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RECEIVED
MAY 11 2015
HEALTH FACILITIES & SERVICES REVIEW BOARD

May 7, 2015

Mike Constantino,
Supervisor, Project Review Section
Illinois Health Facilities & Services Review Board
525 West Jefferson Street (2nd Floor)
Springfield IL 62761

Project: 15-003
Applicant: DaVita Vermilion County Dialysis
RE: Written comments in opposition

Dear Mr. Constantino;

I represent Danville Dialysis Services, LLC in Danville, Illinois and I write to oppose the Application of DaVita/Vermilion County Dialysis for a Certificate of Need to construct a second ESRD facility in Danville.

Firstly, as you know, DaVita originally, though inexplicably, sought to call their project "Danville Dialysis" even though the existing ESRD provider in the community is called Danville Dialysis Services, LLC. This has created a number of problems. DDS sent a cease and desist letter to DaVita insisting that they discontinue the improper infringement upon DDS's business name. And they have done so. But the Board has continued to use the original "Danville Dialysis" name on its documentation. This created some confusion at the public hearing where the sign-in sheets asked if the attendees supported or opposed "Danville Dialysis". Many of the attendees at the public hearing were there to oppose the DaVita project and to support the existing provider, Danville Dialysis Services, LLC. We believe that the name "Danville Dialysis" on the sign-in sheets may have caused a number of people who oppose the project to mark "Support" on those sign-in sheets to indicate their support for DDS. Even with this issue, it was clear that the overwhelming majority of attendees opposed the project.

Similarly, we ask that the Board take care in review of the transcript of the public hearing so as to not confuse the many supports of DDS who spoke in opposition to the project with the few who spoke in support. Many started their remarks with a statement of "I support Danville Dialysis" which should not be viewed as support for DaVita.

Turning to the alleged need of the project, it is irrefutable that there is no need for the project under state standards. The existing facility is operating at just 61.4% of capacity. By the Board's calculations for the HSA, there is already an excess number of stations in the Service Area. The Applicant does not dispute these facts. Instead, the Applicant has identified three reasons why this project is needed in spite of the excess capacity. As you can see, however, each of these bases is unfounded.

1. Alleged Insurance Restrictions

The Applicant repeatedly alleges that the existing provider, DDS, has a restrictive admission policy based upon insurance. Applicant claims that it will accept self-pay patients and that DDS does not. This argument is uncompelling and disingenuous. Firstly, with the passage of the Patient Protection and Affordable Care Act, the number of self-pay patients is sharply declining with each enrollment period. The goal of the individual mandate provision of the ACA was to require every American to be covered by a qualified health plan by January 2014. Under the PPACA, every qualified plan must provide coverage for ESRD services. So lack of coverage is not a legitimate basis upon which to approve an unneeded additional facility.

More importantly on this point, however is DaVita's own restrictive admission policy. Looking at the State's own data from prior to the January 2014 PPACA implementation date, it is clear that DaVita facilities in Illinois do not usually accept self-pay or charity care patients. It is wholly disingenuous for DaVita to claim that its proposed Danville facility is needed to treat self-pay patients when the other DaVita facilities almost never do so. Attached hereto and incorporated herein are the 2011-2013 DaVita facility profiles for Illini Renal Dialysis from the IHFSRB website. It is claimed by DaVita that the new facility is needed to treat self-pay patients from Danville who were refused by DDS and instead forced to travel to Illini in Champaign, some 40 miles away. As you can see, however, DaVita's own data doesn't support this claim.

In 2013, DaVita-Illini treated no self-pay patients and no charity care patients. In 2012, DaVita-Illini treated no self-pay patients and no charity care patients. We have to go back to 2011 to find the one self-pay and one charity care patient treated by Illini. In three years of reported data, 1 self-pay and 1 charity care patient were reported. And that was more than three years ago.

Finally, it is noted that two "supporters" of the project at the public hearing were covered by the Department of Veterans Affairs presumably through TRICARE/CHAMPUS or a similar program. It is true that in the past, DDS was unable to see these patients because DaVita held the only contract with the VA in the service area. All patients where thus forced to travel to a DaVita facility outside of Danville to utilize their insurance coverage. But they were not forced to do so because of a policy of DDS, but because of DaVita's exclusive arrangement with the

VA. But as of March 18, 2015 (as was testified to by Rita Casner at the public hearing) DDS is now, effectively immediately, an approved in-network provider for TRICARE/CHAMPUS and all other applicable VA insurance programs. Any past restriction has thus been removed and is no longer a justification for the project.

