for corrective action.

Carrier Comments

In its response to our draft report, DCI indicated that it has revised policies and internal controls at its Boston and Somerville locations relating to the ordering, administration and billing of Epogen as well as its procedures for monitoring compliance at both facilities. Employees at each facility are being trained to ensure compliance with the revised policies and system for monitoring compliance has been established. DCI is in the process of conducting a comprehensive review of its policies and procedures with respect to the ordering, administration and billing of Epogen. The goal of this review is to ensure that each of DCI's dialysis facilities is in compliance with applicable Federal and state laws.

[1] DCI, headquartered in Nashville, Tennessee, has made a voluntary disclosure of Epogen overpayments to our Office of Investigations located in Atlanta, Georgia. Accordingly, we are not recommending recoupment of specific overpayments identified in the review of the two facilities in Massachusetts pending official resolution of the national voluntary disclosure.

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 Center 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 latest options in the treatment of kidney disease include transplantation, hemodialysis and peritoneal dialysis. Transplantation involves the placement of a healthy kidney inside your body to do the work of your own kidneys. Hemodialysis is performed at a clinic usually three times a week and involves the cleansing of the blood through a dialysis machine operated by trained personnel. Peritoneal dialysis is performed independently at home after completing a successful training 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 coinsurance.

Dialysis Clinic Incorporated (DCI), headquartered in Nashville, Tennessee, has 160 clinics nationwide. We selected two of their clinics, located in Somerville and Boston, Massachusetts.

OBJECTIVE, SCOPE AND METHODOLOGY

Our review was conducted in accordance with generally accepted government auditing standards. The objective of our review was to determine whether these DCI facilities have established adequate internal controls and procedures to ensure the 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 claim submission because the objective of our review did not require an understanding or assessment of the complete internal control structure of DCI. 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 DCI's internal control structure.
To accomplish our objective, we:

- Researched applicable laws and regulations related to EPO;

- Performed a one hundred percent review of Medicare claims submitted by DCI, at the Somerville and Boston locations, for services rendered during the period January 1, 1999 through December 31, 1999 that contained billings for EPO equal to or greater than 90,000 units.

- Reviewed the billing and medical records for the 224 claims to determine whether the EPO services billed and reimbursed were supported by the medical records. Billed charges associated with the EPO claims were reviewed and discussed with the DCI and Office of Inspector General (OIG) medical review staff to determine whether claims were erroneously billed. Our audit did not include determining whether the beneficiary's medical condition warranted the need of EPO.

- Interviewed appropriate DCI officials concerning internal controls pertaining to the submission of Medicare claims for EPO.

Our fieldwork was conducted from August through November 2001 at DCI in Somerville, Massachusetts; and the Boston Regional OIG Office.

FINDINGS AND RECOMMENDATION

We reviewed beneficiaries' (1) written physician orders prescribing the number of units of EPO to be administered per patient treatment, (2) DCI hemodialysis treatment records to determine the amount of EPO administered per treatment, and (3) UB-92 Form 1450s and the patient remittance advices to determine the number of units billed to the Medicare program. In 101 out of the 224 claims reviewed (45%), we found 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.

For ESRD providers, Title 42 Code of Federal Regulations Section 405.2139(a) "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..."

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 DCI received Medicare reimbursement for EPO services that did not meet Medicare rules and regulations:

- The DCI administered and billed for 152,900 units of EPO and was paid $1,223 and the treatment sheets indicate that DCI staff administered 152,900 units of EPO to the patient; however, we found no physician order authorizing the administration of EPO to the patient. Therefore, we are questioning 152,900 units of EPO totaling $1,223 because a physician order was not provided.

- The DCI billed for 160,000 units of EPO and was paid $1,280. Physician orders and patient records show that only 144,000 units were administered to the patient. Therefore, we are questioning 16,000 units of EPO totaling $128 because not all treatment forms were provided.

- DCI billed for administering 132,000 units of EPO and was paid $1,056.00. Physician orders and patient records showed that 144,000 units were actually ordered and administered. Therefore, the charge for EPO was under billed by $96.00 because of a clerical error.

As a result, we are questioning 92 claims that were either not documented in the medical record as being administered, or that the number of units administered exceed what the prescribed written physician order indicated. Ninety-two claims resulted in over billings and the remaining 9 claims resulted in under billings. The 101 claims were incorrectly billed because DCI had not established adequate internal controls and procedures. These claims were not supported and billed in accordance with Medicare rules and regulations

RECOMMENDATION

We recommend that DCI strengthen its procedures to ensure that the claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations.[1] We will provide the interested parties with the results of our review for corrective action.

CARRIER COMMENTS

In its response to our draft report, DCI indicated that it has revised policies and internal controls at its Boston and Somerville locations relating to the ordering, administration

[1] DCI, headquartered in Nashville, Tennessee, has made a voluntary disclosure of Epogen overpayments to our Office of Investigations located in Atlanta, Georgia. Accordingly, we are not recommending recoupment of specific overpayments identified in the review of the two facilities in Massachusetts pending official resolution of the national voluntary disclosure.

and billing of Epogen as well as its procedures for monitoring compliance at both facilities. Employees at each facility are being trained to ensure compliance with the revised policies and system for monitoring compliance has been established. DCI is in the process of conducting a comprehensive review of its policies and procedures with respect to the ordering, administration and billing of Epogen. The goal of this review is to ensure that each of DCI's dialysis facilities is in compliance with applicable Federal and state laws.

