



STATE OF ILLINOIS
HEALTH FACILITIES AND SERVICES REVIEW BOARD

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DOCKET NO: I-03	BOARD MEETING: July 24, 2018	PROJECT NO: 17-066	PROJECT COST:
FACILITY NAME: North Dunes Dialysis		CITY: Waukegan	Original: \$3,428,482
TYPE OF PROJECT: Substantive			HSA: VIII

PROJECT DESCRIPTION: The Applicants (DaVita Inc. and Botkins Dialysis, LLC) propose to establish a 12-station ESRD facility in 7,095 GSF of lease space at a cost of \$3,428,482. The expected completion date is April 30, 2020.

EXECUTIVE SUMMARY

PROJECT DESCRIPTION:

- The Applicants (DaVita Inc. and Botkins Dialysis, LLC) propose to establish a 12-station ESRD facility in 7,095 GSF of lease space at a cost of \$3,428,482. The expected completion date is April 30, 2020.
- This project was deferred from the April 17, 2018 Agenda at the request of the applicants and received an Intent to Deny at the June 2018 State Board Meeting.
- On June 19, 2018 the State Board received additional information to address the Intent to Deny. At the end of this report is the additional information and the transcripts from the June 2018 State Board Meeting.
- As part of the additional information the Applicants also addressed questions raised by the Board Members at the June Meeting concerning Social Security and Home Dialysis.

WHY THE PROJECT IS BEFORE THE STATE BOARD:

- The applicants are proposing to establish a health care facility as defined by the Illinois Health Facilities Planning Act (20 ILCS 3960/3) based on the need to improve access to life sustaining dialysis services to the residents of Waukegan, Illinois and the surrounding area.
- One of the objectives of the Health Facilities Planning Act is *“to assess the financial burden to patients caused by unnecessary health care construction and modification. Evidence-based assessments, projections and decisions will be applied regarding **capacity, quality, value and equity** in the delivery of health care services in Illinois. Cost containment and support for safety net services must continue to be central tenets of the Certificate of Need process.”* [20 ILCS 3960/2]
- As part of the Illinois Health Care Facilities Plan Section 77 ILAC 1100.410 states that *“Health care services should be appropriately located to best meet the needs of the population. Illinois residents needing services should not be forced to travel excessive distances. Where feasible, underutilized services should be consolidated to promote efficiency of operation and quality when such consolidation does not create access problems.”*

PUBLIC HEARING/COMMENT:

- A public hearing was offered in regard to the proposed project, but none was requested. **The Applicants submitted 18** letters of support for the proposed project. These letters were from residents of the community, other health care providers, and members of the medical community, community officials and business/industry representatives. Some of these support letters are individually composed and some are of a form letter variety. All of the letters urged the State Board to approve the proposed project because *“both Waukegan dialysis clinics are very busy and have limited ability to accommodate more patients. This creates access problems for Waukegan residents who require kidney treatments. Kidney disease continues to rise and for the foreseeable future, these services will be needed.”*
- **No letters of opposition** were received by the State Board Staff. Opposition comments were provided at the June 2018 State Board Meeting regarding the proposed project.

SUMMARY:

- The State Board has **projected an excess of 43 ESRD stations by CY 2020**. This projected excess is based upon an estimated increase in the population in this planning area of approximately 9.92% and an approximate increase of 33% in the number of ESRD patients in this ESRD Planning Area for the period 2015 to 2020.
- The proposed facility will be located in an economically disadvantaged area and an area where there is a large percentage of Hispanics. The City of Waukegan has been designated as a Medically Underserved Area and a Health Professional Shortage Area. The incidence of chronic

kidney disease and end-stage renal disease is higher within this population than within other populations. The 30-minute service area contains 5 existing ESRD facilities, and based upon the physician referral letter, there appears to be a sufficient number of pre-ESRD patients that will require dialysis within 12-24 months after project completion to justify the 12 stations being requested. Of these five facilities, one (1) is in ramp up/not fully operational. The average utilization at the four (4) remaining facilities is approximately 84%. All of the 116 pre-ESRD patients reside within the planning area as attested to by the Applicants.