2. Alleged "Permanent Access" Restrictions

The Application makes the additional accusation that DDS doesn't accept patients without "permanent access". In other words, DaVita claims that DDS will refuse to treat any patient without an AV Fistula to provide access. But this accusation is completely false. As was testified to by Dr. Sodhi, Nurse Casner and another DDS nurse at the public hearing, DDS accepts all patients regardless of permanent or temporary access. Always has. Always will. Currently DDS's patient population is a broad mix of permanent and temporary access. The accusation that DDS will only accept patients with an AV Fistula is simply false and should be disregarded by the Board.

3. In-center treatment for Home Dialysis and PD patients

Finally, the Applicant claims that the new facility is needed to provide occasional respite in-center treatment to DaVita home hemodialysis and peritoneal dialysis patients. DaVita has a Home Dialysis/PD business in Danville. Occasionally, for a variety of reasons, those patients will require in-center treatment. DaVita concedes that they wish to keep these patients in the DaVita system by not referring them out to DDS but instead making them travel to DaVita-Illini in Champaign, some 40 miles away. But this is NOT because DDS can't or wont service the patients. This is solely because DaVita (or the referring physician) has only referred the patient to Illini in order to keep the patient within the DaVita system. The obvious fear is that once a patient received in-center treatment at DDS, DaVita may lose that patient forever. But this Board is not charged with the task of enabling DaVita to protect its market share at the expense of the long-standing local provider. DDS has more than enough capacity to provide in-center services to DaVita home dialysis patients.

Having refuted the only justifications offered by the Applicant to support this unneeded facility, the only possible other explanation is that market growth will consume DDS's excess capacity. This assertion is, of course, rank speculation. The DDS facility approved by the Board was designed to permit the expansion of 5 additional licensed stations should the market growth justify that expansion. There is no reason for the Board to approve a separate 8 station facility on the speculation that the market will grow into the capacity, when DDS is already positioned to immediately add 5 stations should market growth justify the application to the Board for that approval. So far, it never has. There is simply no credible evidence that the market will grow into this proposed additional capacity at any time in the foreseeable future.

4. Suitability of the applicant

Finally, it must be noted that there are strong concerns over the apparent suitability of the Applicant to receive yet another certificate of need in this State. In my opinion, it is well known that DaVita has had a rocky past with respect to federal investigations into its referral relationships. It has been reported in various media outlets and on the U.S. Department of Justice website that in October 2014, DaVita agreed to pay $350 million to resolve claims that it violated the False Claims Act by paying kickbacks to induce the referral of patients to its dialysis clinics. (see attached statement from the Department of Justice). The attached article from Nephrology News and Issues from May 5, 2015 discloses that in an entirely separate multi-million dollar settlement, DaVita has apparently agreed to pay a whopping $495 million settlement in a whistleblower law suit filed in Atlanta over its alleged practice of billing for larger volumes of prescription medications that it actually administered to patients. Also attached is an article reported in Dialysis/Nephrology Nursing News from April 2015, asserting that DaVita paid an additional $22 million to four states to settle anti-kickback charges and in 2012 paid $55 million in settlement of another whistleblower lawsuit and other fraud allegations. According to the article, apparently DaVita is now the subject of yet another federal fraud investigations and that concern has precipitated the resignation of its CFO, Garry Menzel.

DDS is not accusing DaVita of any wrongdoing, but is instead, merely raising an issue as to the suitability of an applicant with such an apparent long history of questionable practices from moving into the market to compete with an existing facility never accused of any wrongdoing whatsoever.

In summary, there is no justification for the proposed facility and strong concerns as to the appropriateness of making an exception for this Applicant to construct this unneeded project. Danville Dialysis Services respectfully urges the Board to deny Application 15-003.

Respectfully submitted,

Thomas J. Pliura, M.D., J.D.
Attorney for Danville Dialysis Services, L.L.C.