APPENDIX

DIALYSIS CLINIC, INC.

A Non-Profit Corporation

H. Keith Johnson, M.D., Chairman of the Board
James Perry, President
Ed Attrill, Secretary and Treasurer

1633 Church Street
Suite 500
Nashville, TN 37203
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May 23, 2002

VIA FACSIMILE (617) 565-2690
AND OVERNIGHT MAIL

Michael J. Armstrong
Regional Inspector General for Audit Services
Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203

Re: A-01-01-00544: "Review of Internal Control Procedures at Dialysis Clinic, Inc. Facilities Located at Boston and Somerville, Massachusetts for the Administration of EPOGEN for Calendar Year 1999"

Dear Mr. Armstrong:

This letter constitutes the formal response of Dialysis Clinic, Inc. ("DCI") to the above-referenced draft report (the "Draft Report") prepared by the Office of Inspector General, Office of Audit Services ("OAS").

In the Draft Report, the OAS identifies two general categories of error which it believes are reflected in the Epogen claims submitted by DCI for patients at DCI's Boston and Somerville facilities. The first consists of Epogen claims for which an appropriate physician's order could not be located. The second consists of claims for Epogen where the amount of medication ordered was consistent with the amount administered, as reflected in the medical record, but not with the amount billed. (In certain cases, this was due to the failure to properly record the amount of Epogen administered; in a few cases, it was due to errors in the billing process.) In the Draft Report, the OAS recommends that, to minimize these errors, DCI should "strengthen its procedures to ensure that claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations."

In response to the Draft Report, DCI reviewed its policies and procedures for the ordering, administration and billing of Epogen as well as its procedures for monitoring compliance at both the Boston and Somerville facilities. The following constitutes a summary of the principal policy

regarding the use of protocol orders. These policies and procedures govern the use of individualized standing orders for the administration of Epogen. Among other things, the policies provide that when a dose is modified pursuant to a standing order, the nurse must identify the source of the order, in the patient's chart, as a "standing order" or "s/o".

3. DCI conducted inservices with the nursing staff at both the Boston and Somerville facilities to ensure that each nurse understands that the co-signature of the ordering physician is required whenever a nurse modifies the amount of Epogen administered to a patient in accordance with the protocol set forth in an individualized standing order. DCI revised its documentation procedure to state that the ordering physician must authorize such medication changes in writing within the time frame required by law. Accordingly, the Boston and Somerville facilities have instituted procedures to ensure that a physician's signature is obtained, in accordance with applicable law, when medication changes, including Epogen dosing modifications, are implemented pursuant to an individualized standing order. As part of that procedure, the attending physicians will be notified by phone, facsimile, or electronic messaging of the need to review and co-sign medication orders.

II. Medication Administration

To ensure that documentation standards for the administration of medication are followed, DCI reviewed and updated its existing policies. As a result of that review, the Boston and Somerville facilities revised their documentation policies to require that a nurse include a notation in the flow sheet next to a pre-printed medication order. Upon administration of the medication, the nurse will either initial and date the flow sheet or indicate why the medication was not administered.

III. Training

DCI is in the process of training staff at the Somerville and Boston facilities regarding its new and revised policies relating to Epogen administration. In the training sessions, DCI will specifically review how to record or transcribe a physician's medication order, the process for obtaining a co-signature on a verbal order or a medication change implemented pursuant to a standing order, and the

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[1]DCI is in the process of conducting a comprehensive review of its policies and procedures with respect to the ordering, administration and billing of Epogen. The goal of this review is to ensure that each of DCI's dialysis facilities is in compliance with applicable federal and state laws.

maintenance of complete and accurate records regarding medication administration. In addition, DCI will consult with the attending physicians at the Boston and Somerville facilities to ensure that they understand DCI's policies regarding the co-signature of verbal orders and medication changes administered in accordance with individualized standing orders.

IV. Monitoring

The Boston and Somerville facilities will perform chart audits at the end of each day to ensure that all medications identified on the flow sheet have been administered as ordered, or, if not, that there is a notation indicating why the medication was not administered. Both facilities have adopted a specific procedure which requires these daily chart audits.

The Boston and Somerville facilities will also conduct monthly chart audits. Each facility will review approximately twenty percent (20%) of all medical records to ensure that Epogen orders have been written for each patient who is receiving the drug, that physician co-signatures have been obtained where required, and that the administration of Epogen is properly reflected in the patient's chart. The monthly chart audits will be reviewed in the CQI meetings. A similar audit will be conducted every ninety (90) days by DCI's corporate nurse for verification purposes. As part of that audit, the corporate nurse will determine whether the attending physicians are co-signing verbal orders and dose adjustments made pursuant to individualized standing orders within the required time frame. If recurring problems are identified at a facility, the facility will be expected to re-educate its staff or modify its policies as necessary to correct the problem. If, after one year, the audits indicate substantial compliance, DCI will implement a system of semiannual or annual audits at the facility, as deemed necessary.

If you have any questions regarding this response or the procedures which DCI has implemented to ensure that Epogen is ordered, administered and billed in accordance with applicable law, please do not hesitate to contact me.

Very truly yours,

James Perry
President