STATE OF ILLINOIS
HEALTH FACILITIES AND SERVICES REVIEW BOARD

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DOCKET NO: I-04	BOARD MEETING: October 30, 2018	PROJECT NO: 17-066	PROJECT COST: Original: $3,428,482
FACILITY NAME: North Dunes Dialysis		CITY: Waukegan	
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 leased space at a cost of $3,428,482. The expected completion date is July 31, 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 leased space at a cost of $3,428,482. The expected completion date is July 31, 2020.
- This Application for Permit received an Intent to Deny at the June 5, 2018 State Board Meeting.
- This project was deemed complete (December 7, 2017) before the new distance requirements (77 ILAC 1100.510(d)) became effective (March 7, 2018). Therefore, this Application is being reviewed with a Geographic Service Area (GSA) of 30 minutes, adjusted based on the location of the project.
- The Applicants submitted additional information to address the Intent to Deny on June 20, 2018. In part the Applicants stated:
    - There is a need for 94 additional dialysis stations in the HSA VIII ESRD Planning Area rather than a calculated excess of 43 stations in this planning area.
    - The number of ESRD patients in the proposed 30-minute GSA has grown by 7.1% compounded annually over the past four years.
    - The average utilization of the existing dialysis clinics within the proposed 30-minute GSA will exceed the target utilization of 80% by 2020 when the proposed facility will become operational. [See Additional Information submitted by the Applicants on June 20, 2018 for complete discussion]

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]

PUBLIC HEARING/COMMENT:

- A public hearing was offered for the proposed project, but none was requested. **The Applicants submitted 15** 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. There was opposition testimony at the June 5, 2018 Board meeting.

SUMMARY:

- The State Board has estimated **an excess of 43 stations in the HSA VIII ESRD Planning Area** by 2020. The proposed facility will be located in an economically disadvantaged area and an area where the residents are predominantly Hispanic and African American. The 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. All of the 116 pre-ESRD patients reside within the planning area as attested to by the Applicants. The Applicants addressed a total of 21 criteria and received negative findings for the following:

State Board Standards Not Met	
Criteria	**Reasons for Non-Compliance**
Criterion 1110.1430(c)(1) – Planning Area Need	There is a calculated excess of 43-stations in the HSA-VIII ESRD Planning Area. By rule *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.*
Criterion 1110.1430(d)(1), (2), (3) – Unnecessary Duplication/Mal-distribution of Service/Impact on Other Providers	There are five facilities in the proposed 30-minute service area. One of the five facilities is in ramp-up. One of the remaining four facilities is not at target occupancy. Average utilization of the five facilities is approximately 70%.

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	July 31, 2020
Project Completion Date	July 31, 2020
Intent to Deny	June 5, 2018
Review Period Extended by the State Board Staff?	No
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 July 31, 2020.

II. Summary of Findings

A. State Board Staff finds the proposed project **does not** appear to be in conformance with the provisions of 77 ILAC 1110 (Part 1110).

B. State Board Staff finds the proposed project appears to be 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.

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 of forty-three (43) ESRD stations by CY 2020**. The State Board has projected an increase in the population in this planning area of approximately 2% compounded annually and approximately 6.6% increase in the number of ESRD patients compounded annually in this ESRD Planning Area for the period 2015 to 2020.

TABLE ONE	
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**

IV. 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 TWO
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%**

V. 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.

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*

[1] [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)

authority to ensure that such development meets the requirements of this 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))

VI. 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 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."*

TABLE THREE
DaVita Inc.

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

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 is a Health

Professional Shortage Area and Medically Underserved Area. The patient service area for the proposed facility is 30% Hispanic, a population that experiences a higher incidence and prevalence of kidney disease. 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.**

VII. Size of the Project, Projected Utilization, and Assurances

A) Criterion 1110.234(a) –Size of the Project

To demonstrate compliance with this criterion the applicants must document that the size of the project is in conformance with State Board Standards published in Part 1110 Appendix B.

The applicants are proposing a twelve (12) station ESRD facility in 4,680 GSF of clinical space or 390 GSF per station. This is within the State Board Standard of 650 GSF per station or a total of 7,800 GSF.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION SIZE OF THE PROJECT (77 ILAC 1110.234(a))

B) Criterion 1110.234(b) – Projected Utilization

To demonstrate compliance with this criterion the applicants must document that, by the end of the second year of operation, the annual utilization of the clinical service areas or equipment shall meet or exceed the utilization standards specified in Part 1110 Appendix B. The number of years projected shall not exceed the number of historical years documented.

The applicants are projecting sixty (60) patients by the second year after project completion.

60 patients x 156 treatments per year = 9,360 treatments
Twelve (12) stations x 936 treatments available = 11,232 treatments
9,360 treatments/11,232 treatments = 83.3% [3]

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION PROJECTED UTILIZATION (77 ILAC 1110.234(b))

[3] Assumes the proposed facility will operate six (6) days a week fifty-two (52) weeks a year three (3) shifts a day.

C) Criterion 1110.234(e) - Assurances

To demonstrate compliance with this criterion the applicants must submit a signed and dated statement attesting to the applicant's understanding that, by the end of the second year of operation after the project completion, the applicant will meet or exceed the utilization standards specified in Appendix B.

The Applicants have provided the necessary attestation at pages 180-181 of the Application for Permit.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION ASSURANCES (77 ILAC 1110.234(e))

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 September 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, <u>all services within the 30-minute normal travel time meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100</u>.

1. There are 28 ESRD facilities with 451 stations in the HSA VIII ESRD Planning Area as of December 2017.
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, resulting 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 State Board has estimated an **excess of 43 stations** in the HSA VIII ESRD Planning Area by 2020. 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 are excess stations in the planning area (43). Based on these findings, a negative finding results for this criterion.

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

TABLE FOUR
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	142	98.61%	3
FMC Waukegan Harbor	Fresenius	Waukegan	12.7	21	109	86.51%	3
Neomedica Gurnee	Fresenius	Gurnee	18.4	24	111	77.08%	5
FMC Lake Bluff	Fresenius	Lake Bluff	27.6	16	79	82.29%	4
Total Stations/Patients/ Average Utilization				85	441	86.12%	
FMC Zion*	Fresenius	Zion	5.8	12	1	1.39%	N/A
Total Stations/Patients/ Average Utilization				**97**	**432**	**69.18%**	

1. Time from MapQuest and adjusted per 77 IAC 1100.510 (d)
2. Stations as of July 2018
3. Patients as of June 30, 2018.
4. Utilization as of June 30, 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. One of the four facilities is not at target occupancy. Average utilization of the four facilities is 86.12% and the utilization of the five facilities is 69.18%

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 st**a**tions 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	4,850	1 Station per every 2,676 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 4,704 stations *(as of September, 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 2,676 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 1,784 residents. Based upon this methodology there is not a surplus of stations in this service area.

3. The applicants identified five facilities in the 30-minute 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 100th 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 68th 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 is a calculated excess of 43 stations in this planning area. Based upon the information reviewed by the State Board Staff and outlined above the Applicants have not successfully addressed this criterion.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT NOT 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 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 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:**
   ≥ 85% of hemodialysis patient population achieves urea reduction ratio (URR) ≥ 65% and ≥ 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))

VIII. Financial Viability

This Act shall establish a procedure (1) which requires a person establishing, constructing or modifying a health care facility, as herein defined, to have the qualifications, background, character and ***financial resources to adequately provide a proper service for the community;*** *(2) that promotes the orderly and economic development of health care facilities in the State of Illinois that avoids unnecessary duplication of such facilities; and (3) that promotes planning for and development of health care facilities needed for comprehensive health care especially in areas where the health planning process has identified unmet needs.* (20 ILCS 3960)

A) Criterion 1120.120 – Availability of Funds

To demonstrate compliance with this criterion the Applicants must document that the resources are available to fund the project.

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 $1,089,870. A summary of the financial statements of the Applicants is provided below. The Applicants have sufficient cash to fund this project.

TABLE FIVE
DaVita Inc.
Audited Financial Statements
December 31st
(in thousands)

	2017	2016
Cash	$508,234	$674,776
Current Assets	$8,744,358	$3,994,748
Total Assets	$18,948,193	$18,755,776
Current Liabilities	$3,041,177	$2,710,964
LTD	$9,158,018	$8,944,676
Patient Service Revenue	$9,608,272	$9,269,052
Total Net Revenues	$10,876,634	$10,707,467
Total Operating Expenses	$9,063,879	$8,677,757
Operating Income	$1,812,755	$2,029,710
Net Income	$830,555	$1,033,082

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION AVAILABILITY OF FUNDS (77 ILAC 1120.120)

B) Criterion 1120.130 - Financial Viability

To demonstrate compliance with this criterion the Applicants must document that they have a Bond Rating of "A" or better, they meet the State Board's financial ratio standards for the past three (3) fiscal years or the project will be funded from internal resources.

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 Applicants have qualified for the financial

waiver. To qualify for the financial waiver an applicant must document one of the following:

1) all project capital expenditures, including capital expended through a lease, are completely funded through internal resources (cash, securities or received pledges); or

HFSRB NOTE: Documentation of internal resources availability shall be available as of the date the application is deemed complete.

2) the applicant's current debt financing or projected debt financing is insured or anticipated to be insured by Municipal Bond Insurance Association Inc. (MBIA) or its equivalent; or

HFSRB NOTE: MBIA Inc is a holding company whose subsidiaries provide financial guarantee insurance for municipal bonds and structured financial projects. MBIA coverage is used to promote credit enhancement as MBIA would pay the debt (both principal and interest) in case of the bond issuer's default.

