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HEALTH FACILITIES & SERVICES REVIEW BOARD

December 5, 2013

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Via FedEx

Michael Constantino
Illinois Department of Public Health
Health Facilities and Services Review Board
525 West Jefferson Street, Second Floor
Springfield, IL 62761

Re: Comments to RCG Evanston State Agency Report

Dear Mr. Constantino:

This office represents DaVita HealthCare Partners Inc. (“DaVita”). In that capacity, we are writing in response to the Illinois Health Facilities and Services Review Board (the “State Board”) State Agency Report (the “SAR”) on the six station expansion of RCG Evanston. While DaVita appreciates the time and effort of the State Board and staff in preparing the SAR, it failed to apply the correct criterion for Planning Area Need – Service Demand for an expansion of an existing in-center hemodialysis facility. If the correct criterion was utilized, a negative finding would have been made as RCG Evanston has not operated above the State Board’s utilization standard in each of the past two years. This corrected information should be provided to the State Board, so it can properly assess whether an expansion of RCG Evanston is warranted.

Under Section 1110.1430(b)(4) of the State Board’s rules, the purpose of an expansion of an existing in-center hemodialysis facility is to reduce the facility’s high utilization and meet projected demand for services. To satisfy this criterion, an applicant must document: (1) average utilization of the facility met or exceeded the State Board’s utilization standard of 80% in each of the last two years and (2) either provide physician referral letters to justify the expansion or document rapid population growth in the facility’s market area. (Attachment 1).

The SAR applies the incorrect criterion for Planning Area Need – Service Demand. Instead of applying the criterion for Expansion of In-Center Hemodialysis Service (77 Ill. Admin Code § 1110.1430(b)(4)), the SAR utilizes the criterion for Establishment of In-Center

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Hemodialysis Service (77 Ill. Admin Code § 1110.1430(b)(3)). (See SAR pp 11-12) Importantly, the establishment criterion does not require documentation that a facility met or exceeded the State Board's standard for two years.

If the SAR utilized the correct criterion, a negative finding would have been made for Planning Area Need – Service Demand because the facility has not had high utilization in each of the past two years. While the State Board's utilization data, shows RCG Evanston exceeded the State Board's utilization standard as recently as March 31, 2012, it is important to recognize that Fresenius added two stations to RCG Evanston on June 22, 2012 under the State Board's 10% rule. The addition of these two stations alleviated the high utilization at the facility. Since that time, the facility has consistently operated around 75% utilization. The addition of the two stations addressed the high utilization at RCG Evanston, and no additional expansion is warranted at this time. Moreover, Fresenius would also be able to add two stations in June of 2014 under the 10% rule thereby alleviating future demand.

Further, there has been no significant increase in demand at RCG Evanston over the past two years to necessitate a station increase at this time. The number of patients treated at RCG Evanston from June 2011 through September 2012 has remained constant, fluctuating between 60 and 64 patients. Moreover, DaVita's Evanston Renal Center is located approximately 2.5 miles from RCG Evanston and was operating at 56% utilization as of September 30, 2013. (Attachment 2). Importantly, NorthShore Faculty Practice Associates regularly refers patients to DaVita's Evanston Renal Center. Any patients that cannot be treated at RCG Evanston could be accommodated at Evanston Renal Center.

RCG Evanston has not been operating above 80% in each of the past two years and fails to meet the Planning Area Need – Service Demand criterion. Additionally, there has not been a significant increase in demand at the facility and the projected increase could be accommodated at Evanston Renal Center. Therefore, expansion of RCG Evanston is not warranted at this time.

Thank you for your time and consideration of DaVita's comment to the RCG Evanston State Agency Report.

Sincerely,



Anne M. Cooper

Attachments

Joint Committee on Administrative Rules

ADMINISTRATIVE CODE

TITLE 77: PUBLIC HEALTH
CHAPTER II: HEALTH FACILITIES AND SERVICES REVIEW BOARD
SUBCHAPTER a: ILLINOIS HEALTH CARE FACILITIES PLAN
PART 1110 PROCESSING, CLASSIFICATION POLICIES AND REVIEW CRITERIA
SECTION 1110.1430 IN-CENTER HEMODIALYSIS PROJECTS – REVIEW CRITERIA

Section 1110.1430 In-Center Hemodialysis Projects – Review Criteria

a) Introduction

- 1) This Section applies to projects involving the In-Center Hemodialysis category of service. Applicants proposing to establish, expand or modernize this category of service shall comply with the applicable subsections of this Section as follows:

