STATE OF ILLINOIS
HEALTH FACILITIES AND SERVICES REVIEW BOARD

525 WEST JEFFERSON ST. • SPRINGFIELD, ILLINOIS 62761 •(217) 782-3516 FAX: (217) 785-4111

DOCKET NO: I-01	BOARD MEETING: October 30, 2018	PROJECT NO: 17-029	PROJECT COST: Original: $3,341,748
FACILITY NAME: Melrose Village Dialysis		CITY: Melrose Park	
TYPE OF PROJECT: Substantive			HSA: VII

PROJECT DESCRIPTION: The Applicants (DaVita Inc. and Adiron Dialysis, LLC) propose to establish a 12-station dialysis facility located at 1985 North Mannheim Road, Melrose Park, Illinois. The proposed dialysis facility will include a total of 8,052 gross square feet of space and cost $3,341,748. The anticipated completion date is July 31, 2020.

EXECUTIVE SUMMARY

PROJECT DESCRIPTION:

- The Applicants (DaVita Inc. and Adiron Dialysis, LLC) propose to establish a twelve (12) station dialysis facility located at 1985 North Mannheim Road, Melrose Park, Illinois. The proposed dialysis facility will include a total of 8,052 gross square feet of space and cost $3,341,748. The anticipated completion date as stated in the application for permit is July 31, 2020.
- This Application received an Intent to Deny at the January 2018 State Board Meeting.
- On June 27, 2018 the Applicants modified the project by providing revised zip code and population information that increased the population of the 30-minute service area provided in the Original Application for Permit. The State Board Staff review of the revised 30-minute service area confirmed the Applicants contention that the original submittal was incorrect. State Board Staff had relied upon the zip code and population information that was provided in the Original Application for Permit to reach the conclusion that there was a surplus of ESRD stations in the 30-minute service area. The original submittal had used a 10-mile radius to determine the population instead of a 30-minute radius.
- **State Board Staff Notes:** This project was deemed complete (July 13, 2018) before the effective date of 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.

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

PUBLIC HEARING/COMMENT:

- A public hearing was offered in regard to the proposed project, but none was requested. Letters of support and opposition were received by the State Board Staff. Letters of support were received from US Senator Durbin, Illinois Representative Willis, Cook County Board of Commissioners, West Central Municipal Conference, RML Specialty Hospital, Mayor of the Village of Melrose Park, Melrose Commons Senior Residences and the Pastor of Sacred Heart Church all urging the State Board to approve the project. An opposition letter was received from Fresenius Medical Care and a comment on the State Board Staff report was received that opposed the approval of this project.

SUMMARY:

- There is a calculated excess of 2 ESRD stations in the HSA VII ESRD Planning Area, per the September 2018 ESRD Inventory Update.
- It appears that the Applicants will be providing services to residents of the planning area, and based upon the number of physician referrals, there appears to be sufficient demand for the number of stations requested. There are 61 dialysis facilities within 30 minutes of the proposed facility with

an average utilization of approximately 57%. Fourteen of the 61 facilities are in ramp-up or were recently approved, one facility did not provide their second quarter patient census (Satellite Dialysis of Glenview) and one facility has not been above 10% utilization since it became operational.

- The Applicants addressed a total of twenty-one (21) criteria and have failed to adequately address the following:

Criteria	**Reasons for Non-Compliance**
Criterion 77 ILAC 1110.1430 (c) (1) (2) (3) (5) – Planning Area Need	There is a calculated excess of 2 ESRD stations in this planning area. Should this project be approved service accessibility will not be improved because there are existing facilities within the 30-minute service area not at target occupancy.
Criterion 77 ILAC 1110.1430 (d) (1) (2) (3) Unnecessary Duplication of Service, Mal-distribution and Impact on Other Facilities	There are 61 dialysis facilities within 30 minutes of the proposed facility with an average utilization of approximately 57%. Fourteen of the 61 facilities are in ramp-up or were recently approved, one facility did not provide their second quarter patient census (Satellite Dialysis of Glenview) and one facility has not been above 10% utilization since it became operational. Of the 45 facilities currently operating, 30 (66%) are not operating at target occupancy and the average utilization of these 45 facilities is 73%.

STATE BOARD STAFF REPORT
Project #17-029
Melrose Village Dialysis

APPLICATION/CHRONOLOGY/SUMMARY	
Applicants	DaVita Inc. and Adiron Dialysis, LLC D/B/A Melrose Village Dialysis
Facility Name	Melrose Village Dialysis
Location	1985 North Mannheim Road, Melrose Park, Illinois
Permit Holder	Adiron Dialysis, LLC
Operating Entity	Adiron Dialysis, LLC
Owner of Site	V & V, LLC
Total GSF	8,052 GSF
Application Received	July 12, 2017
Application Deemed Complete	July 13, 2017
Review Period Ends	November 9, 2017
Financial Commitment Date	October 30, 2019
Project Completion Date	July 31, 2020
Review Period Extended by the State Board Staff?	Yes
Can the Applicants request a deferral?	Yes
Expedited Review?	No

I. Project Description:

The Applicants (DaVita Inc. and Adiron Dialysis, LLC) propose to establish a 12-station dialysis facility located at 1985 North Mannheim Road, Melrose Park, Illinois. The proposed dialysis facility will include a total of 8,052 gross square feet of space and cost $3,341,748. The anticipated completion date as stated in the application for permit is July 31, 2020.

II. Summary of Findings

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

B. State Board Staff finds the proposed project in conformance with the provisions of 77 ILAC 1120 (Part 1120).

III. General Information

The Applicants are DaVita Inc. and Adiron Dialysis, LLC D/B/A Melrose Village Dialysis. DaVita Inc, a Fortune 500 company, is the parent company of DaVita Kidney Care and HealthCare Partners, a DaVita Medical Group. DaVita Kidney Care 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.

Adiron Dialysis, LLC D/B/A Melrose Village Dialysis is a Delaware Limited Liability Company that has been approved to transact business in Illinois and is in good standing with the State of Illinois. Ownership of Adiron Dialysis, LLC is as follows:

Name	Ownership Interest
DaVita Inc.	51% (Indirect)
Total Renal Care Inc.	51% (Direct)
DuPage Medical Group, Ltd.	25% (Direct)
Primecare Nephrology and Hypertension	14% (Direct)
Dr. Osvaldo Wagener	7% (Indirect)
Dr. Rajani Kosuri	7% (Indirect)
Cocao Associates Inc.	10% (Direct)
Dr. Ogbonnaya Aneziokoro	5% (Indirect)
Dr. Isabella Gurau	5% (Indirect)

Financial commitment will occur after permit issuance. This project is a substantive project subject to a Part 1110 and 1120 review. Substantive projects shall include no more than the following:

- *Projects to construct a new or replacement facility located on a new site; or a replacement facility located on the same site as the original facility and the costs of the replacement facility exceed the capital expenditure minimum.*
- *Projects proposing a new service or discontinuation of a service, which shall be reviewed by the Board within 60 days.*
- *Projects proposing a change in the bed capacity of a health care facility by an increase in the total number of beds or by a redistribution of beds among various categories of service or by a relocation of beds from one facility to another by more than 20 beds or more than 10% of total bed capacity, as defined by the State Board* in the Inventory, *whichever is less, over a 2-year period.* [20 ILCS 3960/12]

IV. Project Costs and Sources of Funds

The Applicants are funding this project with cash of $2,478,255 and a lease with a FMV of $863,493. Start-up and operating deficit is projected to be $ 2,738,928.

TABLE ONE Project Costs And Sources Of Funds				
	Reviewable	**Non-Reviewable**	**Total**	**% of Total**
Modernization Contracts	$846,244	$518,184	$1,364,428	40.83%
Contingencies	$125,000	$75,000	$200,000	5.98%
Architectural/Engineering Fees	$97,152	$59,472	$156,624	4.69%
Consulting and Other Fees	$67,977	$32,131	$100,108	3.00%
Movable or Other Equipment (not in construction contracts)	$536,973	$120,122	$657,095	19.66%
Fair Market Value of Leased Space or Equipment	$535,554	$327,939	$863,493	25.84%
TOTAL USES OF FUNDS	**$2,208,900**	**$1,132,848**	**$3,341,748**	
SOURCE OF FUNDS	Reviewable	Non-Reviewable	Total	% of Total
Cash and Securities	$1,673,346	$804,909	$2,478,255	74.16%
Leases (fair market value)	$535,554	$327,939	$863,493	25.84%
TOTAL SOURCES OF FUNDS	**$2,208,900**	**$1,132,848**	**$3,341,748**	

V. Heath Service Area VII

The proposed facility will be located in the HSA VII ESRD Planning Area. The HSA VII ESRD Planning Area includes Suburban Cook and DuPage Counties. As of September 2018 there is a calculated excess of 2 ESRD stations in this planning area. There are currently 80 dialysis facilities in this planning area with 1,432 ESRD stations.

State Board Staff Notes: The State Board approved the 2017 Inventory of Health Care Facilities and Services and Need Determinations at the September 2017 State Board Meeting. This document estimated the growth in the population from 2015 to 2020 (i.e. five years) and the estimated growth in the number of dialysis patients that will need outpatient dialysis in the HSA VII ESRD Planning Area based upon the 2015 usage. This resulted in an estimate in the number of stations needed by 2020 in the HSA VII ESRD Planning Area.

TABLE THREE Need Methodology HSA VII ESRD Planning Area	
Planning Area Population – 2015	3,466,100
In Station ESRD patients -2015	5,163
Area Use Rate 2015 (1)	1.472
Planning Area Population – 2020 (Est.)	3,508,600
Projected Patients – 2020 (2)	5,163
Adjustment	1.33x
Patients Adjusted	6,867
Projected Treatments – 2020 (3)	1,071,219

Existing Stations	1,432
Stations Needed-2020	1,430
Number of Stations in Excess	**2**

1. Usage rate determined by dividing the number of in-station ESRD patients in the planning area by the 2015 – planning area population per thousand.
2. Projected patients calculated by taking the 2020 projected population per thousand x the area use rate. Projected patients are increased by 1.33 for the total projected patients.
3. Projected treatments are the number of patients adjusted x 156 treatments per year per patient

VI. Background of the Applicants

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

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 owned or operated by applicants or a certified listing of any adverse action taken.

1. The Applicants provided the necessary attestation that no adverse action has been taken against any facility owned or operated by the Applicants and authorization allowing the State Board and IDPH access to all information to verify information in the application for permit. [Application for Permit page 68]

2. The site is owned by V & V, LLC and evidence of this can be found at page 31-41 of the application for permit in the Letter of Intent to lease the property at 1985-1997 N. Mannheim Rd, Melrose Park, IL 60160

3. The Applicants provided evidence that they were in compliance with Executive Order #2006-05 that requires *all State Agencies responsible for regulating or permitting development within Special Flood Hazard Areas shall take all steps within their authority to ensure that such development meets the requirements of this 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*

[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)

effect in such areas. Such State Agencies shall ensure that proposed development within Special Flood Hazard Areas would meet the requirements of this Order.

4. 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 ILAC 1110.1430(b)(1) & (3))

VII. Purpose of Project, Safety Net Impact Statement, Alternatives to the Proposed Project

These 3 criteria are for informational purposes only.