- For the period 2013 to 2017 the State Board has seen an increase in the number of dialysis patients of approximately 9.7% in the HSA VIII ESRD Planning Area.
- The Applicants addressed a total of 21 criteria and received negative findings for the following:

State Board Standards Not Met	
<u>Criteria</u>	<u>Reasons for Non-Compliance</u>
Criterion 1110.1430(c)(1) – Planning Area Need	There is a calculated <u>excess 43 stations</u> in the HSA-VIII ESRD Planning Area, per the June 2018 Inventory Update. This excess of stations takes into account an estimated increase in the population in this planning area of approximately 10% and an increase of 33% in the number of ESRD patients in this ESRD Planning Area for the period 2015 to 2020.

SUPPLEMENTAL
STATE BOARD STAFF REPORT
Project 17-066
DaVita North Dunes Dialysis

APPLICATION/CHRONOLOGY/SUMMARY	
Applicants	DaVita Inc., Botkins Dialysis, LLC.
Facility Name	DaVita North Dunes Dialysis
Location	3113 North Lewis Avenue, Waukegan, Illinois
Permit Holder	DaVita Inc., Botkins Dialysis, LLC.
Operating Entity	Botkins Dialysis, LLC.
Owner of Site	Vequity, LLC
Total GSF	7,095 GSF
Application Received	November 21, 2017
Application Deemed Complete	December 7, 2017
Review Period Ends	April 6, 2018
Financial Commitment Date	April 30, 2020
Project Completion Date	April 30, 2020
Review Period Extended by the State Board Staff?	No
Intent to Deny?	June 5, 2018
Can the applicants request a deferral?	Yes
Expedited Review?	No

I. Project Description

The Applicants (DaVita Inc. and Botkins Dialysis, LLC) propose to establish a 12-station ESRD facility in 7,095 GSF of lease space at a cost of \$3,428,482. The expected completion date is April 30, 2020.

II. Summary of Findings

- A. State Board Staff finds the proposed project **is not** in conformance with the provisions of 77 ILAC 1110 (Part 1110).
- B. State Board Staff finds the proposed project in conformance with the provisions of 77 ILAC 1120 (Part 1120).

III. General Information

The applicants are DaVita Inc. and Botkins Dialysis, LLC. DaVita Inc, a Fortune 500 company, is the parent company of Botkins Dialysis, LLC. DaVita Inc. is a leading provider of kidney care in the United States, delivering dialysis services to patients with chronic kidney failure and end stage renal disease. DaVita serves patients with low incomes, racial and ethnic minorities, women, handicapped persons, elderly, and other underserved persons in its facilities in the State of Illinois. The operating entity will be Botkins Dialysis, LLC and the owner of the site is Vequity, LLC. Financial commitment will occur after permit approval.

Table One below outlines the current DaVita projects approved by the State Board and not yet completed.

TABLE ONE Current DaVita Projects			
Project Number	Name	Project Type	Completion Date
16-015	Forest City Dialysis	Establishment	6/30/2018
16-023	Irving Park Dialysis	Establishment	8/31/2018
16-033	Brighton Park Dialysis	Establishment	10/31/2018
16-037	Fox Point Dialysis	Establishment	7/31/2018
16-040	Jerseyville Dialysis	Establishment	7/31/2018
16-041	Taylorville Dialysis	Expansion	7/31/2018
16-051	Whiteside Dialysis	Relocation	3/31/2019
17-014	Rutgers Park Dialysis	Establishment	6/30/2019
17-016	Salt Creek Dialysis	Establishment	6/30/2019
17-032	Illini Dialysis	Relocation/Expansion	5/31/2019
17-040	Edgemont Dialysis	Establishment	5/31/2019
17-049	Northgrove Dialysis	Establishment	7/31/2019
17-053	Ford City Dialysis	Establishment	8/31/2019
17-062	Auburn Park Dialysis	Establishment	2/29/2020
17-063	Hickory Creek Dialysis	Establishment	11/30/2019
18-001	Garfield Kidney Center	Establishment	6/30/2020

IV. Health Planning Area

The proposed facility will be located in the HSA-VIII Planning Area, in an area designated as a health professional shortage area, and a medically underserved area. This planning area includes the counties of McHenry, Lake and Kane. The State Board has **projected an excess 43 ESRD stations by CY 2020**. This projected excess is based upon an estimated increase in the population in this planning area of approximately 9.92% and an approximate increase of 33% in the number of ESRD patients in this ESRD Planning Area for the period 2015 to 2020.