3) the applicant provides a third-party surety bond or performance bond letter of credit from an A-rated guarantor (insurance company, bank or investing firm) guaranteeing project completion within the approved financial and project criteria.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION FINANCIAL VIABILITY (77 ILAC 1120.130)

IX. Economic Feasibility

A) Criterion 1120.140(a) – Reasonableness of Financing Arrangements

B) Criterion 1120.140(b) – Terms of Debt Financing

To demonstrate compliance with these criteria the Applicants must document that leasing of the space is reasonable. The State Board considers the leasing of space as debt financing.

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 lease is for ten years at a base rent of $22.00/psf[5] for years 1 through 5, and $24.20/psf for years 6-10. It would appear the lease is reasonable when compared to previously approved projects.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERIA REASONABLENESS OF FINANCING ARRANGEMENTS AND TERMS OF DEBT FINANCING (77 ILAC 1120.140(a) & (b))

[5] Price per square foot

C) Criterion 1120.140(c) – Reasonableness of Project Costs

To demonstrate compliance with this criterion the Applicants must document that the project costs are reasonable by the meeting the State Board Standards in Part 1120 Appendix A.

As shown below, the Applicants have met all of the State Board Standards published in Part 1120, Appendix A.

Only Clinical Costs are reviewed in this criterion.

Modernization and Contingencies Costs are $911,991 or $194.86 per GSF for 4,680 GSF of clinical space. This appears reasonable when compared to the State Board Standard of $200.71 per GSF, with 2019 listed as mid-point of construction.

Contingencies – These costs total $82,907, and are 9.9% of the modernization costs identified for this project. This is in compliance with the State standard of 10%-15%.

Architectural Fees are $96,000 and are 10.5% of modernization and contingencies. This appears reasonable when compared to the State Board Standard of 7.18% to 10.78%.

Consulting and Other Fees are $80,000. The State Board does not have a standard for these costs.

Movable or Other Equipment – These costs are $644,079 or $53,673 per station (12 stations). This appears reasonable when compared to the State Board Standard of $55,293 per station.

Fair Market Value of Leased Space and Equipment – These costs are $718,840. The State Board does not have a standard for these costs.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION REASONABLENESS OF PROJECT COSTS (77 ILAC 1120.140(c))

D) Criterion 1120.140(d) – Projected Operating Costs

To demonstrate compliance with this criterion the Applicants must document that the projected direct annual operating costs for the first full fiscal year at target utilization but no more than two years following project completion. Direct costs mean the fully allocated costs of salaries, benefits and supplies for the service.

The Applicants are projecting $273.74 operating expense per treatment.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION PROJECTED OPERATING COSTS (77 ILAC 1120.140(d))

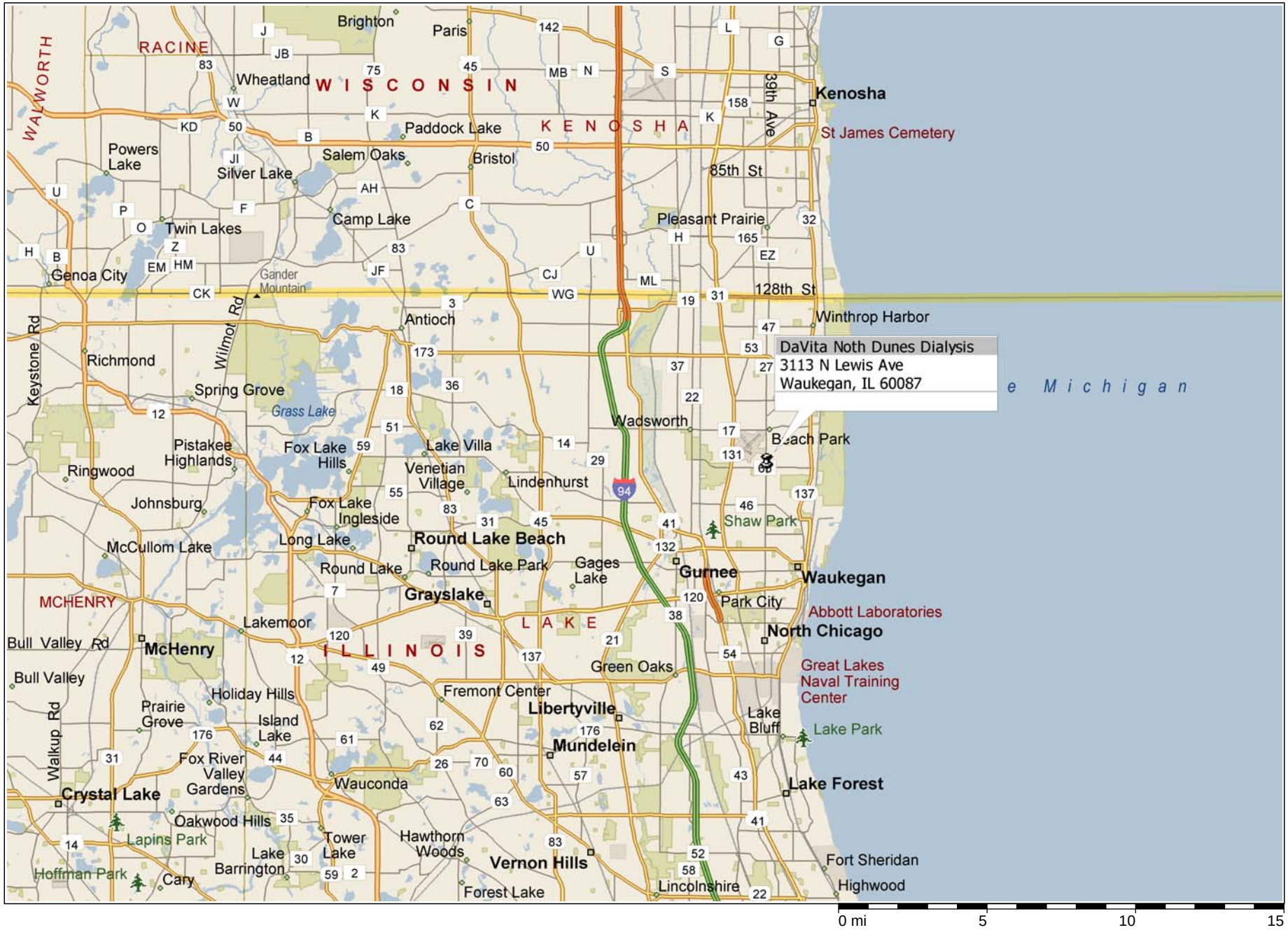
E) Criterion 1120.140(e) – Total Effect of the Project on Capital Costs

To demonstrate compliance with this criterion the Applicants must provide the total projected annual capital costs for the first full fiscal year at target utilization but no more than two years following project completion. Capital costs are defined as depreciation, amortization and interest expense.

The Applicants are projecting capital costs of $23.90 per treatment.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION TOTAL EFFECT OF THE PROJECT ON CAPITAL COSTS (77 ILAC 1120.140(e))

17-066 DaVita North Dunes Dialysis - Waukegan



POLSINELLI

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June 19, 2018

Via Federal Express

Anne M. Cooper
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Ms. Kathryn J. Olson, Chair
IL Health Facilities & Services Review Board
525 West Jefferson Street, 2nd Floor
Springfield, Illinois 62761

Re: DaVita North Dunes Dialysis (Proj. No. 17-066) ("Proposed Clinic")
Submission of Additional Information

Dear Ms. Olson:

Polsinelli represents DaVita Inc. and Botkins Dialysis, LLC (collectively, the "Applicants") in the above-referenced proposal to establish a 12-station dialysis clinic in Waukegan, Illinois (the "Proposed Clinic"). In this capacity, we are writing to provide additional information subsequent to the Illinois Health Facilities and Services Review Board's (the "State Board") June 5, 2018 meeting where the Proposed Clinic received four favorable votes but did not pass. Pursuant to Section 1130.670 of the State Board's Procedural Rules, the Applicants respectfully submit supplemental information regarding the Proposed Clinic.

As the Applicants have previously described and as further discussed in this submission, the need for additional dialysis services in Waukegan is compelling. That need, however, was unfortunately overshadowed at the last meeting by the technical excess of dialysis stations in the planning area that is largely accounted for by the expansion of services in the Elgin area, roughly 90 minutes away. As we also detail in this submission, the need for dialysis services in HSA 8 is understated and there is an actual need for dialysis stations in the Planning Area (Lake County specifically), not an excess of stations.

Waukegan is located in a large and diverse planning area comprised of three of the collar counties of the Chicago metropolitan area (Kane, McHenry and Lake County). Despite 470 stations either operating or approved in the larger planning area, according to the most recently published State Board data, there are only 10 dialysis clinics operating in Lake County where over 700,000 people reside including in Waukegan which is the largest city in Lake County. Despite having close to the combined population of the two other planning area counties, the three CON permit applications approved by the Board for the planning area since the last

inventory update was published have all been in Kane County in the Elgin area. These permits covered a total of 31 stations for FMC-South Elgin, (17-038), DCC-Elgin (17- 061) and FMC-Elgin (18-004). As they are all approximately 90 minutes away, none of these additional dialysis services are available for patients with kidney disease who reside in Waukegan.