A) Criterion 1110.230(a) - Purpose of the Project

To demonstrate compliance with this criterion the Applicants must document

1. **That the project will provide health services that improve the health care or well-being of the market area population to be served.**
2. **Define the planning area or market area, or other relevant area, per the applicant's definition.**
3. **Identify the existing problems or issues that need to be addressed as applicable and appropriate for the project.**
4. **Detail how the project will address or improve the previously referenced issues, as well as the population's health status and well-being.**
5. **Provide goals with quantified and measurable objectives, with specific timeframes that relate to achieving the stated goals as appropriate.**

The Applicants stated the following:

"The purpose of the project is to improve access to life sustaining dialysis services to the residents of near west suburbs of Chicago. Excluding the 3 facilities that are not yet open/operational for 2 years and 2 stations from 1 facility that recently added them, there are 27 dialysis facilities within 30 minutes of the proposed Melrose Village Dialysis that have been operational for at least 2 years. Collectively, the 27 facilities were operating at 74.1% as of March 31, 2016, and the existing facilities lack sufficient capacity to accommodate the projected ESRD patients from Dr. Aneziokoro and DuPage Medical Group. Dr. Aneziokoro's practice, Northwest Medical Associates of Chicago, and DuPage Medical Group's patient bases currently include 145

combined CKD[2] patients residing within 30 minutes of the proposed site for Melrose Village Dialysis. Conservatively, based upon attrition due to patient death, transplant, return of function, or relocation, Dr. Aneziokoro and DuPage Medical Group collectively anticipate that at least 68 of these patients will require dialysis within 12 to 24 months following project completion. Based upon March 31, 2017 data from The Renal Network, for ZIP codes containing 10 or more total ESRD patients, there were 2,439 ESRD patients residing within 30 minutes of the proposed Melrose Village Dialysis, and this number is projected to increase. The U.S. Centers for Disease Control and Prevention estimates 10% of American adults have some level of CKD. Further, the National Kidney Fund of Illinois estimates over 1 million Illinoisans have CKD and most do not know it. Kidney disease is often silent until the late stages when it can be too late to head off kidney failure. As more working families have obtained health insurance through the Affordable Care Act (or ACA) and 1.5 million Medicaid beneficiaries transition from traditional fee for service Medicaid to Medicaid managed care, more individuals in high-risk groups will have better access to primary care and kidney screening. As a result of these health care reform initiatives, there ***will*** *likely be tens of thousands of newly diagnosed cases of CKD in the years ahead. Once diagnosed, many of these patients will be further along in the progression of CKD due to the lack of nephrologists care prior to diagnosis. It is imperative that enough stations are available to treat this new influx of ESRD patients, who will require dialysis in the next couple of years.*

Per the 2010-2014 American Community Services 5-Year Estimates, the ZIP code of 60160 has 18.2% of its residents living below the federal poverty level, compared with 14.4% of total Illinois residents. According to a 2014 study, the rate of ESRD was four times higher among people with annual household incomes of less than $20,000 compared to those making more than $75,000. Due to lack of health insurance prior to ACA, many of these residents may have lacked access to primary care and kidney screening in the early stages of CKD when adverse outcomes of CKD can be prevented and delayed. Further, the zip code of 60160 reported over 69% of residents identified as Hispanic or Latino on the 2010 US Census. Per the National Kidney Foundation, Hispanics are at greater risk for kidney disease and kidney failure, being 1½ times more likely to have kidney failure compared to other Americans. Accordingly, there are likely hundreds of residents with undiagnosed CKD who will require dialysis in the near future. An optimal care plan for patients with CKD includes strategies to slow the loss of kidney function, manage co morbidities, and prevent or treat cardiovascular disease and other complications of CKD, as well as ease the transition to kidney replacement therapy. Early identification of CKD and deliberate treatment of ESRD

[2] National Kidney Foundation (NKF) created a guideline to help doctors identify each level of kidney disease. The NKF divided kidney disease into five stages. Glomerular filtration rate (GFR) is the best measure of kidney function. The GFR is the number used to figure out a person's stage of kidney disease. A math formula using the person's age, race, gender and their serum creatinine is used to calculate a GFR. A doctor will order a blood test to measure the serum creatinine level. Creatinine is a waste product that comes from muscle activity. When kidneys are working well they remove creatinine from the blood. As kidney function slows, blood levels of creatinine rise. Below shows the five stages of CKD and GFR for each stage:

- **Stage 1** with normal or high GFR (GFR > 90 mL/min)
- **Stage 2** Mild CKD (GFR = 60-89 mL/min)
- **Stage 3A** Moderate CKD (GFR = 45-59 mL/min)
- **Stage 3B** Moderate CKD (GFR = 30-44 mL/min)
- **Stage 4** Severe CKD (GFR = 15-29 mL/min)
- **Stage 5** End Stage CKD (GFR <15 mL/min)

by multidisciplinary teams leads to improved disease management and care, mitigating the risk of disease advancement and patient mortality. Accordingly, timely referral to and treatment by a multidisciplinary clinical team may improve patient outcomes and reduce cost. Indeed, research has found that late referral and suboptimal care result in higher mortality and hospitalization rates. Deficient knowledge about appropriate timing of patient referrals and poor communication between PCPs and nephrologists has been cited as key contributing factors. Critically, addressing the failure of communication and coordination among primary care physicians ("PCPs"), nephrologists, and other specialists may alleviate a systemic barrier to mitigating the risk of patient progression from CKD to ESRD, and to effective care of patients with ESRD. In addition to research emphasizing the value of care coordination among providers, research has generally displayed that the more information on a single EHR, the better the outcomes are for patient care. Patients receiving care on a single integrated EHR often experience reduced clinical errors and better outcomes as a result. With the development of this proposed facility, patient data generated at the dialysis facility will be migrated to the EHR systems accessible by all DMG providers. This data integration ensures a patient's PCP, nephrologists, and other specialists can readily access the patient dialysis records. DaVita and DMG have the ability to design additional functionalities to address communication and coordination issues between physicians. This removes administrative burden and alleviates risks that a patient's PCP or specialist is missing information regarding their care, including dialysis treatments. The tailoring of familiar DaVita and DMG tools eases the burden on physicians and enhances the likelihood of success in improving care coordination and physician communications. The Applicants anticipate the proposed facility will have quality outcomes comparable to Davita's other facilities. Additionally, in an effort to better serve all kidney patients, the Applicants will require all providers measure outcomes in the same way and report them in a timely and accurate basis or be subject to penalty. There are four key measures that are the most common indicators of quality care for dialysis providers - dialysis adequacy, fistula use rate, nutrition and bone and mineral metabolism. Adherence to these standard measures has been directly linked to 15-20 percent fewer hospitalizations. On each of these measures, DaVita has demonstrated superior clinical outcomes, which directly translated into 7 percent reduction in hospitalizations among DaVita patients, the monetary result of which is more than $1.5 billion in savings to the health care system and the American taxpayer from 2010 -2012. The establishment of a 12-station dialysis facility will improve access to necessary dialysis treatment for those individuals in the near western suburbs who suffer from ESRD. ESRD patients are typically chronically ill individuals and adequate access to dialysis services is essential to their well-being." [Application for Permit, pages 70-71]

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

To demonstrate compliance with this criterion the Applicants must document

- **The project's material impact, if any, on essential safety net services in the community, to the extent that it is feasible for an applicant to have such knowledge.**
- **The project's impact on the ability of another provider or health care system to cross-subsidize safety net services, if reasonably known to the applicant.**
- **How the discontinuation of a facility or service might impact the remaining safety net providers in a given community, if reasonably known by the applicant.**

The Applicants provided a safety net impact statement as required. (See Appendix I)

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

To demonstrate compliance with this criterion the Applicants must identify all of the alternatives considered to the proposed project.

1. The Applicants considered, but ultimately rejected, an **8-station in-center hemodialysis facility**. This **was** rejected due to the expected utilization. The Applicants fully expect the facility to reach the required number of patients for a 12-station facility within two years.

2. DaVita Inc., DuPage Medical Group, Ltd., and additional investors have entered into a **joint venture agreement** to combine resources and areas of expertise in order to offer the highest level of patient care**.** Given the historic growth of ESRD patients and the current utilization levels of area clinics, it is expected that area clinics will exceed the 80% utilization mark over the next few years. The Melrose Village Dialysis facility is necessary to address this growth and allow existing facilities to operate at an optimum capacity.

3. **Utilize existing facilities**. This alternative was rejected because there are 27 dialysis facilities within 30 minutes of the proposed Melrose Village Dialysis that have been operational for at least 2 years. Collectively, the 27 facilities were operating at 74.1% as of March 31, 2016, and the existing facilities lack sufficient capacity to accommodate Dr. Aneziokoro and DuPage Medical Group's projected referrals.

VIII. 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 the size of the proposed facility is in compliance with the State Board Standards published in Part 77 ILAC 1110 Appendix B.

The Applicants are proposing 8,052 GSF of space for the proposed 12-station dialysis facility. Four thousand nine hundred ninety-four (4,994) GSF will be reviewable space and 3,052 GSF will be non-reviewable space. The State Board Standard is 520 GSF per station or a total of 6,240 GSF of space for the 12 stations. The Applicants have successfully addressed this criterion. Below are the definitions of reviewable and non-reviewable space.

Clinical Service Area [reviewable space] means a department or service that is directly *related to the diagnosis, treatment, or rehabilitation of persons receiving services from the health care facility* [20 ILCS 3960/3]. A clinical service area's physical space shall include those components required under the facility's licensure or Medicare or Medicaid Certification, and as outlined by documentation from the facility as to the physical space required for appropriate clinical practice.

Non-clinical Service Area [non reviewable space] *means an area for the benefit of the patients, visitors, staff or employees of a health care facility and not directly related to the diagnosis, treatment, or rehabilitation of persons receiving services from the health care facility. "Non-clinical service areas" include, but are not limited to, chapels; gift shops; newsstands; computer systems; tunnels, walkways, and elevators; telephone systems; projects to comply with life safety codes; educational facilities; student housing; patient, employee, staff, and visitor dining areas; administration and volunteer offices; modernization of structural components (such as roof replacement and masonry work); boiler repair or replacement; vehicle maintenance and storage facilities; parking facilities; mechanical systems for heating, ventilation, and air conditioning; loading docks; and repair or replacement of carpeting, tile, wall coverings, window coverings or treatments, or furniture. Solely for the purpose of this definition, "non-clinical service area" does not include health and fitness centers.* [20 ILCS 3960/3]

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

B) Criterion 1110.234(b) – Projected Utilization

To demonstrate compliance with this criterion the Applicants must document that the proposed facility will be in compliance with the State Board Standards published in Part 77 ILAC 1110 Appendix B two (2) years after project completion.

The Applicants expect to be at the target occupancy of 80% by the second year of operation. The Applicants identified 145 pre-ESRD patients. Based upon attrition due to patient death, transplant, return of function, or relocation, the Applicants are estimating 68 of these patients will initiate dialysis within 12 to 24 months following project completion.

68 patients x 156 treatments/year = 10,608 treatments
12 stations x 936 treatments/year = 11,232 treatments
10,608 treatments/11,232 treatments = 94.44%

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

C) Criterion 1110.234(e) – Assurance

To demonstrate compliance with this criterion the Applicants must document that the proposed facility will be in compliance with the State Board Standards published in Part 77 ILAC 1110 Appendix B two (2) years after project completion.

The Applicants on page 115 of the application for permit attest that they will be at target occupancy within 2 years after project completion.