The five-year need determination is a short-term assessment that applies to the planning area need requirements in the 77 Ill. Adm. Code 1110 category of service review criteria. The in-center hemodialysis or end stage renal disease (ESRD) station need is a five-year projection from the base year. The need for additional treatment stations is projected utilizing the following methodology. [77 ILAC 1100.630 - In-Center Hemodialysis Category of Service]

TABLE TWO	
Need Methodology HSA VIII ESRD Planning Area	
Planning Area Population – 2015 (Est)	1,540,100
In Station ESRD patients -2015	1,541
Area Use Rate 2015 ⁽¹⁾	.910
Planning Area Population – 2020 (Est.)	1,692,900
Projected Patients – 2020 ⁽²⁾	1,541
Adjustment	1.33
Patients Adjusted	2,050
Projected Treatments – 2020 ⁽³⁾	319,727
Existing Stations	470
Stations Needed-2018	427
Number of Stations in Excess	43

V. Project Uses and Sources of Funds

The Applicants are funding the project with cash in the amount of \$2,338,702 and a FMV of a lease in the amount of \$1,089,780. The operating deficit start-up costs are \$2,562,190.

TABLE THREE				
Project Costs and Sources of Funds				
Project Cost	Reviewable	Non reviewable	Total	% of Total Cost
Modernization Contracts	\$829,084	\$427,828	\$1,256,912	36.6%
Contingencies	\$82,907	\$42,782	\$125,689	3.7%
Architectural/Engineering Fees	\$96,000	\$25,000	\$121,000	3.6%
Consulting and Other Fees	\$80,000	\$10,000	\$90,000	2.7%
Moveable and Other Equipment	\$644,079	\$101,022	\$745,101	21.7%
Fair Market Value of Leased Space	\$718,840	\$370,940	\$1,089,780	31.7%
Total Project Costs	\$2,450,910	\$977,572	\$3,428,482	100.00%
Cash	\$1,732,070	\$606,632	\$2,338,702	68.2%
FMV of Leased Space	\$718,840	\$370,940	1,089,780	31.8%
Total Sources of Funds	\$2,450,910	\$977,572	\$3,428,482	100.00%

VI. Background of the Applicants

A) Criterion 1110.1430(b)(1)-(3) – Background of the Applicants

An applicant must demonstrate that it is fit, willing and able, and has the qualifications, background and character to adequately provide a proper standard of health care service for the community. To demonstrate compliance with this criterion the applicants must provide

- A) A listing of all health care facilities currently owned and/or operated by the applicant in Illinois or elsewhere, including licensing, certification and accreditation identification numbers, as applicable;
- B) A listing of all health care facilities currently owned and/or operated in Illinois, by any corporate officers or directors, LLC members, partners, or owners of at least 5% of the proposed health care facility;
- C) Authorization permitting HFSRB and IDPH access to any documents necessary to verify the information submitted, including, but not limited to: official records of IDPH or other State agencies; the licensing or certification records of other states, when applicable; and the records of nationally recognized accreditation organizations. Failure to provide the authorization shall constitute an abandonment or withdrawal of the application without any further action by HFSRB.
- D) An attestation that the applicants have not had *adverse action*¹ taken against any facility they own or operate or a certified listing of any adverse action taken.

1. The applicants have attested that there has been no adverse action taken against any of the facilities owned or operated by DaVita Inc or Botkins Dialysis, LLC, during the three (3) years prior to filing the application. [Application for Permit page 72]
2. The applicants have authorized the Illinois Health Services Review Board and the Illinois Department of Public Health to have access to any documents necessary to verify information submitted in connection to the applicants' certificate of need to establish a twelve-station ESRD facility. The authorization includes, but is not limited to: official records of IDPH or other State agencies; the licensing or certification records of other states, when applicable; and the records of nationally recognized accreditation organizations. [Application for Permit page 72]
3. Botkins Dialysis LLC will be the operator of North Dunes Dialysis. North Dunes Dialysis is a subsidiary of DaVita, Inc. and is not separately organized. As the person with final control over the operator, DaVita Inc. is named as an applicant for this CON application. DaVita Inc. does not do business in the State of Illinois. A Certificate of Good Standing for DaVita Inc. from the state of its incorporation, Delaware, has been provided (Application, p. 27).
4. The site is owned by Vequity, LLC and evidence of this can be found at pages 30-37 of the application for permit in the Letter of Intent to lease the property at 3113 North Lewis Avenue, Waukegan, IL 60087.
5. The applicants provided evidence that they were in compliance with Executive Order #2006-05 that requires *all State Agencies responsible for regulating or permitting development within Special Flood Hazard Areas shall take all steps within their authority to ensure that such development meets the requirements of this*

