TO: Sonia A. Madison  
Regional Administrator  
Centers for Medicare & Medicaid Services

FROM: Regional Inspector General for Audit Services

SUBJECT: Audit Report – Review of Medicare Payments to DaVita, Incorporated for Epogen Services Provided at Franklin Dialysis Center, Philadelphia, Pennsylvania (Report Number A-03-03-00003)

Attached are two copies of the Department of Health and Human Services, Office of Inspector General report entitled “Review of Medicare Payments to DaVita, Incorporated for Epogen Services Provided at Franklin Dialysis Center, Philadelphia, Pennsylvania.” The report covered payments received by DaVita, Incorporated during the period January 1 through December 31, 2001 for claims with dates of service on or after November 1, 2000. Should you have any questions or comments, please contact me or have your staff contact James Maiorano, Audit Manager at (215) 861-4476.

To facilitate identification, please refer to report number A-03-03-00003 in all correspondence relating to this report.

Attachment
APR 21 2004

Report Number: A-03-03-00003

Ms. Lori S. Richardson Pelliccioni
Vice President, Compliance
Chief Compliance Officer
DaVita, Incorporated
601 Hawaii Avenue
El Segundo, California 90245

Dear Ms. Pelliccioni:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG) report entitled “Review of Medicare Payments to DaVita, Incorporated for Epogen Services Provided at Franklin Dialysis Center, Philadelphia, Pennsylvania.” The report covered payments received by DaVita, Incorporated (DaVita) during the period January 1 through December 31, 2001 for claims with dates of service on or after November 1, 2000. A copy of this report will be forwarded to the action official noted below for his/her review and any action deemed necessary.

The objective of our audit was to determine if DaVita established adequate internal controls and procedures to ensure that claims for Epogen were supported and billed in accordance with Medicare requirements.

DaVita did not establish adequate internal controls and procedures to ensure that claims for Epogen were supported and billed in accordance with Medicare requirements. Forty-four of the 143 claims reviewed did not meet Medicare payment requirements for Epogen. We identified inconsistencies between the number of units of Epogen prescribed in the written physician order, administered by the facility, and billed to Medicare. Independent dialysis facilities were required to maintain complete medical records and furnish sufficient information to support the payment. During the period when the services included in our review were provided, DaVita had controls in place for submitting claims that included Epogen. Based on our review, Franklin Dialysis Center (Franklin) personnel did not always follow those procedures. In addition, medical records supporting services provided at Franklin were not always consistently archived. As a result, DaVita received payments of $15,096 for Epogen services that did not meet Medicare requirements.

DaVita personnel could not locate medical records that supported 12 claims. They believed that lack of storage space, purging of records, and staff changes lead to inconsistent archiving of medical records. As a result, we were unable to review those claims to determine if $15,984 in payments for Epogen met Medicare requirements.
DaVita personnel informed us that changes were made to Franklin’s operating procedures since the time period when the services included in this audit were rendered. The changes addressed the processes for ordering and administering medications, and filing and storing medical records. In addition, as a result of the claims we identified where Epogen was administered and the corresponding order was to “Hold EPO,” DaVita conducted a review at Franklin and three other DaVita facilities to determine if “Hold EPO” orders were followed and billed correctly. The review showed that of 55 “Hold EPO” orders, 5 were not followed and Epogen was administered to the patient.

The HHS action official named below will make final determination as to actions taken on all matters reported. 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 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.)

If you have any questions or comments about this report, please do not hesitate to contact me at (215) 861-4470 or James Maiorano, Audit Manager at (215) 861-4476 or through e-mail at James.Maiorano@oig.hhs.gov. To facilitate identification, please refer to report number A-03-03-00003 in all correspondence.

Sincerely yours,

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosures – As stated

Direct Reply to HHS Action Official

Sonia Madison
Regional Administrator
Centers for Medicare & Medicaid Services
Public Ledger Building, Suite 216
150 South Independence Mall West
Philadelphia, Pennsylvania 19106
REVIEW OF MEDICARE PAYMENTS TO DAVIDITA, INCORPORATED FOR EPOGEN SERVICES PROVIDED AT FRANKLIN DIALYSIS CENTER, PHILADELPHIA, PENNSYLVANIA
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**

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**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.
THIS REPORT IS AVAILABLE TO THE PUBLIC
at http://oig.hhs.gov

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General's reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR Part 5.)