Enc.: As indicated

END STAGE RENAL DIALYSIS - FACILITY PROFILE 2013

Ownership, Management and General Information

Name:	Illini Renal Dialysis	**Legal Entity Operator:**	DVA Renal Heathcare, INC
Address:	507 E. University Avenue	**Legal Entity Owner:**	
City:	Champaign	**Ownership Type:**	For Profit Corporation
County:	Champaign	**Property Owner:**	Barr Real Estate
HSA:	4	**Other Ownership:**	
Medicare ID:	14-2633	**Medical Director Name:**	Dr. Attia, Abdel-Moneim
		Provides Incenter Noctural Dialysis:	☐

STATION INFORMATION		FACILITY STAFFING - FULL TIME EQUIVALENT	
Authorized Stations as of 12/31/2013:	11	**Full-Time Work Week:**	32
Certified Stations by CMS:	11	**Regsitered Nurse :**	4
Peak Authorized Stations Operated:	11	**Dialysis Technician :**	4
Authorized Stations Setup and Staffed in Oct 1-7:	11	**Dietician :**	1
Isolation Stations Set up in Oct 1-7:	0	**Social Worker:**	1
(subset of authorized stations)		**LPN :**	0
Number of Shifts Operated per day		**Other Health :**	0
		Other Non-Health:	1

Dialysis Station Utilization for the Week of Oct 1 - 7

Date of Operation	Oct 1	Oct 2	Oct 3	Oct 4	Oct 5	Oct 6	Oct 7
Hours operated	12	14	10	14	12	0	14
Number of Patients Treated	18	26	15	26	16	0	25

Facility Utilization Information

Facility Reported Patient Information		Facility Reported Treatment Information	
Patients treated as of 1/1/2013: (Beginning patients)	43	**In-Center Treatments in calendar year:**	6,710
Patients treated as of 12/31/2013: (Ending patients)	46	**Number of Missed Treatments:**	287
Total Unduplicated patients treated in calendar year:	102	**Average Daily Treatments:**	
		Average Treatment Time (min):	225.0

ADDITIONS to the FACILITY		LOSSES to the FACILITY		USE RATE for the FACILITY	
New Patients:	36	**Recovered patients:**	8	**Treatment Capacity/year (based on Stations):**	10,296
Transient Patients:	29	**Transplant Recipients:**	8	**Use Rate (Treatments/Treatment capacity):**	65%
Patients Re-Started:	1	**Patients transferred out:**	15	**Use Rate (including Missed Treatments):**	68%
Post-Transplant Patien	0	**Patients voluntarily discontinued**	0	**Use Rate (Begining patients treated):**	65%
Total:	**66**	**Patients lost to follow up:**	0	**Use Rate (Year end Patients/Stations*6):**	70%
		Patients deceased:	15	**Renal Network Use Rate:**	70%
		Total:	**46**		

Patients and Net Revenue by Payor Source

	Medicare	Medicaid	Private Insurance	Private Pay	Other Public	TOTAL	Charity Care
	68.6%	*6.9%*	*15.7%*	*0.0%*	*8.8%*	*100.0%*	*0.0%*
Patient	70	7	16	0	9	**102**	0
1/1/2013 to 12/31/2013	*42.8%*	*3.8%*	*41.2%*	*0.0%*	*12.2%*	*100.0%*	*0.0%*
Net Revenue	$1,108,666	$97,736	$1,067,583	$0	$317,267	**$2,591,251**	$0

Patients by Age and Sex

AGE GROUPS	MALE	FEMALE	TOTAL
<14 yrs	0	0	0
15-44 yr	8	4	12
45-64 yr	26	18	44
65-74 yr	8	8	16
75 < yrs	12	18	30
Total	54	48	102

Patients by Race

Asian Patients:	1
Native American/ Indian:	1
Black/ African American :	38
Hawaiian /Pacific Islande	0
White:	58
Unknown :	4
TOTAL:	102

Patients by Ethnicity

Hispanic Latino Patients:	4
Non-Hispanic Latino Patien	97
Unknown Ethnicity Patients	1
TOTAL:	102

Source: Data based on 2013 Annual ESRD Questionnaire administered on behalf of Illinois Department of Public Health, Health Systems Development.