¹ “Adverse action is defined as a disciplinary action taken by IDPH, CMMS, or any other State or federal agency against a person or entity that owns or operates or owns and operates a licensed or Medicare or Medicaid certified healthcare facility in the State of Illinois. These actions include, but are not limited to, all Type "A" and Type "AA" violations.” (77 IAC 1130.140)

Order. State Agencies engaged in planning programs or programs for the promotion of development shall inform participants in their programs of the existence and location of Special Flood Hazard Areas and of any State or local floodplain requirements in effect in such areas. Such State Agencies shall ensure that proposed development within Special Flood Hazard Areas would meet the requirements of this Order.

6. The proposed location of the ESRD facility is in compliance with the Illinois State Agency Historic Resources Preservation Act which requires *all State Agencies in consultation with the Director of Historic Preservation, institute procedures to ensure that State projects consider the preservation and enhancement of both State owned and non-State owned historic resources* (20 ILCS 3420/1).

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION BACKGROUND OF THE APPLICANTS (77 IAC 1110.1430(b)(1) & (3))

VII. Purpose of the Project, Safety Net Impact, Alternatives

A) Criterion 1110.230 – Purpose of the Project

To demonstrate compliance with this criterion the applicants must document that the project will provide health services that improve the health care or well-being of the market area population to be served. The applicant shall define the planning area or market area, or other area, per the applicant's definition.

The applicants stated:

“The purpose of the project is to improve access to life sustaining dialysis services to the residents of Waukegan, Illinois. Waukegan lies 40 miles north of Chicago, and for over a century had a significant presence of manufacturing plants which created a swell in population and economic stability for many years. Over the past 40 years, however, it has seen a sharp decline in its manufacturing sector. Such economic changes have meant not only diminished employment opportunities, but stresses on the local tax base to finance school and municipal services. At the same time, public service requirements have grown with the city’s swelling population. Waukegan’s population expanded by 27% in the 1990s alone. The most significant change has been the rapid growth of its foreign-born population, which increased 148% between 1990 and 2000. Most of these immigrants are recent arrivals to the U.S. The patient service area for the proposed North Dunes Dialysis is 30% Hispanic. This minority population has a higher incidence and prevalence of chronic kidney disease (CKD) than the general population. Further, the patient service area is an area with many low-income patients. The North Dunes geographic services area (Waukegan GSA) has experienced explosive growth over the past three years, with patient census increasing 7% annually (or total increase of 21% from September 2014 to September 2017). Patient growth is anticipated to continue to increase for the foreseeable future, due to the demographics of the community. This planned facility will accommodate the patients of Dr. Omar Dalloul, who is currently treating 116 CKD patients who reside within the zip code of the proposed North Dunes Dialysis (60087), and in other nearby zip codes. Dr. Dalloul anticipates that at least 60 of these 116 patients will initiate in-center hemodialysis within 12 to 24 months following project completion. [Application for Permit page 74].

B) Criterion 1110.230(b) - Safety Net Impact Statement

To demonstrate compliance with this criterion the applicants must document the safety net impact if any of the proposed project. *Safety net services are the services provided by health care providers or organizations that deliver health care services to persons with barriers to mainstream health care due to lack of insurance, inability to pay, special needs, ethnic or cultural characteristics, or geographic isolation. [20 ILCS 3960/5.4]*

A Safety Net Impact Statement has been provided as required and the Applicants state:

“DaVita Inc. and its affiliates are safety net providers of dialysis services to residents of the State of Illinois. DaVita is a leading provider of dialysis services in the United States and is committed to innovation, improving clinical outcomes, compassionate care, education and Kidney Smarting patients, and community outreach. A copy of DaVita's 2016 Community Care report, which details DaVita's commitment to quality, patient centric focus and community outreach, is included as part of the Applicants application (Application, pgs. 59-64). As referenced in the report, DaVita led the industry in quality, with twice as many Four- and Five-Star centers than other major dialysis providers. DaVita also led the industry in Medicare's Quality Incentive Program, ranking No. 1 in three out of four clinical measures and receiving the fewest penalties. DaVita has taken on many initiatives to improve the lives of patients suffering from CKD and ESRD. These programs include Kidney Smart, IMPACT, CathAway, and transplant assistance programs. Furthermore, DaVita is an industry leader in the rate of fistula use and has the lowest day-90 catheter rates among large dialysis providers. During 2000 - 2014, DaVita improved its fistula adoption rate by 103 percent. Its commitment to improving clinical outcomes directly translated into 7% reduction in hospitalizations among DaVita patients.”