PROJECT TYPE	REQUIRED REVIEW CRITERIA
Establishment of Services or Facility	(b)(1) – Planning Area Need – 77 Ill. Adm. Code 1100 (formula calculation)
	(b)(2) – Planning Area Need – Service to Planning Area Residents
	(b)(3) – Planning Area Need – Service Demand – Establishment of In-Center Hemodialysis
	(b)(5) – Planning Area Need – Service Accessibility
	(c)(1) – Unnecessary Duplication of Services
	(c)(2) – Maldistribution
	(c)(3) – Impact of Project on Other Area Providers
	(e) – Staffing
	(f) – Support Services
	(g) – Minimum Number of Stations
	(h) – Continuity of Care
(j) – Assurances	
Expansion of Existing Services	(b)(2) – Planning Area Need – Service to Planning Area Residents
	(b)(4) – Planning Area Need – Service Demand – Expansion of In-Center Hemodialysis
	(e)(1) – Staffing – Availability
	(f) – Support Services

EXHIBIT

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	(j) – Assurances
In-Center Hemodialysis Modernization	(d)(1) – Deteriorated Facilities
	(d)(2)
	& (3) – Documentation
	(f) – Support Services

- 2) If the proposed project involves the relocation of an existing facility or service, the applicant shall comply with the requirements listed in subsection (a)(1) for "Establishment of Services or Facility", as well as requirements in Section 1110.130 (Discontinuation) and subsection (i) (Relocation of Facilities).
 - 3) If the proposed project involves the replacement of a facility or service (onsite or new site), the number of stations being replaced shall not exceed the number justified by historical utilization rates for each of the latest two years, unless additional stations can be justified per the criteria for "Expansion of Existing Services".
- b) Planning Area Need – Review Criterion
 The applicant shall document that the number of stations to be established or added is necessary to serve the planning area's population, based on the following:
- 1) 77 Ill. Adm. Code 1100 (formula calculation)
 - A) The number of stations to be established for in-center hemodialysis is in conformance with the projected station deficit specified in 77 Ill. Adm. Code 1100, as reflected in the latest updates to the Inventory.
 - B) The number of stations proposed shall not exceed the number of the projected deficit, to meet the health care needs of the population served, in compliance with the utilization standard specified in 77 Ill. Adm. Code 1100.
 - 2) Service to Planning Area Residents
 - A) Applicants proposing to establish or add stations shall document that the primary purpose of the project will be to provide necessary health care to the residents of the area in which the proposed project will be physically located (i.e., the planning or geographical service area, as applicable), for each category of service included in the project.
 - B) Applicants proposing to add stations to an existing in-center hemodialysis service shall provide patient origin information for all admissions for the last 12-month period, verifying that at least 50% of admissions were residents of the area. For all other projects, applicants shall document that at least 50% of the projected patient volume will be from residents of the area.
 - C) Applicants proposing to expand an existing in-center hemodialysis service shall submit patient origin information by zip code, based

upon the patient's legal residence (other than a health care facility).

- 3) **Service Demand – Establishment of In-Center Hemodialysis Service**
The number of stations proposed to establish a new in-center hemodialysis service is necessary to accommodate the service demand experienced annually by the existing applicant facility over the latest two-year period, as evidenced by historical and projected referrals, or, if the applicant proposes to establish a new facility, the applicant shall submit projected referrals. The applicant shall document subsection (b)(3)(A) and either subsection (b)(3)(B) or (C).

A) **Historical Referrals**

- i) If the applicant is an existing facility, the applicant shall document the number of referrals to other facilities, for each proposed category of service, for each of the latest two years.
- ii) Documentation of the referrals shall include: patient origin by zip code; name and specialty of referring physician; name and location of the recipient facility.