END STAGE RENAL DIALYSIS - FACILITY PROFILE 2012

Ownership, Management and General Information

Name:	Illini Renal Dialysis	**Legal Entity Operator:**	Davita Inc.
Address:	507 E. University Avenue	**Legal Entity Owner:**	
City:	Champaign	**Ownership Type:**	For Profit Corporation
County:	Champaign	**Property Owner:**	Barr Real Estate
HSA:	4	**Other Ownership:**	
Medicare ID:	14-2633	**Medical Director Name:**	Dr.Abdel-Moneim, Attia
		Provides Incenter Noctural Dialysis:	☐

STATION INFORMATION		FACILITY STAFFING - FULL TIME EQUIVALENT	
Authorized Stations as of 12/31/2012:	10	**Full-Time Work Week:**	32
Certified Stations by CMS:	10	**Regsitered Nurse :**	5
Peak Authorized Stations Operated:	10	**Dialysis Technician :**	3
Authorized Stations Setup and Staffed in Oct 1-7:	10	**Dietician :**	1
Isolation Stations Set up in Oct 1-7:	0	**Social Worker:**	1
(subset of authorized stations)		**LPN :**	0
Number of Shifts Operated per day		**Other Health :**	0
		Other Non-Health:	1

Dialysis Station Utilization for the Week of Oct 1 - 7

Date of Operation	Oct 1	Oct 2	Oct 3	Oct 4	Oct 5	Oct 6	Oct 7
Hours operated	12	10	12	10	12	12	0
Number of Patients Treated	23	19	21	18	22	21	0

Facility Utilization Information

Facility Reported Patient Information		Facility Reported Treatment Information	
Patients treated as of 1/1/2012: (Beginning patients)	42	**In-Center Treatments in calendar year:**	5,988
		Number of Missed Treatments:	134
Patients treated as of 12/31/2012: (Ending patients)	43	**Average Daily Treatments:**	
		Average Treatment Time (min):	225.0
Total Unduplicated patients treated in calendar year:	91		

ADDITIONS to the FACILITY		LOSSES to the FACILITY		USE RATE for the FACILITY	
New Patients:	25	**Recovered patients:**	2	**Treatment Capacity/year (based on Stations):**	9,360
Transient Patients:	21	**Transplant Recipients:**	1	**Use Rate (Treatments/Treatment capacity):**	64%
Patients Re-Started:	0	**Patients transferred out:**	30	**Use Rate (including Missed Treatments):**	65%
Post-Transplant Patien	2	**Patients voluntarily discontinued**	4	**Use Rate (Begining patients treated):**	70%
Total:	**48**	**Patients lost to follow up:**	0	**Use Rate (Year end Patients/Stations*6):**	72%
		Patients deceased:	9	**Renal Network Use Rate:**	72%
		Total:	**46**		

Patients and Net Revenue by Payor Source

	Medicare	Medicaid	Private Insurance	Charity	Private Pay	Other Public	TOTAL
	62.6%	*9.9%*	*22.0%*	*0.0%*	*0.0%*	*5.5%*	*100.0%*
Patient	57	9	20	0	0	5	**91**
1/1/2012 **to** 12/31/2012	*36.0%*	*3.5%*	*54.2%*	*0.0%*	*0.0%*	*6.2%*	*100.0%*
Net Revenue	$1,113,897	$109,298	$1,677,703	$0	$0	$191,982	**$3,092,880**

Patients by Age and Sex

AGE GROUPS	MALE	FEMALE	TOTAL
<14 yrs	0	0	0
15-44 yr	9	1	10
45-64 yr	29	13	42
65-74 yr	9	4	13
75 < yrs	10	16	26
Total	57	34	91

Patients by Race

Asian Patients:	1
Native American/ Indian:	1
Black/ African American :	37
Hawaiian /Pacific Islande	0
White:	52
Unknown :	0
TOTAL:	91

Patients by Ethnicity

Hispanic Latino Patients:	7
Non-Hispanic Latino Patien	84
Unknown Ethnicity Patients	0
TOTAL:	91

Source: Data based on 2012 Annual ESRD Questionnaire administered on behalf of Illinois Department of Public Health, Health Systems Development.

