



STATE OF NEW YORK
OFFICE OF THE MEDICAID INSPECTOR GENERAL
584 Delaware Ave
Buffalo, New York 14202

ANDREW M. CUOMO
GOVERNOR

JAMES C. COX
MEDICAID INSPECTOR GENERAL

June 24, 2013

[REDACTED]
DaVita, Inc.
2000 16th Street
Denver, CO 80202

FINAL AUDIT REPORT
Epogen/Aranesp Acquisition Cost Review

Audit #09-4234, 09-4235, 11-6138, 11-6139
11-6140, 11-6141, 11-6142, 11-6143,
11-6144, 11-6145, 11-6146, 11-6147,
11-6148, 11-6149, 11-6150, 11-6151,
11-6152, 11-6153, 11-6154, 11-6155,
11-6156, 11-6157, 11-6158, 11-6159,
11-6160, 11-6161, 11-6162, 11-6163,
11-6164, 11-6165, 11-6166, 11-6167
Provider # See Attachment A

Dear [REDACTED]:

The New York State Office of the Medicaid Inspector General (the "OMIG") completed an audit of Medicaid payments to DaVita facilities for the drug Epoetin Alpha ("Epogen"- procedure code J0886) paid as an ordered ambulatory service by NYS Medicaid. In accordance with Section 517.6 of Title 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York (18 NYCRR), this report represents the final determination on issues found during the OMIG's review.

This audit report incorporates consideration of any additional documentation and information presented in response to the reissued draft audit report dated August 28, 2012. Documentation and/or information provided resulted in no changes to the audit findings; therefore, the findings in the final report remain the same as the draft report. A detailed Final Report, along with supporting exhibits, is appended to this notice. The total Medicaid overpayment is \$3,290,143.81.

In accordance with 18 NYCRR Part 518 which regulates the collection of overpayments, your repayment options are described below.

OPTION #1: Make a full payment by check or money order within 20 days of the date of the final report. The check should be made payable to the New York State Department of Health and be sent with the enclosed Remittance Advice form, signed and dated, to:

[REDACTED]
 New York State Department of Health
 Medicaid Financial Management
 GNARESP Coming Tower, Room 2266
 Albany, New York 12237-0048

OPTION #2: Enter into a repayment agreement with the Office of the Medicaid Inspector General to have the overpayments applied against your future Medicaid payments. If your repayment terms exceed 90 days from the date of the final report, recoveries of amounts due are subject to interest charges at the prime rate plus 2%. If the process of establishing the repayment agreement exceeds 20 days from the date of the final report, the OMIG will impose a 15% withhold after 20 days until the agreement is established. The OMIG may require financial information from you to establish the terms of the repayment agreement. If additional information is requested, the OMIG must receive the information within 30 days of the request or a 50% withhold will be imposed. OMIG acceptance of the repayment agreement is based on your repaying the Medicaid overpayment as agreed. The OMIG will adjust the rate of recovery, or require payment in full, if your unpaid balance is not being repaid as agreed. The OMIG will notify you no later than 5 days after initiating such action.

If you wish to enter into a repayment agreement, you must forward your written request within 20 days to the following:

Bureau of Collections Management
 NYS Office of the Medicaid Inspector General
 800 North Pearl Street
 Albany, New York 12204
 [REDACTED]

Do not submit claim voids or adjustments in response to this Final Report.

If within 20 days you fail to make full payment or contact the OMIG to make repayment arrangements, the OMIG will establish a withhold equal to 50% of your Medicaid billings to secure payment and liquidate the overpayment amount, interest and/or penalty, not barring any other remedy allowed by law. The OMIG will provide notice to you no later than 5 days after the withholding of any funds.

In addition, if you receive an adjustment in your favor while you owe funds to the State, such adjustment will be applied against the amount owed.