OAS FINDINGS AND OPINIONS

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

BACKGROUND

Independent renal dialysis facilities are paid a composite rate per treatment for providing dialysis services to Medicare patients with end stage renal disease (ESRD). The payment covers the complete dialysis treatment except for physicians’ professional services, and separately billable laboratory services and drugs. A separate payment of $10 per 1,000 units is made for Epogen, subject to the Medicare Part B deductible and coinsurance. Federal regulations provide the medical record requirements for independent dialysis facilities. DaVita, Incorporated (DaVita) provides dialysis services through outpatient dialysis facilities that it operates. Franklin Dialysis Center (Franklin) is an outpatient renal dialysis facility operated by DaVita.

OBJECTIVE

The objective of our audit was to determine if DaVita established adequate internal controls and procedures to ensure that claims for Epogen were supported and billed in accordance with Medicare requirements.

RESULTS OF AUDIT

DaVita did not establish adequate internal controls and procedures to ensure that claims for Epogen were supported and billed in accordance with Medicare requirements. Forty-four of the 143 claims reviewed did not meet Medicare payment requirements for Epogen. We identified inconsistencies between the number of units of Epogen prescribed in the written physician order, administered by the facility, and billed to Medicare. Independent dialysis facilities were required to maintain complete medical records and furnish sufficient information to support the payment. During the period when the services included in our review were provided, DaVita had controls in place for submitting claims that included Epogen. Based on our review, Franklin personnel did not always follow those procedures. In addition, medical records supporting services provided at Franklin were not always consistently archived. As a result, DaVita received payments of $15,096 for Epogen services that did not meet Medicare requirements.

DaVita personnel could not locate medical records that supported 12 claims. They believed that lack of storage space, purging of records, and staff changes lead to inconsistent archiving of medical records. As a result, we were unable to review those claims to determine if $15,984 in payments for Epogen met Medicare requirements.

DaVita personnel informed us that changes were made to Franklin’s operating procedures since the time period when the services included in this audit were rendered. The changes addressed the processes for ordering and administering medications, and filing and storing medical records. In addition, as a result of the claims we identified where Epogen was administered and the corresponding order was to “Hold EPO,” DaVita conducted a review at Franklin and three other DaVita facilities to determine if “Hold
EPO” orders were followed and billed correctly. The review showed that of 55 “Hold EPO” orders, 5 were not followed and Epogen was administered to the patient.

RECOMMENDATIONS

We recommend that DaVita:

1. Provide appropriate oversight to confirm that procedures in place ensure that claims submitted for Epogen are supported and billed in accordance with Medicare requirements;

2. Strengthen procedures to ensure that the Epogen dose administered to a patient is based on the most recent physician order;

3. Improve controls over storage of medical records to ensure that records are readily retrievable; and

4. Reimburse the Medicare program $31,080, $15,096 related to 44 claims reviewed that did not meet Medicare payment requirements for Epogen, and $15,984 for Epogen payments on the 12 claims that were not located and provided to us for review.

AUDITEE’S COMMENTS

In a written response to our draft report dated March 12, 2004, DaVita agreed to reimburse the Medicare program $31,080. In addition, DaVita’s response indicated that changes were made since the period covered by the audit that would improve controls over claims for Epogen. The full text of DaVita’s response is included as Appendix C to this report.

OFFICE OF INSPECTOR GENERAL’S RESPONSE

We are pleased that DaVita agreed to reimburse the Medicare program for payments received for claims for Epogen that did not meet Medicare requirements, and claims that were not located and provided to us for review. We commend DaVita for their stated willingness to improve controls over payments for Epogen, and for performing medical reviews on claims DaVita reviewed where an order to "Hold EPO” was not followed.
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 administered by the Centers for Medicare & Medicaid Services (CMS). Medicare covers persons 65 years of age and older along with persons under age 65 including those who are disabled and those who have ESRD.