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

IX. In-Center Hemodialysis Projects

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

This criterion was addressed earlier in this report.

B) Criterion 1110.1430(c)(1), (2), (3) and (5) – Planning Area Need
To demonstrate compliance with this criterion the Applicants must document

1. Calculated Planning Area Need
To demonstrate compliance with this sub-criterion the Applicants must document that there is a calculated need for stations in the HSA7 ESRD Planning Area.

As of the September 2018 Update to the Inventory of Health Care Facilities and Services and Need Determinations there is a calculated excess of 2 ESRD stations in the HSA7 ESRD Planning Area.

2. Service to Residents of the Planning Area
To demonstrate compliance with this sub-criterion the Applicants must document that the proposed facility will provide dialysis service to the residents of the planning area.

The Applicants identified 145 pre-ESRD patients by zip code of residence as required currently receiving care. As can be seen from the table below, approximately 88% of the pre-ESRD patients reside in the HSA7 ESRD Planning Area. [See Appendix II for 30 minute service area]

TABLE FIVE
Pre-ESRD Patients Identified by the Applicants

Zip Code	City	#
60160	Melrose Park	2
60104	Bellwood	5
60164	Melrose Park	3
60171	Schiller Park	1
60153	Maywood	3
60305	River Forest	2
60163	Berkeley	3
60707	Elmwood Park	14
60155	Broadview	3
60162	Hillside	6
60130	Forest Park	1
60301	Oak Park	1
60154	Westchester	21
60176	Schiller Park	1
60302	Oak Park	3
60634	Chicago	17
60126	Elmhurst	24
60304	Oak Park	3
60546	Riverside	13
60513	Brookfield	11
60106	Bensenville	8

TABLE FIVE Pre-ESRD Patients Identified by the Applicants		
Total		**145**

3. Service Demand

To demonstrate compliance with this criterion the Applicants must document that there is demand for the proposed service.

Ogbonnaya Aneziokoro, M.D., Northwest Medical Associates of Chicago, Inc. has provided a referral letter in which he states "*that I have identified 1,079 patients from my practice who are suffering from Stage 3, 4, or 5 CKD. For the purpose of this application, I have identified 30 patients who reside within 5 miles and under 30 minutes of the proposed facility. Conservatively, I predict at least **14 of these patients** will progress to dialysis within 12 to 24 months of completion of Melrose Village Dialysis. My large patient base and the significant utilization at nearby facilities demonstrate considerable demand for this facility."*

DuPage Medical Group, Ltd. ("DMG"), specifically Drs. Barakat, Delaney, Malaria, Rawal, Samad, and Shah, *has provided a referral letter in which they state based on our records, there are 3,529 pre-ESRD patients of DMG who currently have Chronic Kidney Disease ("CKD") Stage 3, 4, or 5. For the purpose of this application, I have identified 115 patients who reside within 6 miles and under 30 minutes of the proposed facility. We conservatively estimate that at least **54 patients** of these patients will be treated by our practice, develop end stage renal disease, and require dialysis within the first 12 to 24 months following the proposed project's completion. We anticipate referring these 54 patients to the proposed Melrose Village Dialysis facility within the first two years following project completion.*

Both referral letters included the following information as required.

- The physician's total number of patients (by facility and zip code of residence) who have received care at existing facilities located in the area, at the end of the year for the most recent three years and the end of the most recent quarter;
- The number of new patients (by facility and zip code of residence) located in the area, as reported to The Renal Network, that the physician referred for in-center hemodialysis for the most recent year;
- An estimated number of patients (transfers from existing facilities and pre-ESRD, as well as respective zip codes of residence) that the physician will refer annually to the applicant's facility within a 24-month period after project completion, based upon the physician's practice experience. The anticipated number of referrals cannot exceed the physician's documented historical caseload;
- An estimated number of existing patients who are not expected to continue requiring in-center hemodialysis services due to a change in health status (e.g., the patients received kidney transplants or expired);
- The physician's notarized signature, the typed or printed name of the physician, the physician's office address and the physician's specialty;
- Verification by the physician that the patient referrals have not been used to support another pending or approved CON application for the subject services; and
- Each referral letter shall contain a statement attesting that the information submitted is true and correct

The Applicants identified 68 patients that will utilize the proposed facility within 2 years after completion of the project**.**

5. Service Accessibility

To demonstrate compliance with this sub-criterion the Applicants must document one of the following:

- The absence of the proposed service within the planning area;
- 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;
- Restrictive admission policies of existing providers;
- 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;
- For purposes of this subsection (c)(5) only, all services within the 30-minute normal travel time meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100.

There is no absence of ESRD service within the HSA7 ESRD planning area as there are 1,430 ESRD stations in this ESRD Planning Area. There have been no access limitations due to payor status of the patients nor have any restrictive admission policies of existing providers been identified by the applicants. There is no indication of medical care problems of the area population.

Summary

The State Board has calculated an excess of **2 stations** in the HSA VII ESRD Planning Area by 2020. Should this project be approved service access will not be improved as there are existing facilities currently operating within the 30-minute service area not at target occupancy.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IS NOT IN CONFORMANCE WITH PLANNING AREA NEED CRITERION (77 ILAC 1110.1430(c)(1), (2), (3) and (5))

C) Criterion 1110.1430(d) – Unnecessary Duplication/Maldistribution/Impact on Other Facilities

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 facilities in the area.**

1. The State Board does not define unnecessary duplication of service. The State Board is asked to determine if the establishment of additional ESRD stations within a 30 minute service area will result in **unneeded** ESRD stations given the existing stations utilization. To do this, the State Board Staff reviews the most current utilization at existing operating facilities within the 30-minute service area. There are 61 dialysis facilities within 30 minutes of the proposed facility with an average utilization of approximately 57%. Fourteen of the 61 facilities are in ramp-up or were recently approved, one facility did not provide their second quarter patient census (Satellite Dialysis of Glenview) and one facility has not been above 10% utilization since it became operational. Of the 45 facilities currently operating, 30

(66%) are not operating at target occupancy and the average utilization of these 45 facilities is 73%.

2. The population in the 30-minute service area is 3,403,251 and there are 1,154 ESRD stations in the 30-minute service area. The ratio of stations to population in the 30-minute service area is 1 station per 2,949 residents. There are 4,850 stations in the State of Illinois and a population of 12,978,800 (Est. 2015 Population). The ratio of stations to population in the State of Illinois is 1 station per 2,676 residents. A mal-distribution of stations (surplus of stations) exists when the ratio of stations to population in the 30-minute service area is 1.5 times the ratio of stations in the State of Illinois. For there to be a surplus of stations in the 30 minute service area the ratio must be 1 station for every 1,784 residents. Based upon this ratio there is no surplus of stations in this 30 minute service area.

3. **The Applicants stated:** "*The proposed dialysis facility will not have an adverse impact on existing facilities in the GSA. As discussed throughout this application, the utilization of ICHD* (In-Center Hemodialysis) *facilities operating for over 2 years and within 30 minutes of the proposed Melrose Village Dialysis is 74.1%. 2,439 ESRD patients reside within 30 minutes of the proposed facility and this number is projected to* ***increase.*** *The proposed facility is necessary to allow the existing facilities to operate at an optimum capacity, while at the same time accommodating the growing demand for dialysis services. As a result, the Melrose Village Dialysis facility will not lower the utilization of area provider below the occupancy standards. Excluding the 3 facilities that are not yet open/ operational for 2 years, as well as a recent 2-station expansion, there are 27 existing dialysis facilities that have been operating for 2 or more years within the proposed 30 minute GSA of Melrose Village Dialysis. As of March 31, 2017, the 27 facilities were operating at an average utilization of 74.1%. Based upon March 31, 2017 data from The Renal Network, for ZIP codes containing 10 or more total ESRD patients, there were 2,439 ESRD patients residing within 30 minutes of the proposed Melrose Village Dialysis, and this number is projected to increase. The proposed facility is necessary to allow the existing facilities to operate at an optimum capacity, while at the same time accommodating the growing demand for dialysis services. As a result, the Melrose Village Dialysis facility will not lower, to a further extent, the utilization of area provider below the occupancy standards."*

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IS <u>NOT</u> IN CONFORMANCE WITH UNNECESSARY DUPLICATION MALDISTRIBUTION IMPACT ON OTHER FACILITIES CRITERION (77 ILAC 1110.1430(d)(1)-(3))

D) Criterion 1110.1430(f) - Staffing

To demonstrate compliance with this criterion the Applicants shall 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 Medical Director for the proposed facility will be Rajani Kosuri, M.D. A copy of Dr. Kosuri's curriculum vitae has been provided. Initial staffing for the proposed facility will be as follows:

- Administrator (0.98 FTE)

- Registered Nurse (3.88 FTE)
- Patient Care Technician (8.73 FTE)
- Biomedical Technician 0.28FTE)
- Social Worker (licensed MSW) (0.60 FTE)
- Registered Dietitian (0.60 FTE)
- Administrative Assistant (0.87 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. 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, ARFICRF, 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.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT TO BE IN CONFORMANCE WITH STAFFING CRITERION (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 a letter from Arturo Sida, Assistant Corporate Secretary of DaVita Inc. and Adiron Dialysis, LLC, attesting that the proposed facility will participate in a dialysis data system, will make support services available to patients, and will provide training for self-care dialysis, self–care instruction, home and home-assisted dialysis, and home training. [See Application for Permit pages 105-106] The Applicants have successfully addressed this criterion.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT TO BE IN CONFORMANCE WITH SUPPORT SERVICES CRITERION (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 there will meet 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 dialysis facility will be located in the Chicago-Joliet-Naperville metropolitan statistical area ("MSA"). A dialysis facility located within an MSA must have a minimum of eight dialysis stations. The Applicants propose to establish a 12-station dialysis facility. The Applicants have met this criterion.

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

G) Criterion 1110.1430(i) - Continuity of Care

To demonstrate compliance with this criterion the Applicants must 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.

Total Renal Care Inc., a subsidiary of DaVita Inc., has an agreement with Community First Healthcare of Illinois, Inc. d/b/a Community First Medical Center to provide inpatient care and other hospital services for the patients of Melrose Village Dialysis. [Application for Permit pages 98-104]

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

H) Criterion 1110.1430(j) - Relocation of Facilities

The Applicants are proposing to establish a 12-station ESRD facility and will not be relocating an existing facility

STATE BOARD STAFF FINDS THE PROPOSED PROJECT TO BE IN CONFORMANCE WITH RELOCATION OF FACILITIES CRITERION (77 ILAC 1110.1430(j))

I) Criterion 1110.1430 (k) - Assurances

To demonstrate compliance with this criterion the applicant representative who signs the CON application must 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 Applicants attested:

"*By the second year after project completion, Melrose Village Dialysis expects to achieve and maintain 80% target utilization; and Melrose Village Dialysis also expects hemodialysis outcome measures will be achieved and maintained at the following minimums:*

- *> 85% of hemodialysis patient population achieves urea reduction ratio (URR) > 65%[3] and*
- *>85% of hemodialysis patient population achieves Kt/V Daugirdas II .1.2"[4]*

The Applicants have successfully addressed this criterion.