After considering that data at a macro level, it is essential to carefully assess the target area to be served for a better understanding of the clear health planning rationale for the establishment of the Proposed Clinic. The key points of this submission are summarized as follows:

- As it is targeting Waukegan, a highly populated area, which is one of the most population dense areas of the planning area, the addition of the Proposed Clinic will help to properly distribute needed stations in the planning area.
- The Proposed Clinic would not create a maldistribution of stations based on the high utilization of existing providers and the total population to be served.
- There is a need for 94 more dialysis stations than the current Need Determination of State Board identifies (43 station excess) and, conservatively, a need for 43 stations in Lake County
- The growth rate of ESRD patients in the patient service area far outpaces growth of ESRD patients in the State of Illinois as a whole and also outpaces growth in the HSA and Lake County
- The rapid increase in utilization of dialysis clinics in the patient service area indicates that the average utilization of those clinics will well exceed 80% in 2020 when this clinic will come online
- Recognizing the demand for additional services, the Proposed Clinic is well supported by community stakeholders including by Vista Health System, which operates the only acute care hospital in Waukegan; Erie Family Health Centers, a leading provider of free health clinics in the Chicago area including Waukegan; State Rep. Rita Mayfield and Waukegan Mayor Sam Cunningham; and numerous physicians and business leaders

As discussed below, DaVita's primary competitor's business partner, the Fresenius affiliated nephrologists who are part of Nephrology Associates of Northern Illinois and Indiana, provided misleading comments in opposition to the Proposed Clinic. As you will see from the data provided in this letter, however, the project is fully justified by patient demand and will address one of the most significant and growing needs for additional dialysis services in the State of Illinois.

1. Proposed Clinic is well placed to meet Planning Area Demand

The planned site for the Proposed Clinic has extremely high population density when compared to other parts of the HSA 8 planning area. As shown in the table below, a substantial majority of the population of HSA 8 resides in Lake County. More specifically, Waukegan is among the most densely populated areas in Lake County.

HSA 8 Population Density			
	2017 Population Estimate[1]	% HSA 8 Population	Pop. per Square Mile
HSA 8	1,547,309		424
Lake County	703,520	45.5%	1,585
Waukegan	87,729	5.7%	3,724
Kane County	534,667	34.5%	1,028
McHenry County	309,122	20.0%	513

As you can see, Waukegan is nearly nine times denser from a population perspective than the planning area as a whole, so it is no surprise that the need for additional services would be focused in Lake County and Waukegan specifically.

Waukegan lies 40 miles north of Chicago, on the coast of Lake Michigan in Lake County. Over the past 40 years, Waukegan has seen a sharp decline in its manufacturing sector. In 1972, Waukegan had 10,100 manufacturing jobs; approximately 15.5% of its total work force. By 2002, manufacturing employment numbers had dropped down to 4,780, making up only about 5% of Waukegan's work force. 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 along with the city's swelling population. Waukegan's population expanded by 27% in the 1990s decade alone. The most significant change has been the rapid growth of its foreign-born population, which increased 148% between 1990 and 2000.

Unlike other towns in Lake County, Waukegan has not enjoyed rising prosperity. From 2000 to 2016, the median family income in Lake County increased 27% (from $76,424 to $97, 079) whereas the median family income in Waukegan increased 12% (from $47,341 to

[1] Source: U.S. Census Bureau, Census 2010, American Factfinder available at https://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml (last visited June 14, 2018)

$52,872).[2] As discussed further in the Applicants' February 28, 2018, income disparities create systematic health inequities. As a result, more individuals in Waukegan lack timely access to physicians and experience higher rates of hypertension and diabetes than other areas of Lake County. Importantly, hypertension and diabetes are two leading causes of kidney disease. The Proposed Clinic will be well-positioned to meet the growing need for dialysis services in Waukegan.

2. Need for Dialysis Clinic in Waukegan

In the June 2018 State Board Report, the Proposed Clinic received a single negative finding for Planning Area Need, but the reality is there is a need for 51 stations in HSA 8 and 43 stations in Lake County. Further, the State Board's new need numbers are not projected to be released until late summer/early fall of 2019. As discussed more fully below, there is an acute need for dialysis stations in Waukegan today. Patients should not have to wait two years for improved access to dialysis, particularly an economically challenged community like Waukegan that has more barriers to access health care than other more affluent communities.

a. Medically Underserved Area and Health Professional Shortage Area

As noted in the Proposed Clinic's certificate of need application, Waukegan is federally designated as ***both*** a Health Professional Shortage Area ("HPSA") and a Medically-Underserved Area ("MUA") by the Health Resources and Services Administration. Residents suffer from health inequities – differences in population health status and health conditions that are systemic, patterned, and actionable. Given the high rates of poverty and the high Hispanic population in Waukegan, these federal designations become even more concerning because many area residents lack the ability to travel elsewhere for care and face other issues, including language barriers, that further limit their access to health care services.

b. High Rates of Poverty/Disease Incidence

Waukegan has the highest number of persons living in poverty in Lake County and the poverty rates are worsening. From 2009 to 2016, the number of persons living below the Federal Poverty Level increased nearly 50%. Additionally, the percentage of Waukegan residents living in poverty[3] is over twice the percentage of Lake County as a whole and 1.5 times greater than the State. The Lake County Health Assessment found a correlation between educational attainment and household income and overall rates of hypertension, obesity and diabetes – all three of

[2] U.S. Census Bureau, American Fact Finder, Selected Economic Characteristics (Employment, Commute, Income, Health Insurance, Poverty) *available at* https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml# (last visited Jun. 16, 2018).

[3] These individuals live below 150% of the Federal Poverty Level, the metric frequently used to determine eligibility for government assistance programs and low-income data.

which are precursors to kidney disease. The application also cited higher rates of kidney disease incidence in the community due to the fact that a vast majority of the population, 71.3% is Hispanic or African-American. This high disease incidence is also reflected in the demographic mix of the two existing Waukegan clinics. Of 290 patients between the two clinics, 85% were either Hispanic or African-American.[4]

c. Waukegan Clinics are Highly Utilized

Both DaVita and Fresenius' existing clinics in Waukegan operate in excess of 90% utilization. As noted in the June 2018 State Board Report, the four fully operational clinics within 30 minutes of the Proposed Clinic are operating at 84.81%, well above the State Board Standard. The State Board Report appropriately concluded that the Proposed Clinic would not cause unnecessary duplication of services.

d. Planning Area Need

Based on the June 11, 2018 update to the inventory of hemodialysis stations, the State Board calculated an excess of 43 stations in HSA 8. As discussed more fully in the Applicants' April 30, 2018 submission, due to significant growth in patient census over the past four years and insufficient capacity among existing clinics within the North Dunes 30 minute GSA, there is a need for 51 dialysis stations in HSA 8, and more specifically 43 dialysis stations in Lake County. See Attachment – 1.

3. Response to Opposition

a. Existing Clinics are Underutilized

Several commenters at the June 5, 2018 State Board meeting claimed existing facilities within the 30 minute geographic service area ("GSA") are underutilized and adding stations would negatively affect existing clinics. As of March 31, 2018, there are five clinics within 30 minutes of the Proposed Clinic. As shown in the table on the following page, average utilization of the existing clinics was 74%; excluding Fresenius Medical Care Zion ("FMC Zion"), which is currently under construction, average utilization is 85%. Among the existing and approved clinics in the GSA, there is insufficient capacity to accommodate all of Dr. Omar Dalloul's projected patients. The two dialysis clinics in Waukegan are operating well over 90%, with the Applicant's clinic operating 4 shifts to accommodate patient need. Further, the other two operational dialysis clinics in the GSA will likely reach target utilization by the time the Proposed Clinic is operational. Finally, FMC Zion is not a viable option for patients whose kidneys fail. First, it is a 12 station dialysis clinic and can only accommodate 72 patients. Importantly, these stations are committed to a different patient base. Specifically, Dr. Omaiam

[4] See IDPH End Stage Renal Dialysis 2016 Profiles for DaVita Waukegan and Fresenius Medical Care Waukegan.

Degani certified 69 of her chronic kidney disease patients would initiate dialysis by the second year of operation.[5] Dr. Dalloul has identified 60 patients, so this clinic does not address his patients' needs. Finally, Fresenius Medical Care certified FMC Zion would achieve and maintain average utilization of 80% by the second year of operation.[6] Accordingly, additional stations are needed to maintain access to life sustaining dialysis services in Waukegan.

North Dunes GSA Utilization							
Facility	**Ownership**	**City**	**Distance**	**Adjusted Time**	**Number of Stations 03/31/18**	**Number of Patients 03/31/18**	**Utilization % 03/31/18**
FMC Zion	Fresenius	Zion	3.0	5.8	12	-	0.00%
Waukegan Renal Center	DaVita	Waukegan	5.0	5.8	24	145	101%
FMC Waukegan Harbor	Fresenius	Waukegan	4.0	12.7	21	115	91 %
FMC Gurnee	Fresenius	Gurnee	6.5	18.4	24	97	67%
FMC Lake Bluff	Fresenius	Lake Bluff	11.4	27.6	16	75	78%
Total					**97**	**432**	**74%**
Total Facilities Operational > 2 Years					**85**	**432**	**85%**

Additionally, the Proposed Clinic's GSA experienced significant growth over the past four years. From March 2014 to March 2018, the Proposed Clinic's GSA experienced 32% growth (or 104 net patients). See Attachment – 2. This amounts to a compound annual growth rate ("CAGR") of 7.1% in this area during that four year period. If the current trend continues, the Applicants project there will be 496 in-center hemodialysis patients by Q1 2020 when the Proposed Clinic becomes operational, and the 97 existing and approved stations will operate at 85% utilization.