You have the right to challenge this action and determination by requesting an administrative hearing within sixty (60) days of the date of this notice. In accordance with 18 NYCRR Section 519.18(a), "The issues and documentation considered at the hearing are limited to issues directly relating to the final determination. An appellant may not raise issues regarding the methodology used to determine any rate of payment or fee, nor raise any new matter not considered by the department upon submission of objections to a draft audit or notice of proposed agency action."

If you wish to request a hearing, the request must be submitted in writing to:

General Counsel
Office of Counsel
New York State Office of the Medicaid Inspector General
800 North Pearl Street
Albany, New York 12204

If a hearing is held, you may have a person represent you or you may represent yourself. If you choose to be represented by someone other than an attorney, you must supply along with your hearing request a signed authorization permitting that person to represent you. At the hearing, you may call witnesses and present documentary evidence on your behalf.

Questions concerning this audit may be directed to [REDACTED] at [REDACTED].

Sincerely,

[REDACTED]

Division of Medicaid Audit, Buffalo
Office of the Medicaid Inspector General

[REDACTED]
Enclosure

**NEW YORK STATE
OFFICE OF THE MEDICAID INSPECTOR GENERAL
REMITTANCE ADVICE**

NAME AND ADDRESS OF AUDITEE

DAVITA, INC.
2000 16TH STREET
DENVER, CO 80202

PROVIDER ID # - SEE ATTACHMENT A

AUDIT #09-4234, 09-4235, 11-6138, 11-6139,
11-6140, 11-6141, 11-6142, 11-6143, 11-6144,
11-6145, 11-6146, 11-6147, 11-6148, 11-6149,
11-6150, 11-6151, 11-6152, 11-6153, 11-6154,
11-6155, 11-6156, 11-6157, 11-6158, 11-6159,
11-6160, 11-6161, 11-6162, 11-6163, 11-6164
11-6165, 11-6166, 11-6167

AMOUNT DUE: \$3,290,143.81

AUDIT

TYPE

PROVIDER
 RATE
 PART B
 OTHER:

CHECKLIST

1. To ensure proper credit, please enclose this form with your check.
2. Make checks payable to: *New York State Department of Health*
3. Record the Audit Number on your check.
4. Mail check to:

[REDACTED]
New York State Department of Health
Medicaid Financial Management, B.A.M.
GNARESP Corning Tower, Room 2266
File # - **SEE ABOVE**
Albany, New York 12237-0048

Thank you for your cooperation.

NEW YORK STATE OFFICE OF THE MEDICAID INSPECTOR GENERAL

ANDREW M. CUOMO
GOVERNOR

JAMES C. COX
MEDICAID INSPECTOR GENERAL

FINAL REPORT

DAVITA, INC
2000 16TH STREET
DENVER, CO 80202

EPOGEN ACQUISITION COST REVIEW

AUDIT NUMBERS:

09-4234, 09-4235, 11-6138, 11-6139, 11-6140, 11-6141, 11-6142,
11-6143, 11-6144, 11-6145, 11-6146, 11-6147, 11-6148, 11-6149,
11-6150, 11-6151, 11-6152, 11-6153, 11-6154, 11-6155, 11-6156,
11-6157, 11-6158, 11-6159, 11-6160, 11-6161, 11-6162, 11-6163,
11-6164, 11-6165, 11-6166, 11-6167



ISSUED JUNE 24, 2013

BACKGROUND, PURPOSE AND SCOPE

The New York State Department of Health (DOH) is responsible for the administration of the Medicaid program. As an independent office within DOH, the OMIG conducts audits and reviews of providers of Medicaid reimbursable services, equipment and supplies. These audits and reviews are directed at ensuring provider compliance with applicable laws, regulations, rules and policies of the Medicaid program as set forth in NY Public Health Law, NY Social Services Law, regulations of the Department of Health and Social Services [Titles 10 and 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York] and the eMedNY Provider Manuals.