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

[3] **Urea**: A nitrogen-containing substance normally cleared from the blood by the kidney into the urine. **URR** stands for urea reduction ratio, meaning the reduction in urea as a result of dialysis. The URR is one measure of how effectively a dialysis treatment removed waste products from the body and is commonly expressed as a percentage. If the initial, or pre-dialysis, urea level was 50 milligrams per deciliter (mg/dL) and the post-dialysis urea level was 15 mg/dL, the amount of urea removed was 35 mg/dL. The amount of urea removed (35 mg/dL) is expressed as a percentage of the pre-dialysis urea level (50 mg/dL). Although no fixed percentage can be said to represent an adequate dialysis, patients generally live longer and have fewer hospitalizations if the URR is at least 60 percent. As a result, some experts recommend a minimum URR of 65 percent. The URR is usually measured only once every 12 to 14 treatments, which is once a month. The URR may vary considerably from treatment to treatment. Therefore, a single value below 65 percent should not be of great concern, but a patient's average URR should exceed 65 percent.

[4] The **Kt/V** is more accurate than the URR in measuring how much urea is removed during dialysis, primarily because the Kt/V also considers the amount of urea removed with excess fluid. Consider two patients with the same URR and the same post-dialysis weight, one with a weight loss of 1 kg—about 2.2 lbs—during the treatment and the other with a weight loss of 3 kg-about 6.6 lbs. The patient who loses 3 kg will have a higher Kt/V, even though both have the same URR. The fact that a patient who loses more weight during dialysis will have a higher Kt/V does not mean it is better to gain more water weight between dialysis sessions so more fluid has to be removed, because the extra fluid puts a strain on the heart and circulation. However, patients who lose more weight during dialysis will have a higher Kt/V for the same level of URR. On average, a Kt/V of 1.2 is roughly equivalent to a URR of about 63 percent. Thus, another standard of adequate dialysis is a minimum Kt/V of 1.2. The Kidney Disease Outcomes Quality Initiative (KDOQI) group has adopted the Kt/V of 1.2 as the standard for dialysis adequacy.[1] Like the URR, the Kt/V may vary considerably from treatment to treatment because of measurement error and other factors. So while a single low value is not always of concern, the average Kt/V should be at least 1.2. In some patients with large fluid losses during dialysis, the Kt/V can be greater than 1.2 with a URR slightly below 65 percent—in the range of 58 to 65 percent. In such cases, the KDOQI guidelines consider the Kt/V to be the primary measure of adequacy. **[CMS Center for Clinical Standards and Quality]**

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. ***Cost containment and support for safety net services must continue to be central tenets of the Certificate of Need process."*** (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 this project with cash in the amount of $2,478,255 and a lease with a FMV of $863,493. The Applicants attested that the total estimated project costs and related costs will be funded in total with cash and cash equivalents. A summary of the financial statements of the Applicants is provided below. The Applicants have sufficient cash to fund this project.

TABLE SIX
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 this project with cash in the amount of $2,478,255 and a lease with a FMV of $863,493. The Applicants have qualified for the financial waiver[5].

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 this project with cash in the amount of $2,478,255 and a lease with a FMV of $863,493. The lease is for 10 years at a base rent of $15.36/gsf $123,678.72 per year for the first 5 years, with a 10% increase every 5 years. The table below shows the calculation of the FMV of the lease space of 6,250 GSF using an 8% discount factor. It appears the lease is reasonable when compared to previously approved projects.

[5] The applicant is NOT required to submit financial viability ratios if:

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.

TABLE SEVEN FMV of Lease			
Year	PV of 8%	Total Base Rent	PV of Total Space Lease
1	0.92593	$123,678.72	$114,517.84
2	0.85734	$123,678.72	$106,034.71
3	0.79383	$123,678.72	$98,179.88
4	0.73503	$123,678.72	$90,907.57
5	0.68058	$123,678.72	$84,173.26
6	0.63017	$136,046.59	$85,732.48
7	0.58349	$136,046.59	$79,381.82
8	0.54027	$136,046.59	$73,501.89
9	0.50025	$136,046.59	$68,057.31
10	0.46319	$136,046.59	$63,015.42
Total [1]			$863,502.18
1.Does not total because of rounding			

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))

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 in the table below, the Applicants have met all of the State Board Standards published in Part 1120, Appendix A. The Applicants are in compliance with all State Board Standards. [See Appendix II at the end of this report for detail of costs]

TABLE EIGHT
Reasonableness of Project Costs

	Project Costs		**State Board Standard**		
Use of Funds	Project Costs	Project	GSF/%/Station	Total	Met Standard
Modernization and Contingencies	$971,244	$120.62/GSF	$212.94/GSF	$1,714,593	Yes
Contingencies	$125,000	14.77%	15%	$126,936.60	Yes
Architectural/Engineering Fees	$97,152	10.00%	10.78%	$104,389.31	Yes
Movable or Other Equipment (not in construction)	$536,973	$44,748/Station	$58,650/station	$703,800.00	Yes
Consulting and Other Fees		$67,977			
Fair Market Value of Leased Space or Equipment		$535,544			

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 $258.19 operating expense per treatment.

THE 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 $24.28 per treatment.

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

Appendix I
Safety Net Impact Statement

The Applicants stated the following:

"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. 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. The proposed project will not impact the ability of other health care providers or health care systems to cross-subsidize safety net services. As shown in Table 1110.1430(b), the utilization of adult ICHD (In-Center Hemodialysis) *facilities operating for over 2 years and within 30 minutes of the proposed Melrose Village Dialysis is 74.1%. There are 145 combined patients from Dr. Aneziokoro's and DuPage Medical Group practices suffering from CKD and residing within 30 minutes of the proposed site for Melrose Village Dialysis. At least 68 of these patients will be expected to require dialysis treatment within 12 to 24 months of project completion. As such, the proposed facility is necessary to allow the existing facilities to operate at a more optimum capacity, while at the same time accommodating the growing demand for dialysis services. Accordingly, the proposed dialysis facility will not impact other general health care providers' ability to cross-subsidize safety net services."*

DaVita, Inc.
Net Revenue, Charity and Medicaid Information for the State of Illinois

	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	$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 Revenue	$8,603,971	$7,361,390	$4,692,716
% of Medicaid to Net Patient Revenue	3.23%	2.36%	1.33%

Appendix II

Moveable and other Equipment Costs		
	Reviewable	Non Reviewable
Communications	$80,144	
Water Treatment	$153,275	
Bio-Medical Equipment	$11,550	
Clinical Equipment	$273,944	
Clinical Furniture/Fixtures	$18,060	
Lounge Furniture/Fixtures		$3,855
Storage Furniture/Fixtures		$5,862
Business Office Fixtures		$49,905
General Furniture/Fixtures		$48,500
Signage		$12,000
Total Moveable and other Equipment	$536,973	$120,122

State Board Standard Calculation of ESRD Modernization and Contingency Costs inflated by 3% per year						
CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021
$178.33	$183.68	$189.19	$194.87	$200.71	$206.73	$212.94

State Board Standard Calculation of Cost per ESRD Station inflated by 3% per year						
CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021
$49,124.31	$50,598.04	$52,115.98	$53,679.46	$55,289.84	$56,948.54	$58,657.00

Facilities within 30-minutes (adjusted) to the proposed facility

	Facility	City	Stations	Adjusted Time	Utilization	Met Standard	Star Rating
1	Fresenius Kidney Care North Avenue	Melrose Park	24	8.05	84.03%	Yes	5
2	Fresenius Kidney Care Melrose Park	Melrose Park	18	11.5	77.78%	No	3
3	U.S. Renal Care Villa Park Dialysis	Villa Park	13	13.8	88.46%	Yes	3
4	Fresenius Kidney Care Westchester	Westchester	22	14.95	61.36%	No	5
5	Fresenius Kidney Care Elmhurst	Elmhurst	28	14.95	72.02%	No	5
6	Fresenius Kidney Care River Forest	River Forest	22	14.95	75.00%	No	4
7	Loyola Center for Dialysis on Roosevelt	Maywood	30	16.1	78.33%	No	4
8	NxStage Kidney Care Oak Brook, LLC	Oak Brook	8	17.25	43.75%	No	1
9	Fresenius Kidney Care Norridge	Norridge	16	17.25	80.21%	Yes	5
10	Fresenius Kidney Care Elk Grove	Elk Grove Village	28	18.4	75.00%	No	4
11	US Renalcare Oak Brook Dialysis	Downers Grove	13	18.4	83.33%	Yes	3
12	Montclare Dialysis Center	Chicago	16	18.4	95.83%	Yes	4
13	Fresenius Kidney Care Downers Grove	Downers Grove	16	20.7	63.54%	No	3
14	Fresenius Kidney Care Berwyn	Berwyn	30	20.7	77.78%	No	4
15	Davita Schaumburg Renal Center	Schaumburg	22	21.85	54.55%	No	5
16	Fresenius Kidney Care Willowbrook	Willowbrook	20	21.85	62.50%	No	4
17	Fresenius Kidney Care Glendale Heights	Glendale Heights	29	21.85	74.14%	No	5
18	Fresenius Kidney Care Lombard	Lombard	12	23	75.00%	No	5
19	Fresenius Kidney Care Des Plaines	Des Plaines	13	23	76.92%	No	3
20	Fresenius Kidney Care North Kilpatrick	Chicago	28	23	85.71%	Yes	5
21	Fresenius Kidney Care Oak Park	Oak Park	12	23	93.06%	Yes	4
22	Fresenius Kidney Care Niles	Niles	32	24.15	55.21%	No	5
23	Arlington Heights Renal Center	Arlington Heights	18	24.15	62.04%	No	5
24	Fresenius Kidney Care Congress Parkway	Chicago	30	24.15	64.44%	No	4