Independent renal dialysis facilities are dialysis service providers that do not meet CMS’s requirements to be designated a hospital-based dialysis facility. These facilities are paid a composite rate per treatment for providing dialysis services to patients with ESRD. The payment covers the complete dialysis treatment except for physicians’ professional services, and separately billable laboratory services and drugs. A separate payment of $10 per 1,000 units is made for Epogen. The payment is subject to the Medicare Part B deductible and coinsurance.

Federal regulations provide the medical record requirements for independent dialysis facilities. Complete medical records, maintained in accordance with accepted professional standards and practices, should be kept on all patients. They should contain sufficient information to identify the patient clearly, justify the diagnosis and treatment, and document the results accurately. As a basis for payment, the provider must furnish sufficient information to determine whether payment is due and the amount of payment. CMS’s Medicare Intermediary Manual, Provider Reimbursement Manual, and Renal Dialysis Facility Manual include guidelines for coverage of Epogen.

Epogen, manufactured by Amgen, Incorporated, supplements a failing kidney’s inadequate supply of erythropoietin, which is produced by the kidneys and circulates through the blood stream to bone marrow where it stimulates production of red blood cells. Without adequate amounts of erythropoietin, there are too few red blood cells to deliver sufficient oxygen throughout the body. As a result, anemia develops and leaves patients tired, often impairing their ability to work or even perform routine tasks. Prior to the development of Epogen, patients were treated with frequent blood transfusions that could result in additional medical risk. The target hematocrit (percentage of red blood cells in blood volume) range for dialysis patients using Epogen therapy is 30 to 36 percent. Healthy persons have a hematocrit range of 38 to 46.

DaVita provides dialysis services to nearly 47,000 patients in 33 states and the District of Columbia through over 547 outpatient dialysis centers that it operates. DaVita also provides acute inpatient dialysis services in over 320 hospitals across the country.

Franklin is an outpatient renal dialysis facility operated by DaVita located in Philadelphia, PA. Franklin’s Medicare claims are paid by United Government Services (the fiscal intermediary).
OBJECTIVES, SCOPE, AND METHODOLOGY

Objective

The objective of our audit was to determine if DaVita established adequate internal controls and procedures to ensure that claims for Epogen were supported and billed in accordance with Medicare requirements.

Scope

Our audit included payments made by the fiscal intermediary to DaVita during the period January 1 through December 31, 2001. During that period, we identified Medicare payments of $1,747,956 for 926 claims with dates of service on or after November 1, 2000 for services provided at Franklin. Of those claims, we determined that 783 claims, totaling $1,619,254, included Epogen services. Payments for Epogen represented $510,088 of that amount.

We limited consideration of the internal control structure to those controls concerning claims submission since our objective did not require an assessment or understanding of the complete internal control structure. We concluded that our consideration of the internal control structure could be conducted more efficiently through substantive audit testing; thereby placing limited reliance on the internal control structure.

Methodology

To accomplish our objectives, we took the following steps:

- We researched applicable laws, regulations, and guidelines related to Epogen.

- We analyzed claims paid to DaVita by the fiscal intermediary for services provided at Franklin.

- We identified 155 claims with Epogen payments of $255,848 for review. Those claims included: 1) 113 claims ($218,440) where 200,000 or more units of Epogen were administered in one month, and 2) 42 claims ($37,408) where 90,000 or more units of Epogen were administered (excluding those with 200,000 or more units) in one month and the patient had a hematocrit level of 37.5 or greater.

- We reviewed medical records for 143 claims to determine if they supported the billed and reimbursed Epogen services, and payments were in compliance with CMS coverage requirements. DaVita personnel could not locate medical records that supported 12 claims representing Epogen payments of $15,984. As a result, we were unable to determine if those payments met Medicare requirements. Our
audit did not include determining whether the beneficiary’s condition warranted the need for Epogen.

- We reconciled the total payments identified during the period January 1 through December 31, 2001 from fiscal intermediary paid claim data to DaVita’s accounting records.

- We interviewed DaVita personnel and reviewed policies and procedures pertaining to submission of claims for Epogen.