B) **Projected Referrals**

The applicant shall provide physician referral letters that attest to:

- i) The physician's total number of patients (by facility and zip code of residence) who have received care at existing facilities located in the area, as reported to The Renal Network at the end of the year for the most recent three years and the end of the most recent quarter;
- ii) The number of new patients (by facility and zip code of residence) located in the area, as reported to The Renal Network, that the physician referred for in-center hemodialysis for the most recent year;
- iii) An estimated number of patients (transfers from existing facilities and pre-ESRD, as well as respective zip codes of residence) that the physician will refer annually to the applicant's facility within a 24-month period after project completion, based upon the physician's practice experience. The anticipated number of referrals cannot exceed the physician's documented historical caseload;
- iv) An estimated number of existing patients who are not expected to continue requiring in-center hemodialysis services due to a change in health status (e.g., the patients received kidney transplants or expired);
- v) The physician's notarized signature, the typed or printed name of the physician, the physician's office address and the physician's specialty;

- vi) Verification by the physician that the patient referrals have not been used to support another pending or approved CON application for the subject services; and
 - vii) Each referral letter shall contain a statement attesting that the information submitted is true and correct, to the best of the physician's belief.
- C) Projected Service Demand – Based on Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:
- i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;
 - ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;
 - iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;
 - iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;
 - v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to or in excess of the projection horizon;
 - vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFPB, for each category of service in the application; and
 - vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFPB.
- 4) Service Demand – Expansion of In-Center Hemodialysis Service
The number of stations to be added for each category of service is necessary to reduce the facility's experienced high utilization and to meet a projected demand for service. The applicant shall document subsection (b)(4)(A) and either (b)(4)(B) or (C):
- A) Historical Service Demand
 - i) An average annual utilization rate that has equaled or exceeded utilization standards for in-center hemodialysis service, as specified in 77 Ill. Adm. Code 1100, for each of

the latest two years.

- ii) If patients have been referred to other facilities in order to receive the subject service, the applicant shall provide documentation of the referrals, including: patient origin by zip code; name and specialty of referring physician; and name and location of the recipient facility, for each of the latest two years.

B) Projected Referrals

- i) The applicant shall provide physician letters that attest to:
- the physician's total number of patients (by facility and zip code of residence) who have received care at existing facilities located in the area, as reported to The Renal Network at the end of the year for the most recent three years and the end of the most recent quarter;
 - the number of new patients (by facility and zip code of residence) located in the area, as reported to The Renal Network, that the physician referred for in-center hemodialysis for the most recent year;
 - an estimated number of patients (transfers from existing facilities and pre-ESRD, as well as respective zip codes of residence) that the physician will refer annually to the applicant's facility within a 24-month period after project completion, based upon the physician's practice experience. The anticipated number of referrals cannot exceed the physician's documented historical caseload. The percentage of project referrals used to justify the proposed expansion cannot exceed the historical percentage of applicant market share, within a 24-month period after project completion;
- ii) Each referral letter shall contain the physician's notarized signature, the typed or printed name of the physician, the physician's office address and the physician's specialty;
- iii) The physician shall verify that the patient referrals have not been used to support another pending or approved CON application for the subject services; and
- iv) Each referral letter shall contain a statement attesting that the information submitted is true and correct, to the best of the physician's belief.

- C) Projected Service Demand – Based on Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:
- i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;
 - ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;
 - iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;
 - iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;
 - v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to or in excess of the projection horizon;
 - vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFPB, for each category of service in the application; and
 - vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFPB.

5) Service Accessibility

The number of stations being established or added for the subject category of service is necessary to improve access for planning area residents. The applicant shall document the following:

A) Service Restrictions

The applicant shall document that at least one of the following factors exists in the planning area:

- i) The absence of the proposed service within the planning area;
- ii) Access limitations due to payor status of patients, including, but not limited to, individuals with health care coverage through Medicare, Medicaid, managed care or charity care;
- iii) Restrictive admission policies of existing providers;
- iv) The area population and existing care system exhibit indicators of medical care problems, such as an average

family income level below the State average poverty level, high infant mortality, or designation by the Secretary of Health and Human Services as a Health Professional Shortage Area, a Medically Underserved Area, or a Medically Underserved Population;

- v) For purposes of this subsection (b)(5) only, all services within the 30-minute normal travel time meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100.