Ordered Ambulatory Services (OAS) are specific services performed by a hospital or diagnostic and treatment center on an ambulatory basis upon the order of a qualified physician, nurse practitioner, physician's assistant, dentist, podiatrist or the appropriate staff of a clinic not affiliated with the hospital or diagnostic and treatment center which is providing the ordered ambulatory service (the ordered ambulatory provider). The ordered ambulatory service is to test, diagnose or treat a recipient or a specimen taken from a recipient. Such services may include a singular occasion of service or a series of tests or treatments provided by or under the direction of a qualified practitioner.

The OMIG conducted a review of payments to DaVita facilities for the drug Epoetin Alpha ("**Epogen**" – **procedure code J0886**) paid as an ordered ambulatory service by NYS Medicaid for the service date period January 1, 2007 through December 31, 2010. For the services examined, DaVita facilities were paid \$10,543,108.04. The purpose of the review was to ensure the propriety of claims submitted to the Program for the drug Epoetin Alpha. The OMIG requested completion of a questionnaire and examined facility documentation to determine whether the actual acquisition cost of Epoetin Alpha was used at the time of claim submission. This included an examination of contracts with drug manufacturers, rebate agreements, and data on Epogen rebates during the review period provided to OMIG by DaVita.

Please note that due to the implementation of the National Provider Identifier (NPI) on September 1, 2008, there may be multiple Provider Identification Numbers associated with the Primary Provider Identification Number. The NPI is linked to the Primary Provider Identification Number. The Primary Provider Identification Number is used for correspondence and recoupment.

DETAILED FINDINGS

In addition to any specific detailed findings, rules and/or regulations which may be listed below, the following regulations pertain to all audits:

Regulations state: "By enrolling the provider agrees: (a) to prepare and to maintain contemporaneous records demonstrating its right to receive payment . . . and to keep for a period of six years from the date the care, services or supplies were furnished, all records necessary to disclose the nature and extent of services furnished and all information regarding claims for payment submitted by, or on behalf of, the provider . . . (e) to submit claims for payment only for services actually furnished and which were medically necessary or otherwise authorized under the Social Services Law when furnished and which were provided to eligible persons; (f) to submit claims on officially authorized claim forms in the manner specified by the department in conformance with the standards and procedures for claims submission; . . . (h) that the information provided in relation to any claim for payment shall be true, accurate and complete; and (i) to comply with the rules, regulations and official directives of the department." *18 NYCRR Section 504.3*

Regulations state: "All bills for medical care, services and supplies shall contain: . . . (8) a dated certification by the provider that the care, services and supplies itemized have in fact been furnished; that the amounts listed are due and owing . . . ; that such records as are necessary to disclose fully the extent of care, services and supplies provided to individuals under the New York State Medicaid program will be kept for a period of not less than six years from the date of payment . . . ; and that the provider understands that payment and satisfaction of this claim will be from Federal, State and local public funds and that he or she may be prosecuted under applicable Federal and State laws for any false claims, statements or documents, or concealment of a material fact provided. . . ."

18 NYCRR Section 540.7(a)

Regulations state: "An overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake."

18 NYCRR Section 518.1(c)

Furthermore, according to regulations, all providers must prepare and maintain contemporaneous records demonstrating their right to receive payment under the medical assistance program. In addition, the provider must keep, for a period of six years, all records necessary to disclose the nature and extent of services furnished and the medical necessity therefore, including any prescription or fiscal order for the service or supply. This information is subject to audit for a period of six years and must be furnished, upon request.

18 NYCRR Section 517.3(b)

The following detailed findings reflect the results of the audit:

1. **Failure to Claim Epogen at Acquisition Cost**

The MMIS Manual states: "Reimbursement for supplies and materials (including drugs, vaccines and immune globulins) furnished by practitioners to their patients is based on the acquisition cost to the practitioner. For all items furnished in this fashion, it is expected that the practitioner will maintain auditable records of the actual itemized invoice cost represented on the invoice. New York State Medicaid does not intend to pay more than the acquisition cost, as established by invoice, to the practitioner. Regardless of whether an invoice must be submitted to Medicaid for payment, the practitioner is expected to limit his or her Medicaid claim amount to the actual invoice cost of the item provided. Itemized invoices must document acquisition cost, the line item cost from a manufacturer or wholesaler net of any rebates, discounts or other valuable considerations."