END STAGE RENAL DIALYSIS - FACILITY PROFILE 2011

Ownership, Management and General Information

Name:	Illini Renal Dialysis	**Legal Entity Operator:**	Davita, Inc.
Address:	507 E. University Avenue	**Legal Entity Owner:**	
City:	Champaign	**Ownership Type:**	For Profit Corporation
County:	Champaign	**Property Owner:**	Barr Real Estate
HSA:	4	**Other Ownership:**	
Medicare ID:	14-2633	**Medical Director Name:**	Abdel Moniem-Attia
		Provides Incenter Noctural Dialysis:	☐

STATION INFORMATION		FACILITY STAFFING - FULL TIME EQUIVALENT	
Authorized Stations as of 12/31/2011:	10	**Full-Time Work Week:**	40
Certified Stations by CMS:	10	**Regsitered Nurse :**	4
Peak Authorized Stations Operated:	10	**Dialysis Technician :**	2
Authorized Stations Setup and Staffed in Oct 1-7:	10	**Dietician :**	1
Isolation Stations Set up in Oct 1-7:	0	**Social Worker:**	1
(subset of authorized stations)		**LPN :**	0
Number of Shifts Operated per day	2	**Other Health :**	0
		Other Non-Health:	1

Dialysis Station Utilization for the Week of Oct 1 - 7

Date of Operation	Oct 1	Oct 2	Oct 3	Oct 4	Oct 5	Oct 6	Oct 7
Hours operated	12	0	12	12	12	12	12
Number of Patients Treated	21	0	21	22	22	19	18

Facility Utilization Information

Facility Reported Patient Information		Facility Reported Treatment Information	
Patients treated as of 1/1/2011: (Beginning patients)	39	**In-Center Treatments in calendar year:**	5774
Patients treated as of 12/31/2011: (Ending patients)	43	**Number of Missed Treatments:**	196
Total Unduplicated patients treated in calendar year:	77	**Average Daily Treatments:**	20
		Average Treatment Time (min):	3

ADDITIONS to the FACILITY		LOSSES to the FACILITY		USE RATE for the FACILITY	
New Patients:	20	**Recovered patients:**	3	**Treatment Capacity/year (based on Stations):**	9360
Transient Patients:	16	**Transplant Recipients:**	1	**Use Rate (Treatments/Treatment capacity):**	62%
Patients Re-Started:	2	**Patients transferred out:**	22	**Use Rate (including Missed Treatments):**	64%
Post-Transplant Patient	1	**Patients voluntarily discontinued**	2	**Use Rate (Begining patients treated):**	65%
Total:	**39**	**Patients lost to follow up:**	0	**Use Rate (Year end Patients/Stations*6):**	72%
		Patients deceased:	4	**Renal Network Use Rate:**	75%
		Total:	**32**		

Patients and Net Revenue by Payor Source

	Medicare	Medicaid	Private Insurance	Charity	Private Pay	Other Public	TOTAL
Patients	*66.2%*	*3.9%*	*24.7%*	*1.3%*	*1.3%*	*2.6%*	*100.0%*
	51	3	19	1	1	2	**77**
1/1/2010 to 12/31/2010	*28.0%*	*4.9%*	*50.5%*	*1.5%*	*1.5%*	*13.6%*	*100.0%*
Net Revenue	$1,144,485	$198,884	$2,065,291	$63,068	$63,068	$558,055	**$4,092,850**

Patients by Age and Sex

AGE GROUPS	MALE	FEMALE	TOTAL
<14 yr	0	0	0
15-44 yr	5	4	9
45-64	17	14	31
65-74 yr	8	9	17
75 < yr	12	8	20
Total	42	35	77

Patients by Race

Asian Patient	2
Native American/ India	0
Black/ African American	25
Hawaiian /Pacific Islande	0
White:	50
Unknown	0
TOTAL:	77

Patients by Ethnicity

Hispanic Latino Patient	4
Non-Hispanic Latino Patient	73
Unknown Ethnicity Patient	0
TOTAL:	77

Source: Data based on 2011 Annual ESRD Questionnaire administered on behalf of Ilinois Department of Public Health, Health Systems Development.

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, October 22, 2014

DaVita to Pay $350 Million to Resolve Allegations of Illegal Kickbacks

DaVita Healthcare Partners, Inc., one of the leading providers of dialysis services in the United States, has agreed to pay $350 million to resolve claims that it violated the False Claims Act by paying kickbacks to induce the referral of patients to its dialysis clinics, the Justice Department announced today. DaVita is headquartered in Denver, Colorado and has dialysis clinics in 46 states and the District of Columbia.