B) Supporting Documentation

The applicant shall provide the following documentation concerning existing restrictions to service access:

- i) The location and utilization of other planning area service providers;
- ii) Patient location information by zip code;
- iii) Independent time-travel studies;
- iv) A certification of waiting times;
- v) Scheduling or admission restrictions that exist in area providers;
- vi) An assessment of area population characteristics that document that access problems exist;
- vii) Most recently published IDPH Hospital Questionnaire.

c) Unnecessary Duplication/Maldistribution – Review Criterion

- 1) The applicant shall document that the project will not result in an unnecessary duplication. The applicant shall provide the following information:
 - A) A list of all zip code areas that are located, in total or in part, within 30 minutes normal travel time of the project's site;
 - B) The total population of the identified zip code areas (based upon the most recent population numbers available for the State of Illinois population); and
 - C) The names and locations of all existing or approved health care facilities located within 30 minutes normal travel time from the project site that provide the categories of station service that are proposed by the project.
- 2) The applicant shall document that the project will not result in maldistribution of services. Maldistribution exists when the identified area

(within the planning area) has an excess supply of facilities, stations and services characterized by such factors as, but not limited to:

- A) A ratio of stations to population that exceeds one and one-half times the State average;
 - B) Historical utilization (for the latest 12-month period prior to submission of the application) for existing facilities and services that is below the utilization standard established pursuant to 77 Ill. Adm. Code 1100; or
 - C) Insufficient population to provide the volume or caseload necessary to utilize the services proposed by the project at or above utilization standards.
- 3) The applicant shall document that, within 24 months after project completion, the proposed project:
- A) Will not lower the utilization of other area providers below the occupancy standards specified in 77 Ill. Adm. Code 1100; and
 - B) Will not lower, to a further extent, the utilization of other area hospitals that are currently (during the latest 12-month period) operating below the occupancy standards.
- d) Category of Service Modernization
- 1) If the project involves modernization of an in-center hemodialysis service, the applicant shall document that the areas to be modernized are deteriorated or functionally obsolete and need to be replaced or modernized, due to such factors as, but not limited to:
 - A) High cost of maintenance;
 - B) Non-compliance with licensing or life safety codes;
 - C) Changes in standards of care (e.g., private versus multiple bed rooms); or
 - D) Additional space for diagnostic or therapeutic purposes.
 - 2) Documentation shall include the most recent:
 - A) IDPH CMMS inspection reports; and
 - B) Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reports.
 - 3) Other documentation shall include the following, as applicable to the factors cited in the application:

- A) Copies of maintenance reports;
 - B) Copies of citations for life safety code violations; and
 - C) Other pertinent reports and data.
- 4) Projects involving the relocation or modernization of in-center hemodialysis or a facility shall meet or exceed the utilization standards for the categories of service, as specified in 77 Ill. Adm. Code 1100.
- e) **Staffing**
 The applicant shall document that relevant clinical and professional staffing needs for the proposed project were considered and that licensure and JCAHO staffing requirements can be met. In addition, the applicant shall document that necessary staffing is available by providing letters of interest from prospective staff members, completed applications for employment, or a narrative explanation of how the proposed staffing will be achieved.
- 1) **Qualifications**
 - A) **Medical Director** – Medical direction of the facility shall be vested in a physician who has completed a board-approved training program in nephrology and has at least 12 months experience providing care to patients receiving dialysis.
 - B) **Registered Nurse** – The nurse responsible for nursing services in the unit shall be a registered nurse (RN) who meets the practice requirements of the State of Illinois and has at least 12 months experience in providing nursing care to patients on maintenance dialysis.
 - C) **Dialysis Technician** – This individual shall meet all applicable State of Illinois requirements (see 210 ILCS 62, the End Stage Renal Disease Facility Act). In addition, the applicant shall document its requirements for training and continuing education.
 - D) **Dietitian** – This individual shall be a registered dietitian with the Commission on Dietetic Registration, meet the practice requirements of the State of Illinois (see the Dietetic and Nutrition Services Practice Act [225 ILCS 30]) and have a minimum of one year of professional work experience in clinical nutrition as a registered dietitian.
 - E) **Social Worker** – The individual responsible for social services shall have a Master's of Social Work and meet the State of Illinois requirements (see 225 ILCS 20, the Clinical Social Work and Social Work Practice Act).
 - 2) **Documentation shall consist of:**
 - A) **Medical Director**

Curriculum vitae of Medical Director, including a list of all in-center hemodialysis facilities where the position of Medical Director is held.