State of Illinois Managed Care Contracts

The Applicants provided the following:

All patients who have worked the requisite number of quarters (equivalent to 10 years) are eligible for Medicare if they are diagnosed with end stage renal disease (ESRD). Consistent with that fact, the published HFSRB data for 2016 for DuPage County shows that the 10 Fresenius/NANI clinics operating in DuPage County treated a total of 15 Medicaid patients or an average of 1.5 patients per year per clinic compared with 862 Medicare patients in those 10 clinics for the same period.

- DVA = DaVita Inc
- DMG = DuPage Medical Group

For Option A – Statewide

- Blue Cross Blue Shield of Illinois (Both DVA and DMG participate)
- Harmony Health Plan (DVA participates)
- IlliniCare Health Plan (DVA participates)
- Meridian Health (DVA participates)
- Molina Healthcare of IL (DVA in negotiations to participate)

For Option B – Cook County Only

- CountyCare Health Plan (DVA participates)
- NextLevel Health. (Neither DVA or DMG participates)

For DCFS Youth

- IlliniCare Health Plan (DVA participates)

Each of DaVita and DMG participate in a range of insurance plans, including Medicare and Medicaid plans (HealthChoice Illinois and Medicare-Medicaid Alignment Initiative Plans (MMAI)) as identified above. While DMG providers do not participate in all Medicaid managed care plans, the plan it does participate in reflects the population it serves and the plan that is most in demand in DuPage County. Just under half of the HealthChoice beneficiaries residing in DuPage County are enrolled in the Blue Cross Medicaid products that DMG is enrolled in. Further, in their provision of services at the various area hospitals, DMG physicians regularly treat Medicaid patients who are not routinely seen by them as assigned patients without expectation of reimbursement for providing that care. [Source: Email dated 5/8/2018]

TABLE FOUR

DaVita Inc.

	2014	2015	2016	2017
Net Patient Revenue	\$266,319,949	\$311,351,089	\$353,226,322	\$357,821,315
Amt of Charity Care (charges)	\$2,477,363	\$2,791,566	\$2,400,299	\$2,818,603
Cost of Charity Care ⁽¹⁾	\$2,477,363	\$2,791,566	\$2,400,299	\$2,818,603
% of Charity Care/Net Patient Revenue	0.93%	0.90%	0.68%	0.78%
Number of Charity Care Patients	146	109	110	98
Number of Medicaid Patients	708	422	297	407
Medicaid	\$8,603,971	\$7,381,390	\$4,692,716	\$9,493,634
% of Medicaid to Net Patient Revenue	3.23%	2.36%	1.33%	2.65%

1. The charity care listed above does not meet the State Board's definition of Charity Care. Charity Care is defined by the State Board as *care provided by a health care facility for which the provider does not expect to receive payment from the patient or a third party payer.* [20 ILCS 3960/3].

C) Criterion 1110.230(c) – Alternatives to the Proposed Project

To demonstrate compliance with this criterion the applicants must document that the proposed project is the most effective or least costly alternative for meeting the health care needs of the population to be served by the project.

The applicants considered three (3) alternatives

1. Maintain Status Quo/Do Nothing
2. Utilize Existing Facilities
3. Establish New Facility

1. The purpose of the proposed project is to meet the need of the community by providing access to life sustaining dialysis services to the residents of Waukegan, Illinois, which are a Health Professional Shortage Area and Medically Underserved Area. Socioeconomic indicators such as race/ethnicity, income and education attainment that drive health inequities are present in Waukegan. The patient service area for the proposed facility is 30% Hispanic, a population that experiences a higher incidence and prevalence of kidney disease. Thirteen percent (13%) of the population lives below 150% of the Federal Poverty Level (138% of the Federal Poverty Level is the income eligibility limit for the Medicaid program in Illinois). Persons with low socioeconomic status experience higher rates of death across the spectrum of causes. The option to do nothing would not address the access issues the

community currently faces, nor address the needs of Dr. Dalloul's 116 CKD patients. Based on the findings, this alternative was rejected. No cost was identified with this alternative.