The settlement today resolves allegations that, between March 1, 2005 and February 1, 2014, DaVita identified physicians or physician groups that had significant patient populations suffering renal disease and offered them lucrative opportunities to partner with DaVita by acquiring and/or selling an interest in dialysis clinics to which their patients would be referred for dialysis treatment. DaVita further ensured referrals of these patients to the clinics through a series of secondary agreements with the physicians, including entering into agreements in which the physician agreed not to compete with the DaVita clinic and non-disparagement agreements that would have prevented the physicians from referring their patients to other dialysis providers.

“Health care providers should generate business by offering their patients superior quality services or more convenient options, not by entering into contractual agreements designed to induce physicians to provide referrals,” said Deputy Assistant Attorney General for the Justice Department’s Civil Division Jonathan F. Olin. “The Justice Department is committed to protecting the integrity of our healthcare system and ensuring that financial arrangements in the healthcare marketplace comply with the law.”

The government alleged that DaVita used a three part joint venture business model to induce patient referrals. First, using information gathered from numerous sources, DaVita identified physicians or physician groups that had significant patient populations suffering renal disease within a specific geographic area. DaVita would then gather specific information about the physicians or physician group to determine if they would be a “winning practice.” In one transaction, a physician’s group was considered a “winning practice” because the physicians were “young and in debt.” Based on this careful vetting process, DaVita knew and expected that many, if not most, of the physicians’ patients would be referred to the joint venture dialysis clinics.

Next, DaVita would offer the targeted physician or physician group a lucrative opportunity to enter into a joint venture involving DaVita’s acquisition of an interest in dialysis clinics owned by the physicians, and/or DaVita’s sale of an interest in its dialysis clinics to the physicians. To make the transaction financially attractive to potential physician partners, DaVita would manipulate the financial models used to value the transaction. For example, to decrease the apparent value of clinics it was selling, DaVita would employ an assumption it referred to as the “HIPPER compression,” which was based on a speculative and arbitrary projection that future payments for dialysis treatments by commercial insurance companies would be cut by as much as half in future years. These manipulations resulted in physicians paying less for their interest in the joint ventures and realizing returns on investment which were extraordinarily high, with pre-tax annual returns exceeding 100 percent in some instances.

Last, DaVita ensured future patient referrals through a series of secondary agreements with their physician partners. These included paying the physicians to serve as medical directors of the joint venture clinics, and entering into agreements in which the physicians agreed not to compete with the clinic. The non-compete agreements were structured so that they bound all physicians in a practice group, even if some of the physicians were not part of the joint venture arrangements. These agreements also included provisions prohibiting the physician partners from inducing or advising a patient to seek treatment at a competing dialysis clinic. These agreements were of such importance to DaVita that it would not conclude a joint venture transaction without them.

The Government's complaint identifies a joint venture with a physicians' group in central Florida as one of several examples illustrating DaVita's scheme to improperly induce patient referrals. The group had previously been in a joint venture arrangement involving dialysis clinics with Gambro, Inc., a dialysis company acquired by DaVita in 2005. Prior to the acquisition, Gambro had entered into a settlement with the United States to resolve alleged kickback allegations that, among other things, required Gambro to unwind its joint venture agreements. As a consequence, Gambro purchased the group's interest in the joint venture clinics and agreed to a "carve-out" of the associated non-competition agreement which allowed the group to open its own dialysis clinic nearby, which it did. After acquiring Gambro, DaVita bought a majority position in the group's newly established dialysis clinic, and sold a minority position in three DaVita-owned clinics. Despite the fact that each of the clinics involved were roughly comparable in terms of size and profits, DaVita agreed to pay $5,975,000 to acquire a 60 percent interest in the group's clinic, while selling a 40 percent interest in the three clinics it owned for a total of $3,075,000. As part of this joint venture, the group agreed to enter into new non-compete agreements.

"This case involved a sophisticated scheme to compensate doctors illegally for referring patients to DaVita's dialysis centers. Federal law protects patients by making buying and selling patient referrals illegal, so as to ensure that the interest of the patient is the exclusive factor in the referral decision," said U.S. Attorney John Walsh. "When a company pays doctors and/or their practice groups for patient referrals, the company's focus is not on the patient, but on the profit to be extracted from providing services to the patient."

In conjunction with today's announcement, the U.S. Attorney's Office noted that after extensive review, it is closing its criminal investigation of two specific joint ventures.