Finally, within the Proposed Clinic's smaller patient service area, which is an approximate 10 mile radius around the Proposed Clinic and aligns with the State Board's new travel radius rules, the growth is more pronounced than in either the 30 minute geographic service area or HSA 8. As shown in Attachment – 3, patient census at the clinics within 10 miles

[5] See FMC Zion Application for Permit pp 66, 69-77 *available* at https://www2.illinois.gov/sites/hfsrb/Projects/ProjectDocuments/2015/15-036/2015-07-30%2015-036%20APPLICATION.pdf (last visited Jun. 16, 2018).
[6] Id. at 94.

of the Proposed Clinic grew by 40% from March 2014 to March 2018, which is a compound annual growth rate of 8.7%. Applying the 8.7% growth rate to the March 2018 patient census, the Applicants project there will be 422 dialysis patients in the 10 mile patient service area by Q1 2020, which will result in average utilization of 86.7% for the existing and approved clinics.

Importantly, this data shows there is an acute need for stations in Waukegan, where the Proposed Clinic will be located.

b. Excess Stations in HSA 8

One commenter stated the Proposed Clinic was not needed to due to an excess of stations in HSA 8. While there may be a technical excess of stations, the need calculation does not always accurately portray the need for dialysis stations or lack thereof, in all areas of an HSA, particularly those vastly populated over large geographic areas like HSA 8. HSA 8 encompasses 3 counties, totaling 1,567 square miles. It is important to understand the need calculation is largely based upon the ratio of dialysis patients to total population and assumes the dialysis stations are uniformly distributed throughout the HSA. When a maldistribution occurs, a calculated excess of stations may exist despite an actual need in some communities.

c. Fresenius Submitted Its Application Before DaVita

One commenter noted Fresenius submitted its application prior to DaVita, implying the Fresenius project should be approved over the Proposed Clinic. The Applicants have not yet opposed the Fresenius Waukegan Park project, but if the State Board members believe only one project should be approved, the Applicants believe their application is better positioned to address the need for dialysis services in Waukegan.

As shown in the table on the following page, there are 10 approved and operational clinics within the Waukegan Park GSA, compared to five clinics within the Proposed Clinic's GSA. Average utilization of the existing and approved clinics is 68% in the Proposed Clinic GSA, compared to 74% in the Proposed Clinic's GSA. Excluding FMC Zion, which is currently under construction, the Proposed Clinic's GSA utilization is significantly higher than the proposed Waukegan Park GSA utilization (85% to 73%). Further, the existing clinics in the Waukegan Park GSA, excluding FMC Zion, can accommodate 112 patients before reaching the State Board's 80% utilization standard, well above Dr. Nino Alapishvili's 61 projected patients. Finally, the 4 year CAGR is higher in the Proposed Clinic's GSA than the Waukegan Park GSA (7.1% to 6.1%). Applying the respective CAGRs to these proposed projects, the Proposed Clinic's GSA is projected to reach 85% by Q1 2020 whereas the Waukegan Park GSA will achieve 77% utilization, below the State Board's 80% utilization standard. Accordingly, the need for additional stations is more acute in the Proposed Clinic's GSA than Waukegan Park.

FMC Waukegan Park GSA Utilization							
Facility	**Ownership**	**City**	**Time**	**Distance**	**Number of Stations 03/31/18**	**Number of Patients 03/31/18**	**Utilization % 03/31/18**
Waukegan Renal Center	Davita	Waukegan	4	2.0	24	145	101%
FKC Waukegan Harbor	Fresenius	Waukegan	5	2.2	21	115	91%
FKC Gurnee	Fresenius	Gurnee	6	2.5	24	97	67%
FKC Lake Bluff	Fresenius	Lake Bluff	11	7.0	16	75	78%
FKC Deerfield	Fresenius	Deerfield	19.2	25.0	12	26	36%
Lake County Dialysis Center	Davita	Vernon Hills	21	13.8	16	66	69%
FKC Highland Park	Fresenius	Highland Park	21	14.0	20	49	41%
FMC Zion[1]	Fresenius	Zion	22	10.4	12	-	0.00%
FKC Round Lake	Fresenius	Round Lake	22	11.9	16	79	82%
FKC Mundelein	Fresenius	Mundelein	22	15.0	14	64	76%
Total					**175**	**716**	**68%**
Total Facilities Operational > 2 Years					**163**	**716**	**73%**

[1]December 31, 2018 project completion date

4. Response to Other State Board Member Comments

a. Dialysis Government Coverage

Board members inquired as to whether age was a factor in Medicare eligibility for patients diagnosed with end-stage renal disease ("ESRD"). Most patients qualify for insurance coverage whether through an employer, Medicare or Medicaid. Medicare is the primary payor of dialysis, covering nearly 80% of ESRD patients.[7] As discussed at the June 5, 2018, people of any age diagnosed with ESRD who need a transplant or dialysis, including children, may qualify for Medicare coverage, provided one of the following requirements is met:

[7] United States Renal Data System. 2017 USRDS annual data report: Epidemiology of kidney disease in the United States 437. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2017 *available at* https://www.usrds.org/2017/download/v2_c09_MedExp_17.pdf (last visited Jun. 18, 2018).

- Worked the required amount of time under Social Security,[8] the Railroad Retirement Board (RRB), or as a government employee;
- Receiving or eligible for Social Security or Railroad Retirement benefits; or
- Spouse or dependent child of a person who meets either of the requirements listed above.

Patients who do not qualify for Medicare and are not covered by commercial insurance can generally obtain health benefits coverage through Medicaid. In Illinois, the Illinois State Chronic Renal Disease program assists Illinois residents diagnosed with ESRD and requiring a regular course of dialysis to maintain life. The program is for patients with chronic renal disease who require lifesaving care and treatment, but do not qualify for Medicaid or All Kids or cannot meet the spend down requirements.[9]

b. Home Support

At least one Board member inquired as to whether a technician could be provided by a dialysis provider to assist ESRD patients with home dialysis as a method of encouraging the home modality. Unless a patients pays separately for such service, under current federal law, this type of arrangement constitutes a beneficiary inducement is prohibited for Medicare and Medicaid patients who receive dialysis. Section 1128A(a)(5) of the Social Security Act provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the provider knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). The provision of a technician to assist patients with home dialysis constitutes an impermissible beneficiary inducement as it could influence an ESRD patient's choice of dialysis provider. As such home support would provide ongoing one-to-one assistance, if it were integrated into payment program benefits, it does not appear to be a method that would generally reduce the cost of care compared to that provided in an in-center, staff-assisted setting where a higher ratio of patients' care can be overseen more cost effectively.

While the Applicants are prohibited from providing patient technicians from assisting patients with home dialysis, the Illinois Department of Human Services administers the Home Services Program, which provides services to individuals with severe disabilities so they can

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[8] Generally, 40 credits are required to qualify for Social Security disability benefits. Social Security work credits are based on total yearly wages or self-employment income. Individuals can earn up to four credits each year. See Social Security Administration, How You Qualify *available* at https://www.ssa.gov/planners/disability/ qualify.html#anchor2 (last visited Jun. 18, 2018).

[9] See Department of Healthcare and Family Services, State Chronic Renal Disease Program *available at* https://www.illinois.gov/hfs/medicalclients/renal/Pages/default.aspx (last visited Jun. 18, 2018).

remain in their homes and be as independent as possible.[10] Patients, who are eligible for this program,[11] may be able to obtain assistance with their home dialysis. The policy objective here is likely to reduce nursing home costs.

Thank you for your consideration of the additional information for North Dunes Dialysis. If you have any questions or need further information, please do not hesitate to contact me.

Sincerely,

Anne M. Cooper

Anne M. Cooper

Attachments

Cc: Gaurav Bhattacharyya

[10] Illinois Department of Human Services, Home Services Program *available at* http://www.dhs.state.il.us/page.aspx?item=29738 (last visited Jun. 18, 2018).

[11] Eligibility criteria for the Home Services Program are: (1) Be under age 60 at the time of application unless in the AIDS or Brain Injury Medicaid Waiver Program; (2) Have a significant disability lasting 12 months or longer, or for the duration of life; (3) Be at imminent risk of nursing facility placement; (4) Have applied, cooperated and obtained a decision on Medicaid eligibility unless already on Medicaid or spend-down; (5) Require services in the home costing the same or less than nursing facility costs; (6) Be a State of Illinois resident with U.S. citizenship or show proof of legal entry into the United States; (7) Have assets under the asset limit which is different for individuals under age 18 and those 18 and older; (8) Have a physician's approval of the initial plan of care; and (9) Score the required points on the Determination of Need (DON). See Illinois Department of Human Services, Home Services Program *available at* http://www.dhs.state.il.us/page.aspx?item=60122 (last visited Jun. 18, 2018).

Attachment – 1

	HSA 8	Kane County	Lake County	McHenry County
Population - 2015[12,13]	1,540,100	525,044	702,017	313,039
In Station ESRD Patients - 2017	1,710	709	801	200
Use Rate 2017	1.11	1.35	1.14	0.64
Planning Area Population - 2020 (Est)[14]	1,692,900	583,386	764,458	345,056
Projected Patients - 2020	1,880	788	872	220
Adjustment	1.33	1.33	1.33	1.33
Patients Adjusted	2,500	1,048	1,160	293
Projected Treatments - 2020	389,991	163,449	180,973	45,740
Existing Stations[15]	470	177	199	94
Stations Needed - 2020	521	218	242	61
Number of Stations Needed	**51**	**41**	**43**	**(33)**

[12] Illinois Health Facilities and Services Review Board, Inventory of Other Healthcare Services (Sep. 27, 2017) *available at* https://www2.illinois.gov/sites/hfsrb/InventoriesData/HealthCareFacilities/Documents/Other%20Services%20Inventory%202017.pdf (last visited Apr. 30, 2018).