2. The applicants cite the need for additional stations, based on the explosive population growth over the past three years, and the over utilization (85% average) at existing ESRD facilities in the service area. The utilization of existing facilities would exacerbate access issues at facilities in the service area, and not address the projected population growth in the service area. The applicants identified no project costs with this alternative, and this alternative was rejected.
3. The Applicants decision to establish a new facility was deemed most feasible, based on the current utilization at area facilities, the projected growth in the ESRD population in the North Dunes Dialysis GSA, and the need to increase access for a population considered most in need. **Cost of Chosen Alternative: \$3,428,482.**

IX. In-Center Hemodialysis Projects

A) Criterion 1110.1430(b)(1) & (3)

This criterion has been addressed earlier in this report.

B) Criterion 1110.1430(c) - Planning Area Need

To demonstrate compliance with this criterion the applicants must document that the number of stations to be established or added is necessary to serve the planning area's population.

1) 77 Ill. Adm. Code 1100 (Formula Calculation)

To demonstrate compliance with this sub-criterion the applicants must document that the number of stations to be established is in conformance with the projected station need.

The State Board is estimating an excess of 43 ESRD stations in the HSA VIII ESRD Planning Area per the June 2018 Revised Station Need Determinations.

2) Service to Planning Area Residents

To demonstrate compliance with this sub-criterion the applicants must document that the primary purpose is to serve the residents of the planning area.

The referring physician (Omar Dalloul, M.D. private practitioner from Libertyville) is currently treating 116 CKD patients, who reside within either the ZIP code of the proposed North Dunes Dialysis (60087) or 6 other nearby ZIP codes, all within 30 minutes of the proposed North Dunes Dialysis. Based upon attrition due to patient death, transplant, stable disease, or relocation away from the area and in consideration of other treatment modalities (HHD and peritoneal dialysis), Dr. Dalloul anticipates that at least 60 of these 116 patients will initiate in-center hemodialysis within 12 to 24 months following project completion.

Zip Codes of Pre-ESRD Patients	
60087	14
60099	14
60085	33
60083	15
60031	14
60048	15
60046	11
Total	116

3) Service Demand – Establishment of In-Center Hemodialysis Service

To demonstrate compliance with this sub-criterion the applicants must document that there is sufficient demand to justify the twelve stations being proposed.

The applicants have submitted a referral letter, estimating that at least 60 of the 116 pre-ESRD patients from the 30-minute service area will require dialysis services within 12-24 months of project completion (application, p. 204).

5) Service Accessibility

To demonstrated compliance with this sub-criterion the applicants must document that 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 must document one of the following:

- 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;
 - iv) For purposes of this subsection (c) (5) only, all services within the 30-minute normal travel time meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100.
1. There are 29 ESRD facilities with 470 stations in the HSA VIII ESRD Planning Area as of June 2018.
 2. There has been no documentation provided that there are access limitations due to payor status of patients in the HSA VIII ESRD Planning Area because all ESRD facilities approved by the State Board accept Medicare and Medicaid patients.
 3. No documentation of restrictive admission policies of existing providers has been provided by the Applicants.

4. The service area is federally designated as a health professional shortage area, and a medically underserved area, that could result in access issues to services.⁴
5. There are five (5) facilities within 30 minutes of the proposed facility. Of these five facilities, one (1) is in ramp up/not fully operational. The average utilization at the four (4) remaining facilities is approximately 84%. (See Table Five).

Conclusion:

The physician referral letter shows that there appears to be a sufficient number of pre-ESRD patients that will require dialysis within 12-24 months after project completion to justify the number of stations being requested. All of the 116 pre-ESRD patient reside within the planning area as attested to by the Applicants. However, there is an excess of ESRD stations in the planning area (43 by 2020).