*MMIS Provider Manual for Ordered Ambulatory Services, Fee Schedule
General Information Section, Version 2006-1*

The MMIS Manual states: "Payment will be made for ordered ambulatory goods only on a fee-for-service basis and will be limited to the lower of the actual acquisition cost of the goods or the New York State – approved fee."

*MMIS Policy Guidelines Manual for Article 28 Certified Clinics,
Version 2007-1, Section II*

The Medicaid Update also states, with regard to claiming Epogen: "As a continuation of this new billing policy for hemodialysis drugs, Epogen will no longer be billable as a separate rate code on or after January 1, 2007. Instead, as like Aranesp, it will be billed as an OAS using the procedure code **J0886 effective as of January 1, 2007**. The rate codes for Epogen will become inactive for dates of service as noted above. Please Note: reimbursement for drugs administered by providers to their patients is based on the acquisition cost to the provider for the drug dose administered to the patient. For all drugs administered in this fashion, it is expected that the provider will maintain auditable records of actual itemized invoice cost of the drug, including the numbers of doses of the drug represented on the invoice."

DOH Medicaid Update, November 2006, Vol. 21, No. 12

DaVita Inc.'s failure to comply with stated Medicaid Policy has resulted in a calculated total overpayment of \$3,290,143.81 while claiming Epoetin Alpha. The calculation is based on an examination of detailed Medicaid claims for the review period against the actual acquisition costs incurred by your facilities. The acquisition cost established by OMIG is net of Epogen rebates paid to DaVita Inc during the audit period. Contracts with drug manufacturers, rebate agreements, and data on Epogen rebates during the review period were provided to OMIG by DaVita. Our office previously furnished specific supporting claim detail in electronic format which details the calculated overpayments to respective facilities. Exhibit I contains a list of DaVita facilities and the calculated overpayments.

DETERMINATION

Based on this audit, the total amount of overpayment, as defined in 18 NYCRR 518.1 is \$3,290,143.81 and now due the New York State Department of Health.

Do not submit claim voids or adjustments in response to this Final Audit Report.

List of DaVita Facilities

Audit Number	Provider Name	Provider ID
09-4234	HUNTINGTON ARTIFICIAL KIDNEY	
09-4235	UTICA AVE DIALYSIS CLINIC	
11-6138	BRONX DIALYSIS CTR YONKERS	
11-6139	BRONX DIALYSIS CTR SOUTH BRONX	
11-6140	BRONX DIALYSIS CTR SOUNDVIEW	
11-6141	BRONX DIALYSIS CTR SHEEPSHEAD	
11-6142	BRONX DIALYSIS CTR RIVERDALE	
11-6143	BRONX DIALYSIS CTR QUEENS VILL	
11-6144	BRONX DIALYSIS CTR QUEENS	
11-6145	BRONX DIALYSIS CTR PORT WASHIN	
11-6146	BRONX DIALYSIS CTR PEEKSKILL C	
11-6147	BRONX DIALYSIS CTR LYNBROOK	
11-6148	BRONX DIALYSIS CTR GARDEN CITY	
11-6149	BRONX DIALYSIS CTR CATSKILL	
11-6150	BRONX DIALYSIS CTR	
11-6151	BRONX DIALYSIS CTR BOSTON POST	
11-6152	BRONX DIALYSIS CTR	
11-6153	PELHAM PARKWAY DIALYSIS CTR (I	
11-6154	QUEENS DIALYSIS SOUTH FLUSHING	
11-6155	BEDFORD PARK DIALYSIS CENTER	
11-6156	CELIA DILL DIALYSIS CENTER	
11-6157	CLEVE HILL DIALYSIS CTR	
11-6158	HUNTINGTON ARTIFICIAL KIDNEY F	
11-6159	HUNTINGTON ARTIFICIAL KIDNEY S	
11-6160	HUNTINGTON ARTIFICIAL KIDNEY M	
11-6161	ITHACA DIALYSIS CTR	
11-6162	HUDSON VALLEY DIALYSIS CTR	
11-6163	EASTCHESTER ROAD DIALYSIS CTR	
11-6164	PORT CHESTER DIALYSIS/RENAL	
11-6165	RENAL CARE OF BUFFALO	
11-6166	SOUTH BROOKLYN NEPHROLOGY CTR	
11-6167	UTICA AVE DIALYSIS CLINIC COLM	