- B) All Other Personnel
- i) Letters of interest from potential employees;
 - ii) Applications filed with the applicant for a position;
 - iii) Signed contracts with required staff; or
 - iv) A narrative explanation of how other positions will be filled.
- 3) Training
The applicant proposing to establish an in-center hemodialysis category of service shall document that an ongoing program of training in dialysis techniques for nurses and technicians will be provided at the facility.
- 4) Staffing Plan
The applicant proposing to establish an in-center hemodialysis category of service shall document that at least one RN will be on duty when the unit is in operation and will maintain a ratio of at least one direct patient care provider to every four patients.
- 5) Medical Staff
The applicant shall provide a letter certifying whether the facility will or will not maintain an open medical staff.
- f) Support Services – Review Criterion
An applicant proposing to establish an in-center hemodialysis category of service must submit a certification from an authorized representative that attests to each of the following:
- 1) Participation in a dialysis data system;
 - 2) Availability of support services consisting of clinical laboratory service, blood bank, nutrition, rehabilitation, psychiatric and social services; and
 - 3) Provision of training for self-care dialysis, self-care instruction, home and home-assisted dialysis, and home training provided at the proposed facility, or the existence of a signed, written agreement for provision of these services with another facility.
- g) Minimum Number of Stations
The minimum number of in-center hemodialysis stations for an End Stage Renal Disease (ESRD) facility is:
- 1) Four dialysis stations for facilities outside an MSA;
 - 2) Eight dialysis stations for a facility within an MSA.

- h) **Continuity of Care**
An applicant proposing to establish an in-center hemodialysis category of service shall document that a signed, written affiliation agreement or arrangement is in effect for the provision of inpatient care and other hospital services. Documentation shall consist of copies of all such agreements.
- i) **Relocation of Facilities – Review Criterion**
This criterion may only be used to justify the relocation of a facility from one location in the planning area to another in the same planning area and may not be used to justify any additional stations. A request for relocation of a facility requires the discontinuation of the current category of service at the existing site and the establishment of a new category of service at the proposed location. The applicant shall document the following:
- 1) That the existing facility has met the utilization targets detailed in 77 Ill. Adm. Code 1100.630 for the latest 12-month period for which data is available; and
 - 2) That the proposed facility will improve access for care to the existing patient population.
- j) **Assurances**
The applicant representative who signs the CON application shall submit a signed and dated statement attesting to the applicant's understanding that:
- 1) By the second year of operation after the project completion, the applicant will achieve and maintain the utilization standards specified in 77 Ill. Adm. Code 1100 for each category of service involved in the proposal; and
 - 2) An applicant proposing to expand or relocate in-center hemodialysis stations will achieve and maintain compliance with the following adequacy of hemodialysis outcome measures for the latest 12-month period for which data are available:

≥ 85% of hemodialysis patient population achieves area reduction ratio (URR) ≥ 65% and ≥ 85% of hemodialysis patient population achieves Kt/V Daugirdas II .1.2.

(Source: Amended at 33 Ill. Reg. 3312, effective February 6, 2009)



Trip to:
1922 Dempster St
 Evanston, IL 60202-1016
 2.48 miles / 7 minutes

Notes

RCG Evanston to Evantson Renal Care Center



Fresenius Medical Care
 2953 Central St, Evanston, IL 60201
 (847) 864-0831

Download
 Free App

- 1. Start out going **west** on **Central St** toward **Central Park Ave.** [Map](#)

0.05 Mi
0.05 Mi Total
- ↩

2. Take the 1st **left** onto **Central Park Ave.** [Map](#)
Mobil is on the left
If you reach Marcy Ave you've gone a little too far

0.6 Mi
0.7 Mi Total
- ↩

3. Turn **left** onto **Golf Rd / Simpson St.** Continue to follow **Golf Rd.** [Map](#)
Golf Rd is just past Payne St
If you reach Foster St you've gone about 0.1 miles too far

0.5 Mi
1.2 Mi Total
- ↑

4. **Golf Rd** becomes **Emerson St.** [Map](#)

0.5 Mi
1.7 Mi Total
- ↘

5. Turn **right** onto **Dodge Ave.** [Map](#)
Claire's Korner is on the corner
If you reach Darrow Ave you've gone a little too far

0.8 Mi
2.5 Mi Total
- ↘

6. Turn **right** onto **Dempster St.** [Map](#)
Dempster St is 0.1 miles past Greenwood St
Dunkin Donuts is on the corner
If you reach Crain St you've gone about 0.1 miles too far

0.02 Mi
2.5 Mi Total
- 7. **1922 DEMPSTER ST** is on the **left.** [Map](#)
If you reach Hartrey Ave you've gone about 0.2 miles too far



1922 Dempster St, Evanston, IL 60202-1016

Total Travel Estimate: **2.48 miles - about 7 minutes**

FREE NAVIGATION APP
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