STATE BOARD STAFF FINDS THE PROPOSED PROJECT NOT IN CONFORMANCE WITH CRITERION (77 ILAC 1110.1430(c) (1), (2), (3) & (5))

TABLE FIVE
ESRD Facilities within 30 minutes of the Proposed Facility

Facility	Ownership	City	Time (1)	Stations (2)	Patients (3)	Utilization (4)	Star Rating (5)
Dialysis Center of America	DaVita	Waukegan	5.8	24	145	98.6%	3
FMC Waukegan Harbor	Fresenius	Waukegan	12.7	21	115	90.48%	3
Neomedica Gurnee	Fresenius	Gurnee	18.4	24	97	70.14%	5
FMC Lake Bluff	Fresenius	Lake Bluff	27.6	16	75	76.04%	4
Total Stations/Patients/ Average Utilization				85	432	84.81%	
FMC Zion*	Fresenius	Zion	5.8	12	0	0.0%	N/A
Total Stations/Patients/ Average Utilization				97	432	67.05%	

1. Time from MapQuest and adjusted per 77 IAC 1100.510(d)
2. Stations as of March 2018
3. Patients as of March 31, 2018.
4. Utilization as of March 31, 2018
5. Star Rating taken from Medicare ESRD Compare Website
6. *Newly Established facility in ramp-up

⁴ Medically Underserved Areas/Populations are areas or populations designated by HRSA as having too few primary care providers, high infant mortality, high poverty or a high elderly population. Health Professional Shortage Areas (HPSAs) are designated by HRSA as having shortages of primary medical care, dental or mental health providers and may be geographic (a county or service area), population (e.g. low income or Medicaid eligible) or facilities (e.g. federally qualified health center or other state or federal prisons)
Primary Care Provider A physician (M.D. – Medical Doctor or D.O. – Doctor of Osteopathic Medicine), nurse practitioner, clinical nurse specialist or physician assistant, as allowed under state law, who provides, coordinates or helps a patient access a range of health care services.
Source: Centers for Medicare and Medicaid

C) Criterion 1110.1430(d) - Unnecessary Duplication/Mal-distribution

To demonstrate compliance with this criterion the applicants must document that the proposed project will not result in

1. An unnecessary duplication of service
2. A mal-distribution of service
3. An impact on other area providers

1. To determine if there is an **unnecessary duplication of service** the State Board identifies all facilities within thirty (30) minutes and determines if there is existing capacity to accommodate the demand identified in the application for permit. There are five facilities within 30 minutes of the proposed facility. Of these five facilities four are operational and one is in ramp-up. Average utilization of the four facilities is 84.81% and the utilization of the five facilities is 67.05%
2. To determine a **mal-distribution (i.e. surplus) of stations** in the thirty (30) minute service area the State Board compares the ratio of the number of stations per population in the thirty (30) minute service area to the ratio of the number of stations in the State of Illinois to the population in the State of Illinois. To determine a surplus of stations the number of stations per resident in the thirty-minute service area must be 1.5 times the number of stations per resident in the State of Illinois.

	Population	Stations	Ratio
30 Minute Service Area	370,924	97	1 Station per every 3,824 residents
State of Illinois (2015 est.)	12,978,800	4,818	1 Station per every 2,694 residents

The population in the 30-minute service area is 370,924 residents. The number of stations in the 30-minute service area is 97. The ratio of stations to population is one (1) station per every 3,824 residents. The number of stations in the State of Illinois is 4,818 stations (*as of June, 2018*). The 2015 estimated population in the State of Illinois is 12,978,800 residents (*Illinois Department of Public Health Office of Health Informatics Illinois Center for Health Statistics -2014 Edition*). The ratio of stations to population in the State of Illinois is one (1) station per every 2,694 residents. To have a surplus of stations in this thirty (30) minute service area the number of stations per population would need to be one (1) station per every 1,796 residents. Based upon this methodology there is not a surplus of stations in this service area.

3. The applicants identified five facilities in the North Dunes GSA. Of the five facilities, one (FMC Zion), is currently under construction, with a project completion date of December 2018. DaVita's Waukegan Dialysis has operated in excess of the 90th percentile for the last two quarters, and Fresenius Waukegan Harbor has operated in excess of the 90th percentile for the last two quarters. FMC Gurnee is currently operating at 70th percentile. This is attributed to a recent expansion of 8 stations at the facility, bringing the total station count to 24. The applicants supplied projected referral data from its referring physician (Dr. Rakhi Khanna, M.D.) that projects the operational capacity of FMC Gurnee to surpass the 80th percentile (State standard) before the proposed DaVita North Dunes Dialysis is completed. FMC Lake Bluff has operated steadily in the mid to high 70th percentile for the past four quarters, and is

expected to remain in this operational capacity for the foreseeable future. The applicants note FMC Lake Bluff is the farthest from the proposed North Dunes facility, and no projected North Dunes patients reside in Lake Bluff.