[13] Illinois Health Facilities and Services Review Board, 12/31 ESRD Utilization Data.

[14] Illinois Health Facilities and Services Review Board, Inventory of Other Healthcare Services (Sep. 27, 2017) *available at* https://www2.illinois.gov/sites/hfsrb/InventoriesData/HealthCareFacilities/Documents/Other%20Services%20Inventory%202017.pdf (last visited Apr. 30, 2018).

[15] Illinois Health Facilities and Services Review Board, Update to Inventory of Other Health Services (includes ASTC, ESRD and Alternative Models) (Jun. 11, 2018) *available at* https://www2.illinois.gov/sites/hfsrb/InventoriesData/MonthlyHCFInventory/Documents/OTHER%20SERVICES%20INVENTORY%20UPDATE%20June%2011%202018.pdf (last visited Jun. 16, 2018).

North Dunes 2020 Projected Utilization

Facility	Ownership	Address	City	Distance	Adjusted Time	Number of Stations 03/31/18	Number of Patients 03/31/18	Utilization % 03/31/18
FMC Zion	Fresenius	1920 North Sheridan	Zion	3.0	5.8	12	-	0.00%
Dialysis Center of America - NCDC	Davita	1616 North Grand Avenue	Waukegan	5.0	5.8	24	145	100.69%
Fresenius Medical Care Waukegan Harbor	Fresenius	110 N. West Street	Waukegan	4.0	12.7	21	115	91.27%
Neomedica - Gurnee	Fresenius	40 Tower Court in Gurnee	Gurnee	6.5	18.4	24	97	67.36%
Fresenius Medical Care of Lake Bluff	Fresenius	101 Waukegan Road	Lake Bluff	11.4	27.6	16	75	78.13%
Total						97	432	74.23%
Total Facilities Operational > 2 Years						**85**	**432**	**84.71%**

March 2014 to March 2018	31.7%
4 Year CAGR	7.1%
2019 Projected Patients	463
2020 Projected Patients	496
2020 Projected Utilization	85.2%

Attachment - 2

North Dunes 2020 Projected Utilization

Facility	Ownership	Address	City	Distance	Adjusted Time	Number of Stations 03/31/18	Number Patients 03/31/18	Utilization % 03/31/2018
EMC Zion	Fresenius	1920 North Sheridan	Zion	3.0	5.8	12	-	0.00%
Dialysis Center of America - NCDC	Davita	1616 North Grand Avenue	Waukegan	5.0	5.8	24	145	100.69%
Fresenius Medical Care Waukegan Harbor	Fresenius	110 N. West Street	Waukegan	4.0	12.7	21	115	91.27%
Neomedica - Gurnee	Fresenius	40 Tower Court in Gurnee	Gurnee	6.5	18.4	24	97	67.36%
Total						**81**	**357**	**73.46%**
Total Facilities Operational > 2 Years						**69**	**357**	**86.23%**

March 2014 to March 2018	39.5%
4 Year CAGR	8.7%
2019 Projected Patients	388
2020 Projected Patients	422
2020 Projected Utilization	86.7%

Attachment - 3

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Date: June 5, 2018
Case: State of Illinois Health Facilities and Services Review Board

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ILLINOIS DEPARTMENT OF PUBLIC HEALTH

HEALTH FACILITIES AND SERVICES REVIEW BOARD

OPEN SESSION

Bolingbrook, Illinois 60490

Tuesday, June 5, 2018

9:28 a.m.

BOARD MEMBERS PRESENT:

KATHY OLSON, Chairwoman

RICHARD SEWELL, Vice Chairman

BRAD BURZYNSKI

BARBARA HEMME

JOHN MC GLASSON, SR.

RON MC NEIL

MARIANNE ETERNO MURPHY

Job No. 167323B

Pages: 1 - 181

Reported by: Paula Quetsch, CSR, RPR

EX OFFICIO MEMBERS PRESENT:

BILL DART, IDPH

ARVIND K. GOYAL, IHFS

ALSO PRESENT:

JEANNIE MITCHELL, General Counsel

COURTNEY AVERY, Administrator

MICHAEL CONSTANTINO, IDPH Staff

ANN GUILD, Compliance Manager

GEORGE ROATE, IDPH Staff

C O N T E N T S

C O N T E N T S C O N T I N U E D

C O N T E N T S C O N T I N U E D

these projects will have an adverse impact on patient choice and an adverse impact upon established independent providers.

We ask that the Board give these applications a final denial today.

CHAIRWOMAN OLSON: Thank you.

Next.

DR. DEGANI: Good morning. My name is Dr. Omaima Degani. I'm a nephrologist with NANI, and I am here to testify in opposition to the proposed DaVita North Dunes dialysis facility.

As a medical director of Fresenius Antioch, which is a mere 25 miles from the proposed facility, I can attest that the utilization of the existing facilities is under capacity. As the Board well knows, in 2015 the Board approved a unit in Zion which currently has not even been built yet. So between Antioch being underutilized and Zion not even being built, there's no need at this time for further dialysis chairs in the Waukegan area.

The most important thing as a practitioner in this area is to meet the needs of the patients. As part of NANI, we put patients first more than anything else, and regardless whether it's a

DaVita facility or a Fresenius facility, we will always put patients first and put their best interests first.

By adding another dialysis unit, we would be spreading the care for these patients, which is not in the patients' best interests. Having been in practice in this area for 10 years, it is an underserved area, and we certainly feel that the current dialysis facilities are adequate to meet the needs of the patients, and there's no further need for more chairs in the Waukegan area.

The most important thing, as I said, is to put patient care first and do what's best for the patients. Currently where the patients are receiving dialysis is sufficient to meet the needs of our area.

At NANI the culture of our organization has always been to focus on patient care, and whether it's with Fresenius or with DaVita, as I stated, we put patients first.

I thank you for your time and willingness to consider my comments as you vote on this project. I respectfully request that you vote no on the DaVita North Dunes project as there is no

need for further stations in this area.

CHAIRWOMAN OLSON: Thank you, Doctor.

Next.

MR. BRENNAN: Hello. My name is Bill Brennan. I'm a long-time NANI employee. I'm here to oppose the two DMG DaVita projects.

As you know, within the last 12 months DaVita/DMG has submitted eight projects totaling 84 dialysis stations. There are good reasons why the Board has already voted no on every one of these projects. The applicant has played games with the rules, repeatedly deferring consideration of applications trying to salvage these poorly planned projects. Regardless of how much they try to manipulate the process, you can be confident nothing has changed when you consider these projects today.

Over the last nine months, again, the Board has voted to deny these applications. Since then the applicant has hired new consultants. The consultants submitted additional information that, to their credit, admits incorrect and inaccurate information was previously submitted, confirming what we've been saying all along. The applicants

Medicare program and flood the area with unnecessary stations that can only be utilized by plundering patients from existing providers. All of this to pad the DMG bottom line.

MR. ROATE: Two minutes.

DR. ROHAIL: We don't come here to protect ourselves from competition --

CHAIRWOMAN OLSON: Please conclude.

DR. ROHAIL: We would ask you to deny this project, respectfully.

CHAIRWOMAN OLSON: Thank you.

DR. SUJATA: Good morning. My name is Leon Sujata, L-e-o-n S-u-j-a-t-a, and I'm a nephrologist with NANI. I'm here to oppose the DaVita North Dunes dialysis facility.

I'm the current medical director of another DaVita facility, DaVita Lake County in Vernon Hills, which is located approximately 10 miles from the proposed North Dunes site.

Like my colleagues, Dr. Din and Dr. Degani, I'm already working with patients and other existing facilities in the HSA, and I can confidently state here today that there's no need for additional stations in Waukegan.

I have worked in this community for almost four years, and I've developed a strong relationship with my patients in surrounding communities. As a NANI nephrologist, I am fortunate to work with colleagues whose only focus is patient care.

I too support the findings of your State Board staff report which show an excess of 24 stations in the has. There's simply not enough patients to support another facility in the has, let alone Waukegan.

I work with DaVita Lake County in Vernon Hills in cases where it is in the best interests of my patients. I have other patients that I refer to Fresenius facilities because that's what's best for them. I hope this Board can appreciate the commitment that physicians have for patients and their well-being.

I believe that the plan process works because without it you would not have an opportunity to hear from physicians like myself who are working in the community caring for these patients day in and day out.

I thank you for your time and willingness to consider my comments as you vote on this

project. I respectfully request that you vote no on DaVita North Dunes project in Waukegan, as there's no need for additional stations in the area. Thank you.

CHAIRWOMAN OLSON: Thank you.

DR. DIN: Good morning. My name is Dr. Salima Din, and I'm a nephrologist at NANI and the medical director of the DaVita Waukegan facility located a short 5 miles from the proposed facility, and I'm here to testify in opposition to the proposed DaVita North Dunes facility.

You may be asking yourself why the medical director of a fellow DaVita facility would oppose the establishment of another DaVita facility in the area. The answer is simple. I do not work for DaVita; I work with them to get my patients the care they need. As a medical director already working in Waukegan, I can confidently state today that there is no need for additional stations in Waukegan.