OFFICE OF THE MEDICAID INSPECTOR GENERAL
 Epogen/Aranesp Acquisition Cost Review
 DaVita, Inc.

Audit Number	Provider ID	Provider Name	Total Paid	Overpayment
Bronx				
11-6138		Yonkers	\$85,115.82	\$20,298.04
11-6139		South Bronx	\$408,605.64	\$84,662.25
11-6140		Soundview	\$496,792.78	\$110,357.68
11-6141		Sheepshead	\$42,117.46	\$12,761.57
11-6142		Riverdale	\$267,266.52	\$53,905.91
11-6143		Queens Village	\$199,969.26	\$40,517.64
11-6144		Queens	\$389,603.66	\$82,646.02
11-6145		Port Washington	\$20,882.70	\$4,567.85
11-6146		Peekskill Cortland	\$45,771.16	\$9,065.18
11-6147		Lynbrook	\$4,276.00	\$1,050.40
11-6148		Garden City	\$106,200.24	\$24,577.49
11-6149		Catskill	\$21,496.58	\$3,852.14
11-6150		Bronx at home	\$5,006,402.27	\$1,791,710.00
11-6151		Boston Post rd	\$140,048.34	\$36,331.77
Total			\$2,276,303.94	
Bedford Park				
11-6155		Bedford	\$165,603.42	\$31,884.90
Total			\$31,884.90	
Celia Dill				
11-6156		Celia Dill	\$45,064.00	\$14,201.39
Total			\$14,201.39	
Cleve Hill				
11-6157		Cleve Hill	\$400,168.90	\$126,243.15
Total			\$126,243.15	
Huntington Station				
09-4234		Empire State	\$402,826.12	\$143,915.50
11-6158		Freeport	\$99,628.28	\$22,840.21
11-6159		Syosset	\$2,383.20	\$903.90
11-6160		Medford	\$54,301.58	\$13,564.92
Total			\$181,224.53	
Ithaca Dialysis				
11-6161		Ithaca	\$114,268.39	\$40,155.56
Total			\$40,155.56	
Liberty Renal				
11-6163		Liberty (Eastchester Rd)	\$72,451.26	\$15,807.30
11-6162		Knicker Bocker (Hudson)	\$176,318.02	\$61,323.48
Total			\$77,130.78	

OFFICE OF THE MEDICAID INSPECTOR GENERAL
 Epogen/Aranesp Acquisition Cost Review
 DaVita, Inc.

Audit Number	Provider ID	Provider Name	Total Paid	Overpayment
Port Chester				
11-6164		Port Chester	\$130,624.25	\$46,553.12
Total				\$46,553.12
Renal Care Buffalo				
11-6165		Renal Care	\$260,026.18	\$82,823.34
Total				\$82,823.34
South Brooklyn				
11-6166		South Brooklyn	\$276,221.28	\$94,978.77
Total				\$94,978.77
Utica				
09-4235		Utica Ave	\$950,188.95	\$277,274.92
11-6167		Columbia University	\$158,485.78	\$41,369.41
Total				\$318,644.33
Total Overpayment				\$3,290,143.81