Fieldwork was conducted at Franklin in Philadelphia, PA from March through November 2003. We conducted our audit in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

DaVita did not establish adequate internal controls and procedures to ensure that claims for Epogen were supported and billed in accordance with Medicare requirements. Forty-four of the 143 claims reviewed did not meet Medicare payment requirements for Epogen. We identified inconsistencies between the number of units of Epogen prescribed in the written physician order, administered by the facility, and billed to Medicare. Renal dialysis facilities were required to maintain complete medical records and furnish sufficient information to support the payment. During the period when the services included in our review were provided, DaVita had controls in place for submitting claims that included Epogen. Based on our review, Franklin personnel did not always follow those procedures. In addition, medical records supporting services provided at Franklin were not always consistently archived. As a result, DaVita received payments of $15,096 (see Appendix A) for Epogen services that did not meet Medicare requirements.

DaVita personnel could not locate medical records that supported 12 claims. They believed that lack of storage space, purging of records, and staff changes lead to inconsistent archiving of medical records. As a result, we were unable to review those claims to determine if $15,984 (see Appendix B) in payments for Epogen met Medicare requirements.

DaVita personnel informed us that changes were made to Franklin’s operating procedures since the time period when the services included in this audit were rendered. The changes addressed the processes for ordering and administering medications, and filing and storing medical records. In addition, as a result of the claims we identified where Epogen was administered and the corresponding order was to “Hold EPO,” DaVita conducted a review at Franklin and three other DaVita facilities to determine if “Hold EPO” orders were followed and billed correctly. The review showed that of 55 “Hold EPO” orders, 5 were not followed and Epogen was administered to the patient.
Medical Record Requirements

Title 42 CFR § 405.2139 required ESRD facilities to maintain complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. Medical records should be completely and accurately documented, readily available, and systematically organized to facilitate compilation and retrieval of information. Patient medical records should contain sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately.

As a basis for payment Title 42 CFR § 424.5(a)(6) required the provider to furnish sufficient information to determine whether payment was due and the amount of payment.

Claims Did Not Meet Medicare Requirements

Our review showed that 44\(^1\) (28 percent) of 143 claims reviewed at Franklin did not meet Medicare requirements for payment of Epogen. The claims included inconsistencies between the Epogen units prescribed in the written physician order, administered by the facility, and billed to Medicare. Specifically, we identified the following:

- Thirty claims where the Epogen units administered and billed to Medicare did not agree. For 24 of those claims, the units billed exceeded units administered. The units administered exceeded units billed on the remaining 6 claims.

- Nine claims where Epogen units administered exceeded units ordered by a physician. For those claims, the patient received an Epogen dose in excess of the dosage included in the physician’s orders for one or more days.

- Four claims where Epogen was administered and the corresponding physician’s order was to “Hold EPO.” For those claims, the physician order stated that Epogen was not to be administered for a period of time (the physician order included the statement “Hold EPO” and a period of time was noted). However, the order was not followed and Epogen was administered to the patient.

- Five claims where physician orders for Epogen were missing for corresponding dates of service. For those claims, DaVita personnel could not locate physician orders or any other evidence, such as progress notes, to support the dosage of Epogen to be administered to the patient for a period of time.

\(^1\) We found that 44 claims did not meet Medicare requirements. The number of claims by category totals 48 because 4 claims had errors in 2 categories.
Franklin Personnel Did Not Consistently Follow DaVita Procedures

During the period when the services included in our review were provided, DaVita had controls in place for submitting claims that included Epogen. Based on our review, Franklin personnel did not consistently follow those procedures contributing to claims not meeting Medicare requirements. In addition, factors related to filing and storage of records resulted in Epogen orders missing from medical records.

Prior to submitting monthly billing data to the DaVita’s central billing office (this office in turn submits claims to the fiscal intermediary), an administrative assistant at Franklin was required to reconcile the billing data to the information included in the medical records. Any variances should be resolved. Since the number of units of Epogen administered and billed did not agree on 30 of the 143 claims reviewed, it appeared that this procedure was not followed. In addition, a DaVita representative informed us that an administrative assistant employed at Franklin during the period January through May 2001 had not been following the process.