At NANI the culture of our organization has always been to focus on patient care. We will work with any provider who is dedicated to improving the quality of life of our patients. It doesn't

matter to us if the facility is operated by DaVita, or Fresenius, or US Renal Care because patient care is our only concern. That is the reason we are part of the ESCO. That is why we are strong supporters of organizations like National Kidney Foundation and why so many patients choose NANI doctors.

I can personally attest to the findings of your State Board staff report which indicates there's no calculated need for the stations in this has. By virtue of its location alone, this facility cannot succeed without affecting other existing facilities. In this has there are four operating facilities and a fifth one that is not operational yet. There are shifts and stations that are available for new patients. For anyone to sit here and state otherwise would be a misrepresentation of the facts.

I thank you for your time and willingness to consider my comments as you vote on this project, and I respectfully request that you vote no on the DaVita North Dunes project in Waukegan, as there's no need for additional stations in the area. Thank you.

That's 7 votes in the affirmative.

CHAIRWOMAN OLSON: The motion passes.

MS. FRIEDMAN: Thank you very much.

CHAIRWOMAN OLSON: Next is Project 17-066, DaVita North Dunes Dialysis.

May I have a motion to approve Project 17-066, DaVita North Dunes Dialysis to establish a 12-station ESRD facility in Waukegan?

MEMBER MC GLASSON: So moved.

MEMBER MURPHY: Second.

CHAIRWOMAN OLSON: Okay. Somebody joined us at the table.

(Witness sworn.)

CHAIRWOMAN OLSON: Mr. Constantino, your report.

MR. CONSTANTINO: Thank you, Madam Chair. The applicants propose to establish a 12-station ESRD facility in approximately 7100 gross square feet of lease space at a cost of approximately $3.4 million. The expected completion date April 30th, 2020.

There was no public hearing requested, and there's no opposition to this project. There is an excess of 24 stations in this planning area,

and the average utilization of the existing facilities within 30 minutes is 84 percent.

Thank you, Madam Chair.

CHAIRWOMAN OLSON: There was opposition to this project in public.

MR. CONSTANTINO: We didn't receive any opposition letters.

CHAIRWOMAN OLSON: All right. But there was opposition?

MR. CONSTANTINO: Yes. That's correct.

CHAIRWOMAN OLSON: Okay. Comments for the Board, please.

MR. BHATTACHARYYA: My name is Gaurav Bhattacharyya. I'm the vice president for DaVita here in Chicago. With me today is Dr. Dalloul, our planned medical director for our facility in Waukegan, as well as our legal counsel, Kara Friedman and Anne Cooper.

I would like to thank Board staff for their review of the planned clinic and the generally positive State Board report. We'll touch on the single negative finding in the report in a moment.

I would like to take this time to make three points here today. The first is that Waukegan

is a highly medically underserved community with all the associated socioeconomic indicators. Two, Waukegan needs more dialysis services capacity, as we'll talk about in a second. And three, this proposed clinic is broadly supported by community stakeholders.

So on the first point, underserved community, Waukegan is by far the largest community in Lake County. It is also the poorest and has been designated as a medically underserved community and a health professional shortage area. As you see on the map here, the darkest shade of green represents higher incidence of poverty, and Waukegan County on the far right there as you can see is -- sorry, Waukegan Township -- and that's where this clinic is proposed to be established.

As I was saying, it's also a medically underserved community and a health professional shortage area, and the poverty and health care access issues indicate that Waukegan deserves due consideration from this Board as your service accessibility rules for ESRD care provide.

As I think many of you know, people living in poverty are 50 percent more likely to experience

hypertension and over twice as likely to be diagnosed with diabetes, and both of those conditions are the two leading causes of kidney failure which then requires dialysis for treatment.

I'd also like to comment on the red herring statement that our competitor made today around the ESCOs. Representatives of NANI emphasize that this ESCO is a reason to set aside our proposal. I think it would be helpful to note that DaVita also participates in the same ESCO program around the country. The goal of the ESCOs is really to derive better clinical outcomes at lower cost, as Brian mentioned. And in Chicagoland DaVita is the provider with the highest percentage of clinics with three stars or more under CMS's five-star program. It's also the top performing provider under CMS's quality incentive program.

In addition, DaVita is leading an effort in Congress right now on the Patient Act, which if passed would provide integrated value-based care for a much larger segment of the ESRD population. So our focus on quality in outcomes is in no way limited to the CMS initiatives here. We support our patients with our innovative programs,

including Kidney Smart disease education program that's free and open to anyone in the public, a Fistula First initiative, an impact program, and most recently we collaborated with the University of Chicago on data sharing technology to help patients with the kidney transplant wait list program.

The second point on the need, as we documented in our submission revising the use rates to account for the December 2017 patient census, there's a need for an additional 70 stations in this planning area by 2020, which as Mr. Constantino said is when this project will get online, and 33 of those stations are needed in Lake County. This need methodology is not disputed and provides a more current picture of the needs of this community. However, due to the delay in data reporting, the Board report reflects outdated service need figures based on a two-year-old snapshot.

There are four clinics within a 30-mile drive of this proposed location, and the average utilization of those clinics today is 84 percent, as Mr. Constantino said. Importantly, as indicated in this chart that Anne is holding up, both clinics

located in Waukegan are actually operating above 90 percent today. So there clearly is a need for these patients to get treatment.

Given the Board's rules providing special consideration to clinics which are in health care professional shortage areas or medically underserved areas and with increasing use rates, we feel that this clinic proposal is exactly where we should be locating services. With area clinics highly utilized beyond the target of 80 percent, this clinic warrants approval.

I'd also like to comment on the public testimony as mentioned today. NANI and FMC oppose this project based on a lack of need, though we should say that they themselves have a project in the same service area on this agenda later today. This incongruous messaging is exactly what both FMC and NANI have been doing with this Board over the last several months really in an attempt to confuse the issue. Based on their testimony today I can only assume that they're going to either withdraw their own application because they don't believe there's a need, or they're going to retract their false statements.

Finally, I would like to end with the support. This proposal received significant community support, including Vista Health System which operates the only acute care and hospital in Waukegan, the Erie Family Healthy Centers, a leading provider of free health clinics in the Chicago area including Waukegan, State Representative Rita Mayfield, and Waukegan Mayor Sam Cunningham, as well as numerous physicians and business leaders, and we really appreciate their input in the process.

So with that I'd like to hand it over to Dr. Dalloul, our planned medical director who has taken time from his duties to be here today.

DR. DALLOUL: Good morning. I'm Dr. Dalloul, D-a-l-l-o-u-l. I'm board certified in internal medicine/nephrology and in practice in the Waukegan area for the last 20 years, completing my fellowship at Northwestern University.

My patients in the Waukegan are the most socioeconomically disadvantaged. I participate in the plan that allows transplants for managed care patients in Lake County, and I provide free care for specialties for patients of Lake County Department

of Health. I'm also in the process of working to develop a free clinic in Waukegan. Through this work and my practice I'm very engaged in improving the health care access issues facing these residents in Waukegan.

Families with fewer financial resources obviously have less access to health care and face difficult lifestyle choices. Many of my Waukegan patients work two jobs, travel outside of their community to work, and have difficulty arranging for childcare, too. Cooking nutritious meals and getting appropriate exercise is usually out of reach of these patients. They also do not get the same preventive health care as my patients who are more affluent because they lack insurance and financial resources or they cannot afford to take time off from work.

As a result, kidney disease, which is asymptomatic until the later stages, is frequently not diagnosed until kidney failure is imminent. In the last few years more nephrologists, about 10 of them now in Waukegan, have established office hours in Waukegan, so many more patients in the community are getting an early diagnosis.

Patients who do not crash into dialysis are much more likely to survive. This improved physician access is prolonging the life of those with kidney disease and is part of what is driving demand for these services. My own dialysis patient population has increased about 50 percent over the last three years.

Given language, and income, and education barriers, residents of Waukegan face increasing health care resources at the preventive stage. This trend will continue. Because of this and as noted in the Board report, the two existing facilities in Waukegan are full, and patients are having difficulty scheduling their dialysis. These access issues are hurting patients because patients are more likely to skip sessions when there is limitation of appointments available. As a result, more of my patients are ending up in the hospital, and then I have to catch them up on dialysis treatment. This seriously hurts their long-term prognosis. Without more facilities in Waukegan there are no private treatment options for my patients in Waukegan.

Finally, I really appreciate the support

of the medical community in Waukegan. In my practice I depend on free health clinics and our only acute care hospital to provide other types of care for these patients. Their expression of support for this clinic and support of other stakeholders in the community should help to drive home just how essential this proposal is.

Thank you for your time.

CHAIRWOMAN OLSON: Thank you.

MS. FRIEDMAN: Thank you.

Listening to the testimony earlier I just wanted to note that there were two different nephrologists who spoke of the facilities in the area. One of them mentioned Lake County Dialysis. That clinic is not within 30 minutes of Waukegan, along with some other facilities that are located more than 30 minutes away where those physicians were, which they apparently expect would be an appropriate alternative for a facility Waukegan proper. It's also a little confusing as to why a Waukegan medical director would indicate that there's not a need for service given that our dialysis clinic is operating at 98 percent utilization and operating a fourth shift, and

their dialysis clinic is also operating at 98 percent utilization, and, of course, as Gaurav stated, they have an application pending.