As part of the settlement announced today, DaVita has also agreed to a Civil Forfeiture in the amount of $39 million based upon conduct related to two specific joint venture transactions entered into in Denver, Colorado. Additionally, DaVita has entered into a Corporate Integrity Agreement with the Office of Counsel to the Inspector General of the Department of Health and Human Services which requires it to unwind some of its business arrangements and restructure others, and includes the appointment of an Independent Monitor to prospectively review DaVita's arrangements with nephrologists and other health care providers for compliance with the Anti-Kickback Statute.

"Companies seeking to boost profits by paying physician kickbacks for patient referrals – as the government contended in this case – undermine impartial medical judgment at the expense of patients and taxpayers," said Daniel R. Levinson, Inspector General for the U.S. Department of Health and Human Services. "Expect significant settlements and our continued investigation of such wasteful business arrangements."

The settlement resolves allegations originally brought in a lawsuit filed under the qui tam or whistleblower provisions of the False Claims Act, which allow private parties to bring suit on behalf of the government and to share in any recovery. The suit was filed by David Barbetta, who was previously employed by DaVita as a Senior Financial Analyst in DaVita's Mergers and Acquisitions Department. Mr. Barbetta's share of the recovery has yet to be determined.

This settlement illustrates the government's emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than $22.4 billion through False Claims Act cases, with more than $14.2 billion of that amount recovered in cases involving fraud against federal health care programs.

The case was handled by the United States Attorney's Office for the District of Colorado, the Civil Division of the United States Department of Justice, and the U.S. Department of Health and Human Services, Office of Inspector General.

The lawsuit is captioned *United States ex rel. David Barbetta v. DaVita, Inc. et al.*, No. 09-cv-02175-WJM-KMT (D. Colo.). The claims settled by this agreement are allegations only; there has been no determination of liability.

14-1167

Civil Division

Updated October 22, 2014

NEPHROLOGY
NEWS & ISSUES

Home

DaVita says it will pay up to $495 million to settle Atlanta whistleblower lawsuit

May 5, 2015

A previous version of this story said the plaintiffs contended that DaVita boosted profits by prescribing and billing for vials of drugs that were larger than the doses actually administered. DaVita does not prescribe drugs, it administers them, and the suit reflected that.

Dialysis provider DaVita Kidney Care said it would pay up to $495 million to settle a whistleblower suit filed in Atlanta that dates back to 2007. The money consists of a settlement amount of $450 million and attorney fees and other costs of $45 million, the company said in its first quarter earnings report. DaVita Kidney Care, a division of DaVita HealthCare Partners, said that they have not yet signed a definitive settlement agreement, and cannot guarantee that the suit will not ultimately settle for a larger amount.

"We should be held to high standards of accountability," said Javier Rodriguez, CEO of DaVita Kidney Care. "Our 67,000 teammates across 11 countries look forward to putting this behind us. We can now renew our focus on collaborating with regulators to avoid situations like this going forward."

The case was filed under the federal False Claims Act in 2007 on behalf of Dr. Alon J. Vainer, a board-certified nephrologist who was medical director for several of DaVita's dialysis clinics, and Daniel Barbir, a registered nurse who worked as a Cumming clinic director. The suit was amended in 2011.

The two former employees claimed that, for years, DaVita intentionally created waste when administering Zemplar and Venofer, and submitted claims for such waste for reimbursement, in violation of the False Claims Act.

"DaVita's revenue maximizing decisions, including not to re-enter vials of Zemplar and Venofer and to choose Venofer over Ferrlecit, as well as mandating the most wasteful Zemplar vial combinations and adopting the most wasteful iron protocol, were revenue-based and not for clinical or efficiency purposes. Money, not clinical concerns, dictated protocols within DaVita," according to the complaint.

"Although we believe strongly in the merits of our case, we decided it was in our stakeholders' best interests to resolve it," said Chief Legal Officer for DaVita HealthCare Partners Kim Rivera. "The potential mandatory penalties for being found in the wrong in even a small percentage of instances were simply too large."

The dialysis provider paid $389 million in Oct. 2014 to resolve claims that it paid kickbacks to receive referrals of patients to its dialysis clinics. In 2012, the company paid $55 million plus attorneys' fees for litigation filed in 2002 in Texas that claimed DaVita double-billed Medicare for the anemia drug Epogen.

"Our current compliance program is already much more comprehensive than what we had five to 10 years ago," said Chief Compliance Officer for DaVita HealthCare Partners Jeanine Jiganti. "We will use this experience to take our effectiveness to a whole new level going forward."