DaVita policy required that licensed personnel administer medications in accordance with a physician order. Medications should be administered as prescribed and no medication should be given except on the order of the physician. Since we identified nine claims where Epogen units administered exceeded units ordered by a physician and four claims where a physician’s order not to administer Epogen was not followed, it appeared that this requirement was not followed for those services. According to a Franklin document that described their current and previous processes for identifying Epogen dosage changes, at the time when the services we reviewed were rendered, several factors could contribute to a nurse missing a change to a physician order. They included the medical record returned to a file prior to the nurse recording the change, the page that included the order change was bent and appeared as though there was not a new order, the patient chart was filled and the physician could not open the binder to elevate the physician order sheet that included a dosage change, and the disorganized condition behind the nursing station where physicians would leave medical records that contained order changes.

According to DaVita personnel, the five claims where orders were missing probably represent records that were lost or misplaced in other charts as opposed to services that were not ordered by a physician. They believed that lack of storage space, purging of records, and staff changes lead to inconsistent archiving of medical records.

DaVita Received Overpayments

As a result of Franklin personnel not following DaVita procedures in place for billing Medicare and administering Epogen, and inconsistent archiving of medical records, DaVita was overpaid $15,096. This amount included:

- $4,464 net overpayment for claims where the number of units of Epogen administered and billed did not agree;
• $1,000 overpayment for claims where Epogen units administered exceeded units ordered by a physician;

• $1,992 overpayment for claims where Epogen was administered and the corresponding physician’s order was to “Hold EPO”; and

• $7,640 overpayment for claims where physician orders for Epogen were missing.

Medical Records Supporting 12 Claims Could Not Be Located

DaVita personnel could not locate medical records that supported 12 claims selected for review. They believed that lack of storage space, purging of records, and staff changes lead to inconsistent archiving of medical records. We were unable to review medical records that supported those claims. As a result, we could not determine if payments of $15,984 met Medicare requirements for Epogen.

Changes to Operating Procedures and Actions Taken at Franklin

According to DaVita personnel, changes were made to Franklin operating procedures since 2001, the time period when the majority of the services included in this audit were rendered. Specific changes included automated flow sheets that list all medications to be administered to the patient and a revised process for making treatment changes based on physician orders. The use of medical record binders was discontinued and they started using heavy duty patient records that include a physician’s order tab that is used to show when a new order was written by a physician is included in a patient record. Each month, charts were thinned and the records removed were placed in storage.

As a result of the four claims we identified where Epogen was administered and the corresponding order was to “Hold EPO,” DaVita performed a review at Franklin and three other facilities to determine if “Hold EPO” orders were followed and billed correctly. The review included 60 randomly selected patients (15 at each facility) during the period January 2001 through May 2003. During that period, 19,209 treatment days were billed and there were 1,063 changes to the orders for Epogen for the 60 patients. The changes in orders included 55 to “Hold EPO.” Of the 55, 5 orders (9 percent) were not followed and Epogen was administered to the patient. The five orders covered three claims for three patients totaling $195.20. Of the five “Hold EPO” orders not followed, one occurred at Franklin while the remaining four were at another facility. As a result of the review, training was provided at the facilities where the “Hold EPO” orders were not followed and the related $195.20 overpayment was refunded.
RECOMMENDATIONS

We recommend that DaVita:

1. Provide appropriate oversight to confirm that procedures in place ensure that claims submitted for Epogen are supported and billed in accordance with Medicare requirements;

2. Strengthen procedures to ensure that the Epogen dose administered to a patient is based on the most recent physician order;

3. Improve controls over storage of medical records to ensure that records are readily retrievable; and

4. Reimburse the Medicare program $31,080, $15,096 related to 44 claims reviewed that did not meet Medicare payment requirements for Epogen, and $15,984 for Epogen payments on the 12 claims that were not located and provided to us for review.

DaVITA COMMENTS

In a written response to our draft report dated March 12, 2004, DaVita agreed to reimburse the Medicare program $31,080 for claims that did not meet Medicare requirements and claims that were not located and provided to us for review. In addition, DaVita indicated that changes were made since the period covered by the audit that would improve controls over claims for Epogen. Those changes included:

- a document imaging system to improve controls over storage of medical records to ensure that records are readily retrievable;

- a clinical information system to capture, record, and bill services rendered that would help ensure that a physician’s order is readily accessible to the nursing staff and the most current dose is administered, and facilitates production of a clean claim by minimizing data entry errors as a result of system interfaces between the facility and billing offices; and

- a series of internal controls, including routine auditing and monitoring of billing systems and procedures to ensure that claims for Epogen and other drugs are supported and billed in accordance with Medicare requirements.