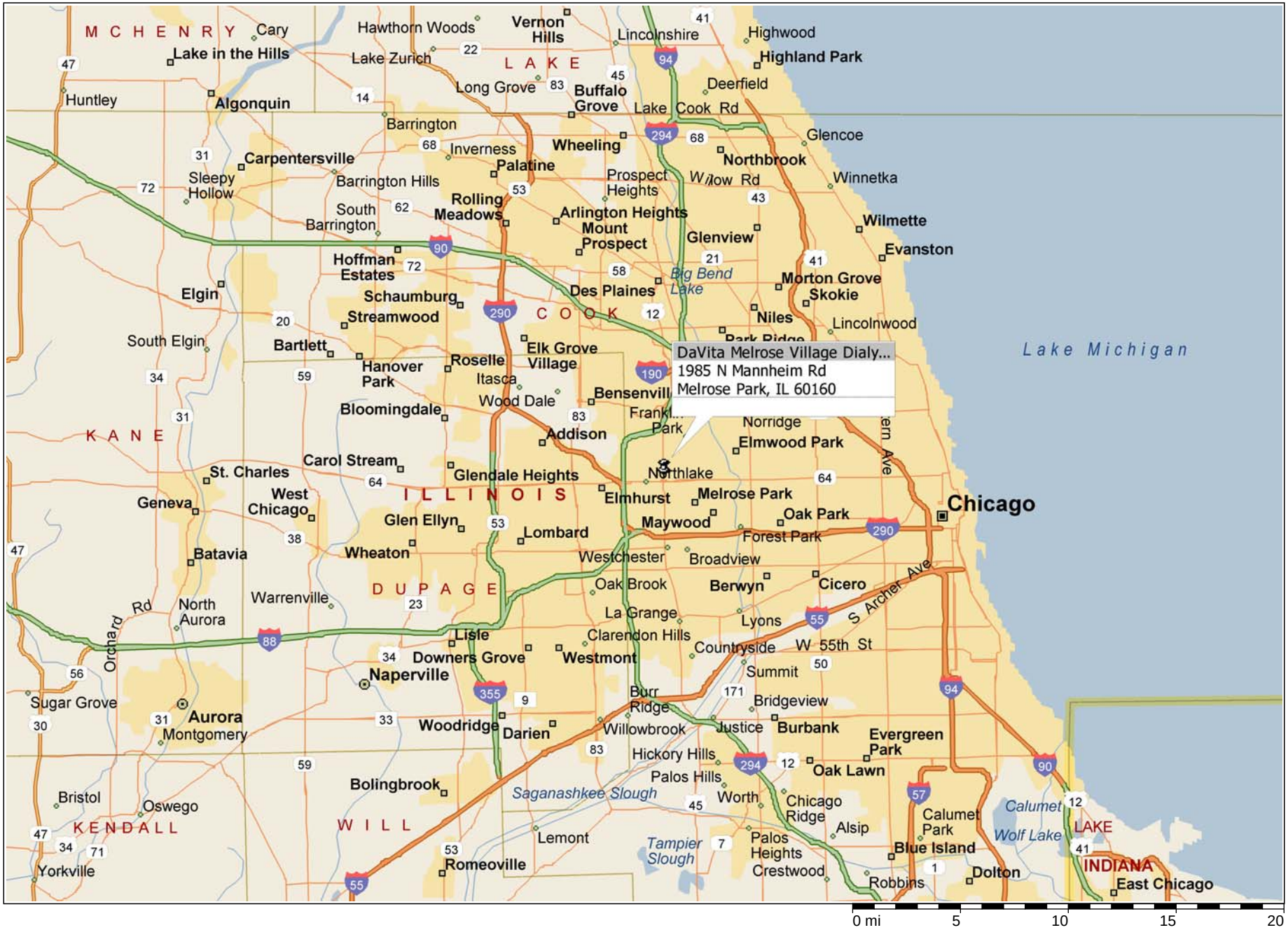
Facilities within 30-minutes (adjusted) to the proposed facility

	Facility	City	Stations	Adjusted Time	Utilization	Met Standard	Star Rating
25	Fresenius Kidney Care West Suburban	Oak Park	46	24.15	87.32%	Yes	4
26	John H. Stroger Hospital of Cook County Dialysis	Chicago	9	25.3	40.74%	No	NA
27	University of Illinois Hospital Dialysis	Chicago	26	26.45	83.97%	Yes	3
28	DaVita Logan Square	Chicago	28	26.45	86.90%	Yes	4
29	Fresenius Kidney Care Rolling Meadows	Rolling Meadows	24	26.45	89.58%	Yes	5
30	West Side Dialysis Center	Chicago	12	27.6	48.61%	No	3
31	Fresenius Kidney Care Summit	Summit	12	27.6	51.39%	No	NA
32	Fresenius Kidney Care Northcenter	Chicago	16	27.6	56.25%	No	5
33	Fresenius Kidney Care Glenview	Glenview	20	27.6	64.17%	No	5
34	Circle Medical Management, Inc.	Chicago	27	27.6	67.90%	No	1
35	Davita - Lincoln Park Dialysis Center	Chicago	22	27.6	68.18%	No	4
36	Fresenius Kidney Care Logan Square	Chicago	14	27.6	73.81%	No	5
37	Fresenius Kidney Care Cicero	Cicero	18	27.6	92.71%	Yes	5
38	DSI Renal Dialysis Center	Chicago	28	28.75	61.90%	No	3
39	Garfield Kidney Center	Chicago	24	28.75	64.58%	No	5
40	Fresenius Kidney Care Austin Community	Chicago	16	28.75	66.67%	No	4
41	Fresenius Kidney Care West Belmont	Chicago	17	28.75	87.25%	Yes	4
42	Fresenius Kidney Care Chicago	Chicago	21	29.9	49.21%	No	3
43	Davita Big Oaks Dialysis Center	Niles	12	29.9	72.22%	No	4
44	DaVita Little Village	Chicago	16	29.9	96.88%	Yes	5
45	Stony Creek Dialysis	Oak Lawn	14	29.9	100.00%	Yes	3
	Total Stations/Average Utilization		922		72.67%		
1	DaVita Salt Creek Dialysis	Villa Park	12	14.95	0.00%		NA
2	Oak Park Kidney Center, LLC	Oak Park	18	20.7	0.00%		2

Facilities within 30-minutes (adjusted) to the proposed facility

	Facility	City	Stations	Adjusted Time	Utilization	Met Standard	Star Rating
3	Nocturnal Dialysis Spa, LLC	Villa Park	12	20.7	8.33%		NA
4	DaVita Brickyard Dialysis	Chicago	12	23	0.00%		NA
5	Fresenius Medical Care Schaumburg	Schaumburg	12	23	19.44%		NA
6	Presence Resurrection Medical Center	Chicago	14	23	27.38%		2
7	Fresenius Kidney Center Mount Prospect	Mount Prospect	8	25.3	0.00%		NA
8	Irving Park Dialysis	Chicago	12	25.3	6.94%		NA
9	Fresenius Kidney Care Woodridge	Woodridge	12	27.6	0.00%		NA
10	Satellite Dialysis of Glenview	Glenview	16	27.6	0.00%		4
11	US Renal Care Hickory Hills	Hickory Hills	13	27.6	23.08%		NA
12	Fresenius Kidney Care Chicago Westside	Chicago	31	27.6	34.41%		3
13	DaVita Geneva Crossing Dialysis	Carol Stream	12	28.75	0.00%		NA
14	Fresenius Kidney Care Polk	Chicago	24	28.75	38.19%		3
15	Fresenius Kidney Care Deerfield	Deerfield	12	28.75	38.89%		4
16	DaVita Rutgers Park Dialysis	Woodridge	12	29.9	0.00%		NA
			1,154		57.09%		

17-029 DaVita Melrose Village Dialysis - Melrose Park



Transcript of Full Meeting

Date: January 9, 2018
Case: State of Illinois Health Facilities and Services Review Board

Planet Depos
Phone: 888.433.3767
Email:: transcripts@planetdepos.com
www.planetdepos.com

ILLINOIS DEPARTMENT OF PUBLIC HEALTH

HEALTH FACILITIES AND SERVICES REVIEW BOARD

OPEN SESSION - MEETING

Bolingbrook, Illinois 60490

Tuesday, January 9, 2018

9:03 a.m.

BOARD MEMBERS PRESENT:

KATHY OLSON, Chairwoman

BRAD BURZYNSKI

DEANNA DEMUZIO

JOEL K. JOHNSON

JOHN MC GLASSON, SR.

MARIANNE ETERNO MURPHY

Job No. 169209A

Pages: 1 - 278

Reported by: Melanie L. Humphrey-Sonntag,

CSR, RDR, CRR, FAPR

ALSO PRESENT:

JEANNIE MITCHELL, General Counsel

COURTNEY AVERY, Administrator

MICHAEL CONSTANTINO, IDPH Staff

GEORGE ROATE, IDPH Staff

ANN GUILD, Compliance Manager

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

CHAIRWOMAN OLSON: Okay. Next, we have applicants subsequent to initial review. First is Project 17-029, DaVita Melrose Village Dialysis.

May I have a motion to approve Project 17-029, DaVita Melrose Village Dialysis, to establish a 12-station ESRD facility in Melrose Park.

MEMBER JOHNSON: So moved.

CHAIRWOMAN OLSON: May I have a second, please.

MEMBER DEMUZIO: Second.

CHAIRWOMAN OLSON: The Applicant will be sworn in.

THE COURT REPORTER: Would you raise your right hands, please.

(Four witnesses sworn.)

THE COURT REPORTER: Thank you.

And please state your names as you start to talk.

MR. NIEHAUS: Good morning. My name is Brian Niehaus, N-i-e- --

CHAIRWOMAN OLSON: Wait. We have -- oh, you want the names? And then we'll let Mike give his report?

THE COURT REPORTER: Just when they speak they can give their names. So we can go ahead to Mike and then --

CHAIRWOMAN OLSON: Your report, please, Mike.

MR. CONSTANTINO: Thank you, Madam Chair.

The Applicants propose to establish a 12-station dialysis facility in Melrose Park, Illinois. The proposed dialysis facility would include a total of 8,000 gross square feet of space at a cost of approximately $3.3 million. The expected completion date is June 30th, 2019.

There was no public hearing requested, we did receive opposition and support letters, and there were findings related to this project.

We also received comments on the State Board staff report. It was sent to you by email last week, and it is placed in your packet here this morning, a hard copy of that comment on the State Board staff report.

Thank you, Madam Chair.

CHAIRWOMAN OLSON: Thank you, Mr. Constantino.

Okay. Now we'll get your names and you

can make comments for the Board, please.

MR. NIEHAUS: Good morning. My name is Brian Niehaus, N-i-e-h-a-u-s.

With me today is Dr. Jean Houlihan, a physician and vice president of the board of directors at DuPage Medical Group; Dr. Bryan Becker, chief medical officer with DaVita Integrated Care; and Dr. Osvaldo Wagener, a nephrologist at Primecare Nephrology & Hypertension.

As the State Board staff noted, there's only one deficiency on this application, relating to maldistribution and duplication of services. The current area facilities within a 30-minute GSA are operating at an average utilization of over 74 percent. The State Board standard is 80 percent.

We're asking to prospectively address that need and have sufficient stations to meet our identified patient population, which we have identified in the physician referral letters.

I will note that the opposition noted a couple of different issues with our applications. It's too numerous for me to address in my opening

statements, but please ask us questions if you have any concerns about any of their comments.

I will turn this over to the clinicians for additional comment.

Thank you.

CHAIRWOMAN OLSON: Thank you.

DR. WAGENER: Good morning. My name is Osvaldo Wagener, W-a-g-e-n-e-r. I'm board certified in nephrology. I have been working in the Melrose area for at least 20 years now, and I came to the Board to represent my patients.

Through this facility we can improve the lives of patients and their family by having more options in their dialysis care providers, locations, and treatment times.

As you know, dialysis care is not simple as an equation for patients that appear to need a dialysis place. Many of them, they have the -- they need family care, they need to leave their work at certain hours, and for them it's important to have an available slot when they need it, not just what is available, which can make it difficult for the family or for the patient themselves, having to relinquish the work that

they are doing -- many times, sometimes -- to be able to accommodate to the available slots.

Currently there is utilization in the area facilities over 74 percent, and it's projected to continue increasing on the annual basis.

Unfortunately, the population that we serve is mainly Hispanic, and, unfortunately, this ethnic group of patients are more propense to develop end stage renal disease than the average population. They have a 1.4 times increased compromise of renal insufficiency, and this is mainly due to diabetes and hypertension.

And, also, this community average household income is around 48,000, which is below the 60,000 that is average for the state. That may put these patients in a more difficult position of having to travel or to hire somebody to travel to a distant dialysis clinic or not -- having to relinquish the work that they are doing to be able to accommodate for the available slots.

I know that many other physicians from other groups talked already about the quality of care, and we all -- as a doctor, I'll speak to quality of care.

What we are trying to do here is to have more available positions of spots for our population of end stage renal disease. Essentially and currently, more than three-fourths of the dialysis clinics are owned by Fresenius Medical Care. So it's like having AT&T dictating where you can go, when you can go, and not having other available phone lines, other phone companies, to choose from.