HEALTHCARE

DaVita HealthCare Partners Inc. (DVA) CFO Resigns Amid Another Federal Inspection

DVA HUM AMGN CS

By: HANNAH ISHMAEL
Published: Mar 29, 2015 at 10:05 am EST

DaVita HealthCare Partners Inc. (NYSE:DVA) announced Friday the resignation of Garry E. Menzel, CFO since November 2013, as the company grapples with another federal inquiry. Mr. Menzel is expected to stay with the company until a smooth transition of the position takes place to chief accounting officer, James Hilger, on a temporary basis. The changeover will be effective from Monday.

The Denver-based company has been involved in several high-profile federal civil and criminal investigation cases since the past few years. The tarnished corporate image resulting from these involvements is believed to be a one of the reasons for Mr. Menzel's resignation from the company.

Recently, DaVita has been pulled into a federal investigation of health insurer Humana Inc's (NYSE:HUM) risk-adjustment practices under its Medicare Advantage Plans, including the insurer's basis for patient diagnoses. The US Heath and Human Services has subpoenaed all Humana Medicare Advantage Plans, which JSA HealthCare Corp., a branch of DaVita HealthCare Partners, served during 2008 to 2013. There are reports that doctors associated with DaVita may have over-billed Medicare.

The US Health and Human Services has discovered patient information regarding transportation services from DaVita. The medical need for these services, reportedly being provided at six dialysis centers operated by DaVita in California, is under scrutiny. DaVita, however, maintains that the company "does not provide transportation or bill for the transport of its dialysis center."

Only last October, DaVita had paid $389.5 million to settle a civil and criminal anti-kickback investigation by the US Department of Justice which alleged that the company has been paying physicians kickbacks in exchange for referrals of dialysis patients to DaVita-operated clinics since 2005. In February 2015, the company paid an additional $22 million to four states as part of the states' portion of the federal anti-kickback case settlement.

In 2012, the company also paid $55 million in settlement of a whistle-blower lawsuit and other fraud allegations. A DaVita employee, who had previously worked at Espogen-maker Amgen, Inc. (NASDAQ:AMGN), had claimed that DaVita overused the anemia drug Espogen in dialysis patients.

While announcing Mr. Menzel's resignation, DaVita maintained that the company has "long maintained a strong finance leadership team." DaVita was also optimistic that the experienced finance leadership will help Mr. Hilger in "guiding and executing the financial strategy of the organization."

Mr. Menzel, a Ph.D in molecular biology from the University of Cambridge and an MBA from Stanford University, previously served as a CFO and chief operating officer at Regulus Therapeutics Inc (NASDAQ:RGLS). He now plans to make a return to the biopharmaceutical industry.

Mr. Menzel has also worked with Credit Suisse Group AG (ADR) (NYSE:CS) as their global head of life sciences and managing director and with Goldman Sachs Group Inc (NYSE:GS) in the position of global head of biotechnology and managing director in the past.

Mr. Hilger has been appointed interim CFO at DaVita twice earlier, once in 2007 and another time in 2012.

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Scott Hendren

From: Rita Casner <rita@bsodhi.com>
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Note #3, they can't seem to stay out of trouble.

From: ANNA National Office [mailto:anna-ealert@ajj.com]
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DIALYSIS / NEPHROLOGY NURSING NEWS

April 2, 2015

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Bi-Weekly News Headlines (March 19 – April 2, 2015)

1. **Taken to the Woodshed... Again**
   Editorial from *Nephrology News & Issues*. Related article from RenalWEB.

2. **An Examination of CMS's Dialysis Star-Rating System**
   (9-page pdf) Report from the healthcare law firm of Hooper, Lundy & Bookman.

3. **DaVita HealthCare Partners Inc. CFO Resigns Amid Another Federal Inspection**
   Articles from Bidness Etc, *Healthcare Finance*, and the *Denver Post*. Press release from DaVita.

4. **FDA Information on Newly Approved Devices To Treat Dialysis-Related Amyloidosis:**
   - Consumer Information on: Lixelle Beta 2-microglobulin Apheresis Column - H130001
   - Summary Information for: Lixelle Beta 2-microglobulin Apheresis Column

5. **Tackling the High Risk of Infection in Dialysis Patients**
   Article from *Nephrology News & Issues*.