The response also stated that medical reviews were performed on all claims DaVita reviewed where a “Hold EPO” order was not followed. The medical reviews showed that there was no impact on patient safety as a result of the errors.

The full text of DaVita’s response is included as Appendix C to this report.
OFFICE OF INSPECTOR GENERAL’S RESPONSE

We are pleased that DaVita agreed to reimburse the Medicare program for payments received for claims for Epogen that did not meet Medicare requirements, and claims that were not located and provided to us for review. We commend DaVita for their stated willingness to improve controls over payments for Epogen, and for performing medical reviews on claims DaVita reviewed where an order to “Hold EPO” was not followed.
APPENDICES
## Review of Medicare Payments to DaVita, Incorporated for Epogen Services Provided at Franklin Dialysis Center, Philadelphia, Pennsylvania

### Claims With Identified Errors

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**Total $15,096**
Review of Medicare Payments to DaVita, Incorporated for Epogen Services
Provided at Franklin Dialysis Center, Philadelphia, Pennsylvania

Claims With Missing Medical Records

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Total $15,984
March 12, 2004

Mr. Stephen Virbitsky
Regional Inspector General for Audit Services
Office of Audit Services, Regiona III
Public Ledger Building, Suite 316
150 South Independence Mall West
Philadelphia, PA 19106-3499

RE: Report Number A-03-03-00003

Dear Mr. Virbitsky,

We have reviewed the draft audit report entitled “Review of Medicare Payments to DaVita, Incorporated for Epogen Services Provided at Franklin Dialysis Center, Philadelphia, Pennsylvania” dated February 4, 2004, and offer the following comments:

1. DaVita is in agreement with the Report’s findings that Franklin could not locate medical records in support of 12 claims resulting in a refund of $15,984. The audit period covered by the report was January 1, 2001 through December 31, 2001. Since this time, DaVita has implemented a documentation imaging system to improve control over storage of medical records to ensure that records are readily retrievable.

2. DaVita is in agreement with the Report’s findings that Franklin did not always maintain complete medical records and support sufficient information to support 44 claims resulting in a refund of $15,096. In addition to the above referenced documentation imaging system, DaVita has implemented a Clinical Information System (Snappy) to capture, record and bill services rendered to its patients. Snappy and its associated policies and procedures help ensure that the physician’s order is readily accessible to nursing staff so the most current medication dose is administered. Snappy also facilitates production of a clean claim by minimizing data entry errors as a result of system interfaces between the facility and billing offices.

3. Since 2001, DaVita has implemented a series of internal controls, including the routine auditing and monitoring of its documentation and billing systems and procedures, to ensure that claims submitted for Epogen and other services are supported and billed in accordance with Medicare requirements.

4. As a result of Report findings regarding “Hold EPO” orders, DaVita conducted a further review at Franklin and 3 additional DaVita facilities. The review consisted of 19,209 treatment days in which there were 1,063 changes in orders for 60 patients. DaVita’s findings were an error rate of less than 0.1% by both treatment and patient. Additionally, medical review of those instances where a Hold EPO order was not followed showed that there was no impact on patient safety as a result of the error.

Our Mission: To Be The Provider, Partner And Employer Of Choice
Thank you for the opportunity to comment on the draft audit report. It was a pleasure working with your staff on the review.

Sincerely,

[Signature]

Lori S. Richardson Pelliccioni
Vice President, Compliance
Chief Compliance Officer
ACKNOWLEDGMENTS

This report was prepared under the direction of Stephen Virbitsky, Regional Inspector General for Audit Services. Other principal Office of Audit Services staff that contributed includes:

James Maiorano, Audit Manager
John Carlucci, Senior Auditor
William Hardy, Auditor
Wayne Wright, Auditor

For information or copies of this report, please contact the Office of Inspector General’s Public Affairs office at (202) 619-1343.