I think the mission of the Board is to regulate deployment of the public facilities, and I think that's the main charge. But, also, we have to take in account that we are in a society where competition is helpful, not only for the state, for the patients, and for all the economy.

So it helps to bring quality, it helps to improve the quality, and, also, it helps to improve the availability of making you available for the patient's need.

Thank you.

CHAIRWOMAN OLSON: Thank you, Doctor.

DR. HOULIHAN: Good morning. My name is Jean Houlihan.

I'm actually a board-certified physician.

I work at DuPage Medical Group. I'm an internal medicine physician/primary care doctor, and, as well, I'm the vice president of the board of directors of DuPage Medical Group.

DuPage Medical Group practices a philosophy of clinically integrated and coordinated outpatient care being provided with the highest quality and the lowest cost for patients, and I can't stress that enough. That is truly our philosophy. That's what we're all here for. We provide care to over 800,000 patients, and we also see 41,000 Medicaid patients in the year 2017.

We operate the seventh-largest ACO in the country, ranking in the top 15 percent in quality and the bottom 25 percent in cost. And I want to stress, also, that we are the lowest-cost ACO in the northern part of Illinois, and we are also the second-lowest cost in the entire state. Our quality is very high, and our rankings are very high when you look at quality.

As related by Dr. Wegener, there is a difference between an acceptable level of area dialysis stations and facilities for patients

versus the regulatory requirements. DMG physicians frequently encounter patients that have encountered hardships and frustrations because of limitations in their choices for dialysis care. Limitations patients encounter include choices in providers, choices in shift availability, which is really important, and distances traveled for their care.

Without this facility we expect it to be increasingly difficult for our patients to access dialysis treatments. The State notes that the average utilization of facilities in the area is already over 74 percent. At this level, shift choices become scarce, and patients are often forced to shop for facilities that are farther from their home.

Research confirms this increases the rate of missed appointments, which ultimately increases mortality rates to our patients, which is very unfortunate. As for choice, this facility will increase options for patients and introduce healthy competition for patients.

As a densely populated region, there are currently 17 facilities within 20 minutes of this

proposed location. There is one USRC facility, one NxStage facility, and 15 Fresenius facilities. Clearly, most patients do not have a choice when it comes to their dialysis provider today.

Finally, this facility will extend the DMG/DaVita dialysis care network platforms and experiences for the benefit of our patients. We are partnering with DaVita and other community physicians because we are being asked by our patients to bring the benefits of true clinical integration to the field.

We have the experience, expertise, and the commitment necessary to implement the care and quality improvement programs that will make this facility a success. We need your approval to move forward.

Thank you.

CHAIRWOMAN OLSON: Thank you.

DR. BECKER: Good morning. My name is Bryan Becker. I have practiced as a board-certified nephrologist for up to 25 years. The last few were in the Chicago area, and I now serve as the chief medical officer for DaVita Integrated Care, in which I oversee all of our integrated

care programs across the country. It numbers approximately 20,000 patients in, as you heard, ESCOs but, also, special-needs plans and other types of commercial arrangements.

I want to comment on why this joint venture is unique and offers patients tremendous benefit. Not just the issue raised about integrated medical records but actually provider communication, patient support services that span more than 50 specialties are unique resources for patients with end stage renal disease and not available except in such a unique joint venture partnership between DaVita and DuPage Medical Group.

If you combine those resources with DaVita's emphasis on patient education, treatment, its ability to develop and use predictive models and support diagrams along with this incredibly capable delivery of services from community physicians, you have a care model that's uniquely positioned to do a tremendous amount of good for patients.

We have seen such partnerships work. They do the things you would hope that they would do by

decreasing patient hospitalizations, decreasing patient death, and increasing access to the resources patients need to remain healthy. If you measure some of those, you also see a significant reduction in cost.

Where we've seen success with these programs, linking large integrated delivery systems in large medical groups with services in dialysis, we've seen significant reduction in use of catheters, which leads to improved patient health and at least an $8,000-per-year reduction in patient expense. We've seen significant reductions in hospitalization days, up to 30 percent less, and we've seen an overall savings per patient of about $12,000 a year.

If you add to that that we have expertise continuing to grow in the programs I mentioned at the outset, we're able to bring that in combination with DuPage Medical Group's tremendous expertise and deliver a very unique benefit for patients in this community, and I would urge you to consider that.

Thank you.

CHAIRWOMAN OLSON: Thank you.

Questions from Board members?

(No response.)

CHAIRWOMAN OLSON: I actually have a couple questions. Can I go first?

So this -- this is part -- and I will state that we will, obviously, look at each one of these applications individually.

But as it's been talked about, this is part of six applications in HSA 7 and one in a neighboring HSA, all part of DuPage Medical Group; is that correct?

MR. NIEHAUS: DuPage Medical Group has an ownership in each, correct.

CHAIRWOMAN OLSON: Okay. So I want to address a couple of things.

First of all, I'm a little bit confused because you keep talking about 74 percent area utilization and our report says 65 percent. So what is the discrepancy?

MR. NIEHAUS: So it's in the State Board report, as well. The utilization of 74 percent is when you exclude facilities that have just begun operation and are not yet at the two-year requirement, so they have not had time to get up

to the -- their utilization level that they've testified they'd meet in two years.

CHAIRWOMAN OLSON: So when you talk about 74 percent, you're excluding those facilities?

MR. NIEHAUS: Correct.

CHAIRWOMAN OLSON: Okay. They clearly have access but they're just --

THE COURT REPORTER: I'm sorry. "They clearly" --

CHAIRWOMAN OLSON: They clearly have access but they're just --

MR. NIEHAUS: Correct. Our understanding is based on their applications. They're going to be serving a different patient population that they identified versus those we have identified.

CHAIRWOMAN OLSON: Okay.

And I want to talk a little bit about this EMR because you're saying you have integrated EMRs, but we had other people that testified here today that said your EMR is integrated for people involved in DuPage Medical Group but it's not integrated if you're not inside DuPage Medical Group.

Can you respond to that?

MR. NIEHAUS: Yeah.

So I think that every provider has some EHR integration issues with respect to other providers. My understanding is that all DuPage Medical Group and NANI physicians do eventually get access to all of each other's information; however, realtime is another story. It has to go through an assessment for HIPAA compliance and other requirements before that gets to the patient.

Sometimes that's too late for patients, and I think that's the requirement and the issue that we're seeing with our primary care and nephrologists that we're seeking to address through the development of these facilities.

DR. WAGENER: The integration was one of the goals -- sorry.

Integration was one of the goals of the Obamacare when they adopted the EMR.

CHAIRWOMAN OLSON: Right.

DR. WAGENER: However, unfortunately, for one reason or another -- public relations and a lot of excuses -- it never happened.

I can tell you, as a primary care -- as a

primary nephrologist practicing in four different hospitals and -- I'm meeting patients who are in one hospital and then get admitted to the other hospital; you don't have access to the information, even if -- everything is electronic but each hospital has their own password. They don't communicate, the computer system, with each other.

I practice in an area with 90 doctors associated in nephrology. I don't have access to the records of their patients, in no ways at all. I mean, the -- I have to call them and request some information when I need it, like we do in the usual medical practice for the last 40, 50 years.

But there is no such thing as integration. So I think it's a poor excuse to assume that because -- I mean, really, everything is an electronic medical record because you get penalized by the government when you don't do it. You're penalized by the CMS, but there is no communication between each one because there is no one language.

And that was one of the problems of Obamacare, to allow the communication or the

transfer of information between one place and the other without violating the HIPAA rules.

So that's one of the -- the other feature that I -- I heard about the comments of other groups about our proposal is the quality of care. I'm surprised about that. Everybody talks about quality care; however, nobody knows what my numbers are.

All these people that talk, I don't know them more than by name. So when they say that the quality of care will be affected, I think -- personally, I feel like an insult because nobody knows how I practice. So how they can say that my quality of care would be -- or the quality of the patient's care -- will be compromised?

And what you have to have in your mind-set about all this business is that both groups, the NANI group or Northern Illinois Medical Group and Associates in Nephrology, they have exclusive contracts with Fresenius, so they manage all the clinics or most of the clinics of Fresenius Medical Care, so, essentially, they are representing Fresenius Medical Care.

And you have to take into account that in

our market, when you take 10 miles around our clinic that we are proposing, of 25 clinics, 19 are Fresenius Medical Care. So, essentially -- and then there are two or three independent groups. So, essentially, it's like a monopoly.

And I understand that the Board has a mission of regulating layover -- of the layer of all these facilities to help keep quality and keep the access for patients, but I think in a monopoly it's not a way to go, at least for our system. I think competence is a very unique way to keep quality, to keep access, and to keep the good care of the patients.

CHAIRWOMAN OLSON: Thank you.

I guess I just -- I think that the Board -- well, I shouldn't speak for the Board.

This is a really difficult situation that we have. I mean, clearly, you're aware that it's unprecedented to be asking for 72 stations within this kind of geographic area. So I -- I guess I'm just really trying to reconcile in my own mind how this doesn't appear -- and I understand what you're saying.

MEMBER MC GLASSON: May I ask a question?

CHAIRWOMAN OLSON: Sure. Go ahead.

MEMBER MC GLASSON: It seems to me that, when you're talking about HIPAA regulations and difficulty integrating, that those are technical problems that could be solved.

MR. NIEHAUS: I think that everybody would like to solve them. I don't think it's happened to date.

And so DaVita and DMG and some of the community nephrologists are just trying to take a proactive step to integrate some more of the care through these facilities.

Absolutely, I don't think anyone is opposed to having those issues addressed and solved. I think that health care would be better for it.

CHAIRWOMAN OLSON: So just to go back to where I was kind of going is I -- I'm really struggling with this because I think that -- I understand what you're saying about the balance of power here and it's very clear. Everybody in the room knows there are two major players in this market.

But it's really difficult to see, when you

come before us with this kind of request, that that doesn't appear to be some kind of a turf war or, as somebody, I think, said, hostile corporate takeover.

I mean, how do you not -- how do you respond to that? I'm trying to -- I'm trying to figure that out in my own head. I don't know how you respond to that.

MR. NIEHAUS: So I think I would start with all we can do is present each application on its own. I know that we want to take a macro view at it. Ultimately, it's up to you to decide how many are warranted.

I think the key for me is we look at the State requirements in the State Board report. There's one deficiency. When you look at the utilization level, it's in line with other facilities this Board has approved with -- notwithstanding that deficiency in the past. I think that we are trying to present a new, innovative care model with some additional benefits for you to consider.

Ultimately, we feel that each of these facilities is warranted. And when you look at the

patients we've identified and the growth rates in these areas by 2020 -- these facilities aren't going to be operational until 2019, late in 2019. So -- but when we're talking about 2020 and the need for beds, we're addressing the need that's going to be present two years from now, and we need to address it now because, if we address it two years from now, it's going to be too late for patients.

CHAIRWOMAN OLSON: So how do you speak to the accusations that were made here today or the -- actually, I think it's pretty accurate -- that you used the same referral letters for many of the applications? How does that work?

MR. NIEHAUS: The referral letters are not the same. The historical patient data -- because the physicians at DMG remain the same -- between each application happened to be the same. They also share some wording because the Board has certain requirements for the applications.