There are five facilities within 30-minutes of the proposed facility. One facility (FMC Zion) is in ramp-up and the remaining four facilities are operating at approximately 84%. Based upon the methodology outlined above there is no surplus of the ESRD stations in this 30 minute service area. Based upon the information reviewed by the State Board Staff and outlined above the Applicants have successfully addressed this criterion.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION UNNECESSARY DUPLICATION OF SERVICE, MALDISTRIBUTION OF SERVICE IMPACT ON OTHER FACILITIES (77 ILAC 1110.1430(d)(1), (2) and (3))

D) Criterion 1110.1430(f) - Staffing

To demonstrate compliance with this criterion the applicants must document that relevant clinical and professional staffing needs for the proposed project were considered and that licensure and Joint Commission staffing requirements can be met.

The Applicants stated the following:

“The proposed facility will be staffed in accordance with all State and Medicare staffing requirements.

- a. *Medical Director: Dr. Omar Dalloul, M.D. will serve as the Medical Director for the propose facility. A copy of Dr. Dalloul’s curriculum vitae is attached at Attachment - 24C Application, p. 153).*
- b. *Other Clinical Staff: Initial staffing for the proposed facility will be as follows:*
 - Administrator (1.04 FTE)*
 - Registered Nurse (4.52 FTE)*
 - Patient Care Technician (4.53 FTE)*
 - Biomedical Technician (0.34 FTE)*
 - Social Worker (0.57 FTE)*
 - Registered Dietitian (0.58 FTE)*
 - Administrative Assistant (0.83 FTE)*

As patient volume increases, nursing and patient care technician staffing will increase accordingly to maintain a ratio of at least one direct patient care provider for every 4 ESRD patients. At least one registered nurse will be on duty while the facility is in operation.

- c. *All staff will be training under the direction of the proposed facility's Governing Body, utilizing DaVita's comprehensive training program. DaVita's training program meets all State and Medicare requirements. The training program includes introduction to the dialysis machine, components of the hemodialysis system, infection control, anticoagulation, patient assessment/data collection, vascular access, kidney failure documentation, complications of dialysis, laboratory draws, and miscellaneous testing devices used. In addition, it includes in-depth theory on the structure and function of the kidneys: including, homeostasis, renal failure, ARF/CRF, uremia, osteodystrophy and anemia, principles of dialysis: components of hemodialysis system: water treatment: dialyzer reprocessing: hemodialysis treatment: fluid management: nutrition; laboratory: adequacy: pharmacology; patient education, and service excellence. A summary of the training program has been provided. North Dunes Dialysis will maintain an open medical staff.” [Application for Permit pages 152-155]*

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION STAFFING (77 ILAC 1110.1430(f))

E) Criterion 1110.1430(g) - Support Services

To demonstrate compliance with this criterion the applicants 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.

The applicants have provided the necessary attestation as required at pages 164-166 of the application for permit.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION SUPPORT SERVICES (77 ILAC 1110.1430(g))

F) Criterion 1110.1430(h) - Minimum Number of Stations

To demonstrate compliance with this criterion the applicants must document that 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.

The proposed 12-station facility will be located in the Chicago-Joliet-Naperville metropolitan statistical area ("MSA"). The applicants have met the requirements of this criterion.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION MINIMUM NUMBER OF STATIONS (77 ILAC 1110.1430(h))

G) Criterion 1110.1430(i) - Continuity of Care

To demonstrate compliance with this criterion the applicants 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.

The applicants have provided the necessary signed transfer agreement with Vista Medical Center East And DaVita, Inc. d/b/a North Dunes Dialysis as required. [See pages 169-176 of the Application for Permit]

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION CONTINUITY OF CARE (77 ILAC 1110.1430(i))

H) Criterion 1110.1430(k) - Assurances

To demonstrate compliance with this criterion the 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:
 $\geq 85\%$ of hemodialysis patient population achieves urea reduction ratio (URR) $\geq 65\%$
 and $\geq 85\%$ of hemodialysis patient population achieves Kt/V Daugirdas II 1.2.

The necessary attestation has been provided at pages 180-181 of the application for permit.

**STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN
CONFORMANCE WITH CRITERION ASSURANCES (77 ILAC
1110.1430(k))**