Of the 21 criteria that the Board applied to this clinic proposal, it successfully met all except for a single finding based on a calculated excess of stations in Lake County, McHenry, and Kane County. That's an area that has a population of about 1.5 million people. So the needs of one single community like Waukegan are hard to parse out when you're looking at health planning from a three-county area, but that's why we're here today to talk more specifically about what the challenges to these patients are.

As we documented in the materials that we submitted, Waukegan is one of the poorest communities in Lake County, and it's also one of the largest communities. It has several indicators of health care disparities contributing to a higher incidence of kidney disease, and for that reason dialysis clinics are full in Waukegan.

With regard to health disparities based on demographic and socioeconomic indicators in access to adequate level of health care services, the

Federal government designates Waukegan as needy from a health care access perspective. Waukegan has two specific designations. One is medically underserved population in area, and the other is a health care professional shortage area for primary care. These are important details under your service accessibility details -- excuse me -- under your rules.

Specific to renal care, with lack of access to primary care and health screenings there's a larger incidence of hypertension, diabetes, and kidney disease in low-income communities because these diseases are undetectable by the patient until the late stages when it's often too late to stop or slow the disease progression, and then those patients will require dialysis.

The demographic data for this area supports the need, which is why this project is positive on most of the Part 1110 criteria despite the technical excess of patients in the larger planning area. Over the past four years the census at the clinics within 30 minutes of North Dunes Dialysis increased over 30 percent, or an annual growth rate of 7 percent, which is faster than the older

data predicted it to grow. This trend must be expected to continue, and projections show that there will be average utilization of the clinic at the time that the clinic opens well over 90 percent target utilization.

Because dialysis services utilization in Waukegan is so high and churning up quickly, the Board staff made a favorable Part 1110/1430 finding that this clinic will not duplicate other area services or have a negative impact on other providers.

The DaVita clinic, as I said before, is operating at 99 percent utilization. Since the beginning of the year it's been operating on four shifts. With four shifts some of the patients are on a treatment schedule -- which is really incredible to me to think of like one of my 80-year-old parents going to dialysis in the middle of the night -- that requires them to leave the facility around 1:00 in the morning.

The other clinic in Waukegan is at 90 percent, as well, or well over the 80 percent utilization target. Patients who need access to services have to travel more than 30 minutes to

find a clinic with any meaningful capacity, and traveling this far places an undue hardship on patients as well as their family or other caregivers.

Thank you for your consideration. We ask for your approval and can answer any questions.

CHAIRWOMAN OLSON: Thank you.

Questions. Let's start with Mr. Sewell. Then I'll go to the doctor.

MEMBER SEWELL: Two things. In the State agency report on page 9, it looks like they have a direct quote from your application about the patients who are eligible for ESRD services on Medicare because they've achieved the requisite number of quarters to qualify.

Isn't it true that the age issue is not a factor if you have a diagnosis of ESRD? I know it was at one time. Is that the still the case?

MS. FRIEDMAN: That is --

MR. SEWELL: I mean, a 15-year-old could qualify for Medicare.

MS. FRIEDMAN: Basically, effectively 10 years you have to work in order to be --

MEMBER SEWELL: I'm suggesting that's not

true, that anyone can qualify for Medicare coverage regardless of age, regardless of the quarters if they have a diagnosis of ESRD. That law was passed in '72.

MS. FRIEDMAN: I do not --

MR. SEWELL: Did something change?

MS. FRIEDMAN: I believe so because -- what you're referencing would have had to have occurred in more recent years because I -- my most recent knowledge from looking this up was pretty recent, actually about a week ago, and the 10 calendar -- excuse me -- the 10 quarters were cited in the materials I was looking at. Now, we do have an All Kids program in the state, so I expect them to be able to get coverage.

MEMBER SEWELL: This isn't really relevant to the vote on the issue. I was just trying to correct the record. But you're saying that this is correct?

MS. FRIEDMAN: We'll follow up. I think we actually printed some of those CMS materials, so we can share those with Mr. Constantino.

MEMBER SEWELL: The other question I have, do poor people in the immediate area have difficulty

accessing the services at the existing ESRD facilities? Is that why you showed us the chart on location and where the poverty areas are in and around Waukegan? Do they have difficulty accessing the existing services even though there's excess capacity according to our calculations?

MS. FRIEDMAN: There's only two facilities in Waukegan. One of them DaVita is operating at 98 percent, which results in them operating in the four shifts. Your Board standards indicate that facilities should operate on three shifts. The other facility is operating at 90 percent. It's a competitor facility, so we don't know exactly how they're managing that 90 percent level.

So anytime you're really going over like 72 percent people have issues accessing dialysis services because they're trying to find a spot that the works with their caregiver's schedule and the rest of that.

Then beyond Waukegan proper there's only two other facilities and those are --

MEMBER SEWELL: Within the travel time?

MS. FRIEDMAN: Within the 30 minutes, right.

MEMBER SEWELL: So their access is limited

because of more high occupancy than their poverty status?

MS. FRIEDMAN: With respect to dialysis service, I would say that's right. With respect to primary care services, to the extent that you have a poor community, it's not as easy to attract independent physicians to come to the community to provide physician services. It's similarly designated as a dental medically underserved area because it's difficult to have dentists come to the area.

MEMBER SEWELL: And the final thing, it seems that you're asking this Board to approve this in spite of the excess capacity because our data is old, and I don't know if you used a different method than we did or just more recent data when you stated that by 2020 I think it was that there would be a need for 70 stations. You did say that, didn't you?

MS. FRIEDMAN: That's right. And we did not adopt a different methodology; we just used more recent data than 2015.

MEMBER SEWELL: And ours is old, Mike, because of late reporting?

MR. CONSTANTINO: No, it's based on the 2015 population estimates and 2015 utilization data to come up with the excess of 24 stations by 2020.

MEMBER SEWELL: But that's the way we're required to do it?

MR. CONSTANTINO: Yes. That's the current methodology, yes.

MEMBER MC NEIL: Okay. We can look at this in a macro level at which a number of people testified on. DaVita has 2500-plus units around the country, 237 internationally, 78,000 employees; I can tell you your CEO's salary. That's at a macro level. So you have the business side of it.

What we really look at is the need, the access, and what it does for the patient. So let's focus on that rather than the competitive issues.

If there's more competition, will it drive the $97,500 charge per year down -- or thereabouts -- because you're talking about a competitive environment.

MS. FRIEDMAN: When you're referring to 97,500, what are you referring to?

MEMBER MC NEIL: That's normally the cost

per year for a dialysis patient in an OCC, about that; is that true? Yep. And about 60,000 in-home, but I'll come to that in a minute.

MS. FRIEDMAN: Well, my experience is that that has already occurred. The composite rate reimbursement for dialysis services has gone down substantially over the last several years.

MEMBER MC NEIL: Would you explain how much? Because this is what I'm driving at. This is a huge need. These patients normally live about five years if they don't get a kidney transplant -- I'll come back to you on that -- and that's 3.1 or 3.6 years before they get that. But let's talk about the price going down because this is availability and an absolute need or the patient dies very quickly. We all die as far as I know.

MR. BHATTACHARYYA: I'm sorry, sir; what's the question?

MEMBER MC NEIL: The question is, how much has the price gone down, the 97,500, 98,000? Where we are now from where we use to be?

MR. BHATTACHARYYA: I don't have the specific numbers there, but we did look at across disease states, and when you look at dialysis

versus the other major chronic disease states, cancer, diabetes, et cetera, dialysis over the last 10 years showed the highest improvement in clinical qualities and the highest reduction in cost, system cost relative to those disease states. I don't have those specific numbers, but I do have that comparison.

MEMBER MC NEIL: So it's gone down and that's the competitive environment and the ability to offer services. What percentage of your patients do you refer where they do it in home? And I understand there are patients that don't want the stent, don't want to do it at home, and are afraid to do it. But the percentage -- because they tend to do it maybe six times a week, and your normal inpatient does it about three?

MR. BHATTACHARYYA: Yes. We at DaVita Chicago are at about 10 or 11 percent, and that's true for the broader industry across the country, as well. We would love for that percentage to be significantly higher. And as you mentioned, there's a patient choice element here in terms of the burden that they choose to take on to do it themselves at home.

From our perspective the clinical outcomes are better and patients live longer and resume their renal function a lot better at home. So we have a lot of initiatives about promoting in-home to both our medical directors and our patients, but ultimately it's whether it's the patient's right choice.

DR. DALLOUL: What I can say about home modality for those patients, it's very difficult to find a patient who agrees to do it at home first even if he is fit like medically to practice that in home safely. The two modalities are offered in DaVita widely, and we talk to every patient there about those modalities.

For example, last week I had a patient who was fitting perfectly well to that option for him, and he refused it because he doesn't want his wife -- to overburden with the machine, with the fluid. So a lot of factors interfere with the modality choice at home when the patient is fitting to that modality.

But we offer it up front, and I talk to my patients up front like about all modalities possible. And, of course, they would need like

the training, which would take about six to eight weeks and the training for the PD, also. So multiple factors playing with home choice.

MEMBER MC NEIL: One thing we could think about would be technicians to go to homes to help. That's another way of dealing with it. It doesn't take an MD but a nurse practitioner, whatever from a legal standpoint to take care of it. That's one issue.

What percentage of your patients get kidney transplants?

MR. BHATTACHARYYA: I think it's about 5 to 7 but I --

MR. MC NEIL: That's the only way out, and I recommend everybody sign up for organ donation. It is essential. I have a friend, I've been to dinner with him, at 11:00 at night he'll go do a kidney transplant when one is flown in. It is essential.