But each application clearly identifies individual patients in different zip codes. There's nothing similar between the patients that we're talking about. They keep wanting to refer

to patients that spoke in support. Patients that spoke in support that are on dialysis aren't going to care what these facilities look like because they're receiving care at existing facilities. We're talking about patients that don't have dialysis currently but will require it in the future.

So while the letters share similarities, they are clearly different. Each was notarized and met Board requirements, and that's reflected in the State Board report.

CHAIRWOMAN OLSON: Thank you.

Other questions?

(No response.)

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

MR. ROATE: Thank you, Madam Chair.

Motion made by Mr. Johnson; seconded by Senator Demuzio.

Senator Burzynski.

MEMBER BURZYNSKI: You know, like Madam Chairwoman, I, too, am struggling with this.

I am going to vote yes for this particular application; however, that does not necessarily

mean I'm going to support the others that are appearing in front of us today.

But, anyway, I vote aye.

MR. ROATE: Thank you, sir.

Senator Demuzio.

MEMBER DEMUZIO: Well, I, too, have been struggling with this, and I've looked at all of the applications that are going to be coming before us.

But because of the Board finding of unnecessary duplication, I am voting no.

MR. ROATE: Thank you.

Mr. Johnson.

MEMBER JOHNSON: I'm going to vote no based on the Board report.

MR. ROATE: Thank you.

Mr. McGlasson is absent.

Ms. Murphy.

MEMBER MURPHY: I'm going to vote yes based on the answers to the questions here today.

MR. ROATE: Thank you.

Madam Chair.

Shall we wait for --

MS. AVERY: Yes, please.

MR. ROATE: -- for Mr. McGlasson to return?

Madam Chair, do you wish to cast your vote, or do you want to wait?

CHAIRWOMAN OLSON: Yeah, I'm going to -- I'm going to vote no.

I just have too many unanswered questions in my head and the negative findings in the State Board staff report.

MR. ROATE: Thank you, Madam Chair.

CHAIRWOMAN OLSON: We're going to wait for him to come back.

MR. ROATE: Okay.

CHAIRWOMAN OLSON: He's here.

MEMBER MC GLASSON: I vote aye on the basis that I don't believe it's a function of this Board to choose sides in competition for revenue.

MR. ROATE: Thank you, sir.

That's 3 votes in the affirmative and 3 votes in the negative.

CHAIRWOMAN OLSON: The motion fails. You will get an intent to deny.

MR. NIEHAUS: Thank you.

(Applause.)

CHAIRWOMAN OLSON: Okay. Thank you.

- - -

POLSINELLI

150 N. Riverside Plaza, Suite 3000, Chicago, IL 60606-1599 • 312.819.1900

September 26, 2018

Anne M. Cooper
(312) 873-3606
(312) 276-4317 Direct Fax
acooper@polsinelli.com

Via Federal Express

Ms. Courtney Avery, Administrator
Illinois Health Facilities &
Services Review Board
525 West Jefferson Street, 2nd Floor
Springfield, Illinois 62761

Re: Additional Information for Melrose Village Dialysis (Proj. No. 17-029)

Dear Ms. Avery:

Polsinelli represents DaVita Inc. and Adiron Dialysis, LLC (collectively, the "Applicants") in the above-referenced proposal to establish a 12-station dialysis clinic in Melrose Park, Illinois (the "Proposed Clinic"). In this capacity, we are writing to provide additional information regarding the Proposed Clinic pursuant to Section 1130.670 of the Illinois Health Facilities and Services Review Board's (the "State Board") procedural rules. We also write to request the State Board establish July 31, 2020 as the new completion date for the Proposed Clinic.

As the Applicants have previously described and as further discussed in this submission, there is a compelling need for additional dialysis stations in Melrose Park, an economically disadvantaged community with a demonstrated lack of meaningful access to dialysis. As further detailed below, the stated need for dialysis services in HSA 7 as calculated in 2017 is understated. In fact, there is an existing need for dialysis stations in the planning area, rather than the small excess noted in the most recent update. In addition to these general area needs, it is also essential to understand the target area to be served has a specific need for stations and how establishing the Proposed Clinic is supported by a clear health planning rationale. The key points of this submission are as follows:

- There is a need for 68 additional dialysis stations in HSA 7 by 2020, and 20 of those stations are needed in the immediate vicinity of the Proposed Clinic.
- Stations are particularly needed in the Proposed Clinic's 30 minute Geographic Service Area where each station currently serves **nearly twice** the number of area residents compared to the state average station-to-population ratio.
- The Proposed Clinic would not create a maldistribution of services based on the high utilization of existing providers and existing access disparities.

- 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% by the time the Proposed Clinic is fully operational.

- The Proposed Clinic is necessary to ensure adequate access to dialysis services for Melrose Park, a low-income community with a high chronic disease burden and poor socioeconomic indicators of health.

As discussed in further detail below, there is an ongoing need for dialysis stations in HSA 7 and Melrose Park specifically.

I. Dialysis Station Need in HSA 7 is Understated by 68 Stations, and 20 of those Stations are Needed in the Immediate Vicinity of the Proposed Clinic

Based on the September 14, 2018 update to the inventory of hemodialysis stations in Illinois, there is a calculated excess of two stations in HSA 7.[1] Notably, however, these projections understate existing and projected need due to the fact that the underlying data is out-of-date. In calculating station projections, the State utilized a five-year projection to 2020 from the base year of 2015. As a result, the need calculation utilized dialysis use rates as of December 31, 2015 combined with the population estimates for that same year and then projected that use rate on the anticipated population in 2020.

Fortunately, the State Board staff and providers have the benefit of more accurate, recent hemodialysis utilization data that the State Board collected and published for December 31, 2017. As Exhibit A indicates, there was a 6.93% increase in End-Stage Renal Disease ("ESRD") patients in HSA 7 between 2015 and 2017. Use of the 2015 data therefore results in the State Inventory underestimating projected area needs. Repeating the State's calculation using the more recent 2017 use data, we can more accurately evaluate the demand for ESRD services and the need for the Proposed Clinic. Due to the lag in use rate data reporting, the increased dialysis services use rate based on the projected 2020 population results in **a calculated need for 66 stations**, rather than an excess of two stations as reported by the State Board. This increased station need is due to the dialysis patient census in HSA 7 increasing by 346 patients in that two-year period (or a compound annual growth rate of 3.2%),[2] and illustrates the extent to which the State Inventory underestimates short-term need. Of those 66 stations, **20 stations are needed in the immediate five-mile vicinity of the Proposed Clinic** – the Proposed Clinic's Patient

[1] https://www2.illinois.gov/sites/hfsrb/InventoriesData/MonthlyHCFInventory/Documents/OTHER%20SERVICES%20INVENTORY%20UPDATE%20September%2014%202018.pdf.

[2] Note that this calculation uses the same formula that that State Board uses to calculate ESRD Station Need Determinations, with the only difference being that we used more current dialysis use rates (12/31/2017) rather than older data from 12/31/2015.

Service Area ("PSA") – based on projected increases in the number of area dialysis patients. The Proposed Clinic is essential to help address this need for additional stations in HSA 7 and more specifically in the Melrose Park vicinity.

II. The Proposed Clinic is Well Located to Meet Planning Area Needs

a. Residents of the Geographic Service Area have Poor Access

As indicated by the high projected number of stations needed in the immediate vicinity of the Proposed Clinic, the shortage of stations in HSA 7 is especially true with respect to the Melrose Park area. In the Proposed Clinic's adjusted thirty-minute Geographic Service Area ("GSA") [3], there is currently **one station for every 5,187 residents**.[4] Compared to the average station to population ratio in the state of 1:2,676, the existing stations in the Proposed Clinic's GSA are expected to serve **nearly twice** the number of area residents than the typical dialysis station located in the state.

This ratio indicates a serious maldistribution of services negatively affecting the residents of the Proposed Clinic's GSA and supports a favorable finding by the State Board that the Proposed Clinic will not create an unnecessary duplication of services or maldistribution, but will rather help to correct these issues.

Table 1110.230(c)(2)(A) - Ratio of Stations to Population

	Population	Dialysis Stations	Stations to Population	Standard Met?
Geographic Service Area	3,403,251	656	1:5,187	Yes
State	12,978,800	4,850	1:2,676	

As you know, the Applicants submitted a correction to its application materials on June 27, 2018, which accurately details the population and associated dialysis stations. But for this data error, the last State Board staff report would have been fully positive.

b. Area Clinics are Heavily Utilized

[3] This drive time is modified pursuant to the State Board rules to account for typical traffic congestion in the area and is 26 minutes (30 minutes/1.15).

[4] This updated ratio is from the Applicant's June 27, 2018 submission, available at https://www2.illinois.gov/sites/hfsrb/Projects/ProjectDocuments/2017/17-029/2018-06-27%2017-029%20Melrose%20Village%20Dialysis%20Supplemental.pdf.

Further compounding this access issue, area clinics are heavily utilized and are projected to soon exceed 80% utilization, or the State Board's "Target Utilization" standard. This is particularly true with respect to dialysis clinics in close proximity to the Proposed Clinic. When the five-mile PSA for the Proposed Clinic (which is where the majority of patients for the Proposed Clinic reside) is examined, existing clinics were operating at 78% as of June 30, 2018.[5] Given the projected compound annual growth rate of 4.84%, approved and existing clinics in the Patient Service Area are projected to be at **88% capacity** by March 31, 2021, well in excess of the State Board's 80% Target Utilization standard. As noted above, this five-mile PSA has a projected need of 20 additional stations by 2021. The addition of 12 stations at the Proposed Clinic will help to address this need and avoid potential gaps in area dialysis availability.

III. Melrose Park Residents are at Increased Risk of Developing Kidney Disease

Melrose Park is a low-income community with a large and growing Hispanic population. The village has also been identified as having a particularly high burden of chronic disease across multiple indicators.[6] Each of these factors place residents at increased risk of developing kidney disease.

The incidence and prevalence of chronic kidney disease and end-stage renal disease are higher within certain ethnic groups, including Hispanics. Central Cook County has experienced a tremendous increase in its Hispanic population since 2000.[7] Today, more than 73% of Melrose Park residents are Hispanic.[8] As discussed further in the Application for the Proposed Clinic, Hispanics are at greater risk of developing kidney disease and kidney failure, and they are 1.5 times more likely to experience kidney failure compared to others in the U.S.[9] Other factors contribute to a higher disease burden for these groups, including a family history of disease, impaired glucose tolerance, diabetes during pregnancy, hyperinsulemia and insulin resistance, obesity and low levels of physical activity. Minorities also frequently experience issues with health care access, quality, and barriers due to language and health literacy, which further their susceptibility for chronic disease. Not only do they often lack a "medical home," but the cost of maintenance drugs necessary to manage diabetes and hypertension can be cost prohibitive.

---

[5] This data excludes those clinics currently in "ramp up." If those clinics are included, utilization in the Patient Service Area remains high at 71.26%.

[6] Loyola University Health System and Health Impact Collaborative of Cook County, Community Health Needs Assessment: Central Region, at 82. Available at https://www.loyolamedicine.org/sites/default/files/community-health-needs-assessment-june2016.pdf.

[7] Loyola University Health System and Health Impact Collaborative of Cook County, Community Health Needs Assessment: Central Region, at 13. Available at https://www.loyolamedicine.org/sites/default/files/community-health-needs-assessment-june2016.pdf.

[8] http://factfinder.census.gov.

[9] This statistic is from page 80 of the Melrose Village Dialysis application.