So we're dealing in an underserved area in the sense of people without a lot of education, money, those things that lead to home care more where they can provide for themselves, all of that. We're setting up a competitive environment,

we're giving additional access, and we want to see the cost come down.

I suggest you do more with a medical technician to go into the home and help because the outcomes, as you said, are better.

DR. DALLOUL: That's true.

MR. BHATTACHARYYA: Absolutely.

MEMBER GOYAL: My name is Arvind Goyal, and I represent Medicaid on this Board, and I do not vote, so you're safe, but I do have multiple comments to make, and I apologize for the length of them.

First of all, Professor Sewell when he raised the issue of your statement on page 9, I want to respectfully submit that he's correct and you're not. And the reason I say that is that dialysis services are carved out under Medicare. They have been since the program's inception, and for those people who do not qualify for Medicare for whatever reason, they're on Medicaid.

The only people who fall through the cracks at this time are undocumented people. And, fortunately, in Illinois we have a law that allows undocumented people to get transplants on a fast

road if people were to refer them. And, again, one of the conditions is a family donation. If that happens, the first day of cost of dialysis is equal to lifetime cost of dialysis. I think he made that point very eloquently. So I wanted to put that behind us so you recognize what the deal is.

I think a question was asked of you, and I will modify it a little bit. Can you indicate to me what percentage of your patients are listed for kidney transplant? Not how many get them, how many are listed. Because the average median for a life expectancy with a transplant is almost equal to a normal person who never had kidney disease versus dialysis where the median is about four to eight years.

So could you answer that?

MR. BHATTACHARYYA: Sure. I don't have the percentage, but what I can tell you is anytime a new patient starts on dialysis, their first day we have a program called Start Smart where we go through all the factors that we think will help them be more successful on dialysis and to continue their quality of life, and getting them on the transplant list is a component of their Start Smart program.

So we do it for all of our patients that start. Some of them, as you mentioned, Dr. Goyal, may not be eligible, and so they would come off. But the assumption is that every one of our patients is given a chance to be on a transplant list.

MEMBER GOYAL: So they are all listed at some point if they qualify for listing?

MR. BHATTACHARYYA: I'm sorry. Could you repeat that, please?

MEMBER GOYAL: What you just said, does that mean that all those patients who meet the criterion for transplant, they will all be listed?

MR. BHATTACHARYYA: Correct. And I mentioned we just created a partnership with University of Chicago to make sure that the patients that are on the transplant list stay on the transplant list. Because as you can imagine, there's lots of criteria that they have to make on an ongoing basis, and as patients get dialysis, they go to treatment, they often miss some of their doctors' appointments, and they have some other issues that could cause them to get off that list.

So we're working very hard to make sure that we optimize their likelihood of getting that

transplant by making sure that they continue to meet all those criteria and are sharing that data on a continual basis with the hospital to make sure that those patients have the best chance.

MEMBER GOYAL: Thank you. My last question --

MS. FRIEDMAN: Before we go on to the next question, with respect to the Medicare/Medicaid issue -- and I have to say I couldn't quite hear whether you were saying "care" or "aid" at the end of that -- I want to clarify that I don't believe that we have a disagreement with anyone, but after this consideration we will be sharing the information that we have about payer program eligibility to confirm that we're all on the same page about that because I don't want there to be a misconception that we're trying to misrepresent anything.

MEMBER GOYAL: Thank you for double-checking it and we always welcome that. However, I can say this to you that without knowing exactly what your percentage would be at this new facility, the biggest payers for you would be the Medicare or Medicaid.

MR. BHATTACHARYYA: Absolutely.

MEMBER GOYAL: Given that you're competing with the same type of population, poor, socioeconomically less fortunate, and people in communities like Waukegan where the disease burden may be higher.

MR. BHATTACHARYYA: Completely agree. We consider serving those patients, not competing for them but yes.

MEMBER GOYAL: My next question has to do with the comment you made about three stars. Now, that's three out of five?

MR. BHATTACHARYYA: Correct.

MEMBER GOYAL: The last time I looked at the star ratings about year and a half ago at the beginning of 2017, at that time DaVita's ratings generally were no superior to your competitors.

MR. BHATTACHARYYA: If you look at the most recent one that came out I believe a month or so ago, 95 percent of our clinics are three stars or above relative to 85 percent for the rest of the industry.

MEMBER GOYAL: That's great and I didn't mean to imply that DaVita is any less competent or

any less qualified to provide services, but I just didn't want to put down your competitors based on star ratings.

MR. BHATTACHARYYA: No, sir. But we do have a 10-point incremental benefit that we're providing, and I don't want that to be lost, either.

MEMBER GOYAL: Thank you.

CHAIRWOMAN OLSON: Other questions or comments?

MEMBER SEWELL: I want to make a comment about context in reference to what Dr. McNeil said. I think if we had a health economist here, I think they would say that this association between competition, more competition and lowering costs in the health care field is weak or absent depending on the service. That needs to be said.

We can't think of this as commodities that are out in the general economy. So I don't think we want to make -- we want to say a priori that competition drives down costs. The answer is sort of "it depends." That's all I was going to say.

MR. BHATTACHARYYA: I think our point, Dr. Sewell, would be that competition here is

providing patient access; it's not actually a cost issue.

MEMBER MC NEIL: And I would add new technologies and the home care -- that's the reason I emphasized it -- is the big determinate. The outcomes are better but it's getting patients to do that.

The profit margin for DaVita is about 6.7 percent this year. They lost 48 percent last year. I've already looked that up. So it's not like -- and they reinvested a lot of money, and all of their competitors are doing the same thing. So there is a cost factor and that kind of margin -- I know how we play with numbers as accountants, but having said that, it's not excessive.

CHAIRWOMAN OLSON: I have a question. And I know you've sort of addressed it. But I've been here for quite a while, and I've never had a situation where two employees would come up and say there is no need for this in Waukegan.

And trust me, I know there's another Waukegan application on the agenda here today. Zion is not open. How far is Zion from Waukegan? I'm not familiar with that area. Because Zion is

not even open. Because over 90 percent utilization is pretty full in the two Waukegan facilities, but I'm perplexed as to why --

MS. FRIEDMAN: I think it's about 6 miles north.

CHAIRWOMAN OLSON: And that's not open yet?

MS. FRIEDMAN: No. That's assuming that that facility is dedicated to CKD patients of NANI.

And, Gaurav, did you want to explain the relationship between NANI and --

MR. BHATTACHARYYA: I guess it's a good question for them as to why they would oppose it given that they're medical directors of a facility at 100 percent. My only hypothesis would be that economic interests of their employer being a joint venture partner of those clinics has overridden their judgment.

CHAIRWOMAN OLSON: Thank you.

Other questions or comments from Board members.

(No response.)

CHAIRWOMAN OLSON: Seeing none, I would ask for a roll call vote.

MR. ROATE: Thank you, Madam Chair. Motion made by Burzynski, seconded by Murphy.

Senator Burzynski.

MEMBER BURZYNSKI: First of all, evidently I've been added to the roll since I got here after the roll was taken.

CHAIRWOMAN OLSON: Yes, you have. Thank you for joining us.

MEMBER BURZYNSKI: It's just a little -- I digress but it took eight cycles of the stoplight to get off of 55 onto whatever that road is there.

CHAIRWOMAN OLSON: Everybody in the state is traveling today.

MEMBER BURZYNSKI: Anyway, this has been an interesting education for me this morning, but I'm going to vote in support of the facility in spite of the fact that we have one finding relative to excess -- an excess of stations.

I think you've demonstrated the need based on the demographics of the area, the service -- the people that you're going to serve, and certainly I do believe it could be an access issue, so I vote yes.

MR. ROATE: Thank you.

Ms. Hemme.

MEMBER HEMME: I vote no. Knowing the area up there and how close the Zion facility will be when it opens, I think it will reduce down that rate. And I'd like to encourage you to do the home instruction. It's got better outcomes and it would lower the cost of just capital costs that are overriding in our health care system today.

MR. ROATE: Thank you.

Mr. McGlasson.

MEMBER MC GLASSON: Firstly, this is a conversation that I've been waiting for since I've first come on this Board. It's fascinating and as the Senator said, I've learned quite a lot, and I hope I'll have opportunities to learn a lot more.

I do find in the immediate sense that the fact that this is such an underserved area very compelling and I will vote yes.

MR. ROATE: Thank you.

Dr. McNeil.

MEMBER MC NEIL: Having looked at this, I encourage you to do and really have a technician for the home support as well as those who will be the majority that cannot do it. And I have no

problem with -- it's an underserved area, four shifts a day, the people that need this help really are not in the health necessarily to show up at 6:00 in the morning or 8:00 at night. There are all of these things, so I vote yes based on the staff recommendation and the discussions.

MR. ROATE: Thank you.

Ms. Murphy.

MEMBER MURPHY: Thank you. Based on the project's substantial compliance with the State Board standards, I vote yes.

MR. ROATE: Thank you.

Mr. Sewell.

MEMBER SEWELL: I vote no. I think the new data that will allow us to calculate those use rates will be out soon this year, and the applicant in my opinion can come back, and we can see if they'll change the need to 70 additional stations, but for now I vote no.

MR. ROATE: Thank you.

Madam Chair.

CHAIRWOMAN OLSON: I vote no as well, for the reasons that Mr. Sewell just stated, and I also think once the Zion facility comes online