Loyola University Health System, one of the larger hospital systems in the area, noted in its most recent Community Health Needs Assessment that such disparities in access to care and community resources are key contributors to area health inequities.[10] Not surprisingly, given this increased risk, the assessment found a higher prevalence of diabetes among Hispanics and other minorities compared to Asians and non-Hispanic white residents.[11] As the State Board is aware, diabetes and hypertension are the two principal causes of kidney disease.

Within Melrose Park, nearly 20% of residents live below the Federal Poverty Level. Poverty increases the risk of developing chronic disease, including diabetes, hypertension and kidney disease. This results in a higher prevalence of diabetes, for example, among adults without college degrees and those with lower household incomes.[12] In the context of kidney disease, we also find that individuals who lack access to health care due to income or insurance status are frequently not diagnosed with kidney disease until the later stages when it is often too late to stop or slow the disease progression. Poverty also exacerbates the effect of diseases once they develop because it can be difficult for individuals with limited resources to manage their health. As a recent example, the rising costs of insulin have led many low-income diabetics to try to ration their insulin supply, leading to complications and death (Exhibit B). These financial pressures and health consequences can have far-reaching effects. While diabetes is a primary cause of kidney disease, the better a person keeps diabetes and blood pressure under control, the lower his or her chance of developing or exacerbating kidney disease (Exhibit C). As a result, those who struggle to financially manage one disease unfortunately face higher risk of developing others. Finally, with regard to low-income communities, individuals who have not graduated from college or finished high school often lack the education and financial stability associated with a higher use rate of home dialysis treatment modalities, and transplantation is a more onerous process for low-income individuals who lack resources. As a result, once low-income individuals develop kidney disease, they are also more likely to become dependent on in-center hemodialysis for the foreseeable future.

Given these demographics and their impact on community health, it is not surprising that area hospitals' Community Health Needs Assessments have documented poor health and access to health care in Melrose Park. Melrose Park was recently identified as having the second lowest

---

[10] Loyola University Health System and Health Impact Collaborative of Cook County, Community Health Needs Assessment: Central Region, at 19-20. Available at https://www.loyolamedicine.org/sites/default/files/community-health-needs-assessment-june2016.pdf.

[11] Loyola University Health System and Health Impact Collaborative of Cook County, Community Health Needs Assessment: Central Region, at 45. Available at https://www.loyolamedicine.org/sites/default/files/community-health-needs-assessment-june2016.pdf.

[12] Loyola University Health System and Health Impact Collaborative of Cook County, Community Health Needs Assessment: Central Region, at 45. Available at https://www.loyolamedicine.org/sites/default/files/community-health-needs-assessment-june2016.pdf.

life expectancy of suburban Cook County at 75.2 years, nearly a decade shorter than the average life expectancy of 84.1 years in nearby La Grange Park.[13] The Cook County Department of Public Health's top priority for Suburban Cook County is chronic disease prevention.[14] There are also stark disparities in chronic-disease related mortality in the region, both in terms of geography and in terms of race and ethnicity.[15]

IV. Melrose Park Residents Need Access to Dialysis Services in their Community

Beyond the data driven arguments for the Proposed Clinic outlined above, geographically, Melrose Park is a distinct segment of Suburban Cook County. The village was historically coined the "Industrial King of the Suburbs," and it remains home to many industrial and manufacturing companies.[16] Earlier this year, the village welcomed a $250 million expansion of its drug manufacturing campus that will manufacture sterile injectable medicines for the U.S. market. This is the latest in efforts by the village to encourage manufacturing over the past two decades, and as a result of these efforts, Melrose Park has received hundreds of millions of investment dollars and added thousands of retail, manufacturing and industrial jobs to the area.[17] Each of these developments has improved the local economy and worked to further distinguish Melrose Park and other heavily-industrial areas of Suburban Cook County from DuPage County to the west. This distinction is important for several reasons, but primarily because it influences the way that area residents view their community and existing area resources. As is common in communities separated by major highways, residents of Melrose Park and other villages east of the interstate do not readily cross Interstate 290 to the west on a regular basis for services. In addition to acting as a dividing line between Cook and DuPage Counties, the interstate also acts as a geo-political boundary that influences the way area residents view the borders of their community. For these reasons, while the referring nephrologists for the Proposed Clinic care for some patients who live on the other side of Interstate 290, the vast majority (nearly 80%) of pre-ESRD patients who the Applicants anticipate will be referred to the Proposed Clinic live on the Melrose Park side of Interstate 290

---

[13] Loyola University Health System and Health Impact Collaborative of Cook County, Community Health Needs Assessment: Central Region, at 68. Available at https://www.loyolamedicine.org/sites/default/files/community-health-needs-assessment-june2016.pdf.

[14] WePLAN 2015 report for Suburban Cook County, available at http://www.cookcountypublichealth.org/files/pdf/WePLAN%20Final%20Report%20with%20cover%20051311.pdf.

[15] Loyola University Health System and Health Impact Collaborative of Cook County, Community Health Needs Assessment: Central Region, at 19. Available at https://www.loyolamedicine.org/sites/default/files/community-health-needs-assessment-june2016.pdf.

[16] For a history of farming and industry in Melrose Park, see http://www.melrosepark.org/docs/Industry_and_farms.pdf.

[17] For additional information, see https://www.prnewswire.com/news-releases/250-million-plant-breaks-ground-in-melrose-park-300523583.html.

(Exhibit D). As demonstrated by the data above, the Proposed Clinic is well-located to meet existing needs and access issues for Melrose Park and other residents of central Suburban Cook County. In contrast, recently approved clinics to be located in DuPage County are anticipated to primarily serve patients who reside west of Interstate 290; *i.e.*, those who are live in DuPage County.

An additional benefit of making these needed stations available in Melrose Park is that Melrose Park residents will also be able to take advantage of the village Dial-a-Ride program for transportation to and from dialysis appointments at the Proposed Clinic. This program is limited to transportation within Melrose Park's village borders and provides transportation to appointments between 9 am and 5 pm.[18] Given the typical timing of dialysis sessions at clinics that offer three shifts per day, this transportation is best suited for the second shift appointment time. The Proposed Clinic will improve the number of second shift appointment times available in Melrose Park and allow additional area residents to take advantage of this transportation option for their dialysis needs.

V. Response to Opposition Concerns about Duplication of Services

Finally, the Applicants would like to respond to concerns raised that the two existing dialysis clinics in Melrose Park have sufficient capacity for future patients and will be negatively impacted by the Proposed Clinic. In a letter filed by Associates in Nephrology in December 2017, it was noted that the existing Melrose Park Dialysis Center was experiencing 67.5% utilization and expected to have ongoing available capacity.

There are two dialysis clinics located in Melrose Park, both of which are operated by Fresenius. Significantly, as of June 30, 2018, Melrose Park Dialysis Center was operating at **77.8% capacity** and is expected to soon surpass 80%. The other clinic located in Melrose Park (North Avenue Dialysis Center) was operating at **84.0%**. This utilization near and above the State Board's 80% Target Utilization underscores the growing need for additional capacity in Melrose Park and supports the Applicant's understanding that the Proposed Clinic will not negatively impact area providers. This is further supported by the fact that the Proposed Clinic is intended to serve patients of Dr. Aneziokoro (Northwest Medical Associates of Chicago) and DuPage Medical Group who have kidney disease but do not yet require dialysis. As demonstrated in the application and supplemental materials, these new patients are unique to the Proposed Clinic and are more than sufficient to ensure the Proposed Clinic will reach target utilization within two years of operation.

[18] For additional information, see http://www.melrosepark.org/village-services-a-z/village-of-melrose-park-dial-a-ride-for-residents/.

POLSINELLI

Those area nephrologists who oppose the Proposed Clinic have made other general opposition comments that targeted this application in conjunction with other applications filed by DaVita in recent years. This opposition testimony and comments directed toward the Proposed Clinic were misplaced in that context, however, and these general remarks that really were not project-specific were addressed in the applicants' letter to the State Board dated April 30, 2018 for Salt Creek Dialysis (Project No. 17-016), which is on file with the State Board.

***

We believe the information discussed above and set forth as Exhibits will support the State Board's issuance of a fully positive state report and associated favorable consideration of the Proposed Clinic. Thank you for your consideration of this project. If you have any questions and concerns, please do not hesitate to contact me.

Sincerely,

Anne M. Cooper

Attachments

Cc: Gaurav Bhattacharyya

Exhibit A

Updated Need Calculation Based on 2017 Use Rate	
	HSA 7
Planning Area Population - 2015	3,466,200
In Station ESRD Patients - 2017	5,342
Area Use Rate 2017	1.54
Planning Area Population - 2020 (Est)	3,508,600
Projected Patients - 2020	5,407
Adjustment	1.33
Patients Adjusted	7,192
Projected Treatments - 2020	1,121,916
Existing Stations	1,432
Stations Needed - 2020	1,498
Number of Stations Needed	66

HFSRB Monthly Update 09-14-2018	(2)

In Station ESRD Patients - 12/31/2015	4,996
% Increase in Patients 2015 to 2017	6.93%

Area Use Rate - 2015	1.44

HEALTH INC.

Insulin's High Cost Leads To Lethal Rationing

September 1, 2018 · 8:35 AM ET
Heard on Weekend Edition Saturday

BRAM SABLE-SMITH

"It shouldn't have happened," says Nicole Smith-Holt of Richfield, Minn., gazing at the death certificate of her son Alec Raeshawn Smith.

Bram Sable-Smith for NPR

Diabetic ketoacidosis is a terrible way to die. It's what happens when you don't have enough insulin. Your blood sugar gets so high that your blood becomes highly acidic, your cells dehydrate, and your body stops functioning.

Diabetic ketoacidosis is how Nicole Smith-Holt lost her son. Three days before his payday. Because he couldn't afford his insulin.

"It shouldn't have happened," Smith-Holt says looking at her son's death certificate on her dining room table in Richfield, Minn. "That cause of death of diabetic ketoacidosis should have never happened."

SHOTS - HEALTH NEWS

High Cost Of Diabetes Drugs Often Goes Overlooked

The price of insulin in the U.S. has more than doubled since 2012. That has put the life-saving hormone out of reach for some people with diabetes, like Smith-Holt's son Alec Raeshawn Smith. It has left others scrambling for solutions to afford the one thing they need to live. I'm one of those scrambling.

Not enough time

Most people's bodies create insulin, which regulates the amount of sugar in the blood. In the U.S., the roughly 1.25 million of us with Type 1 diabetes have to buy insulin at a pharmacy because our pancreases stopped producing it.

My first vial of insulin cost $24.56 in 2011, after insurance. Seven years later, I pay more than $80. That's nothing compared with what Alec was up against when he turned 26 and aged off his mother's insurance plan.

Smith-Holt says she and Alec started reviewing his options in February 2017, three months before his birthday on May 20. Alec's pharmacist told him his diabetes supplies would cost $1,300 a month without insurance — most of that for insulin. His options with insurance weren't much better.

Alec's yearly salary as a restaurant manager was about $35,000. Too high to qualify for Medicaid and, Smith-Holt says, too high to qualify for subsidies in Minnesota's health insurance marketplace. The plan they found had a $450 premium each month and an annual deductible of $7,600.

"At first, he didn't realize what a deductible was," Smith-Holt says. She says Alec figured he could pick up a part-time job to help cover the $450 per month.

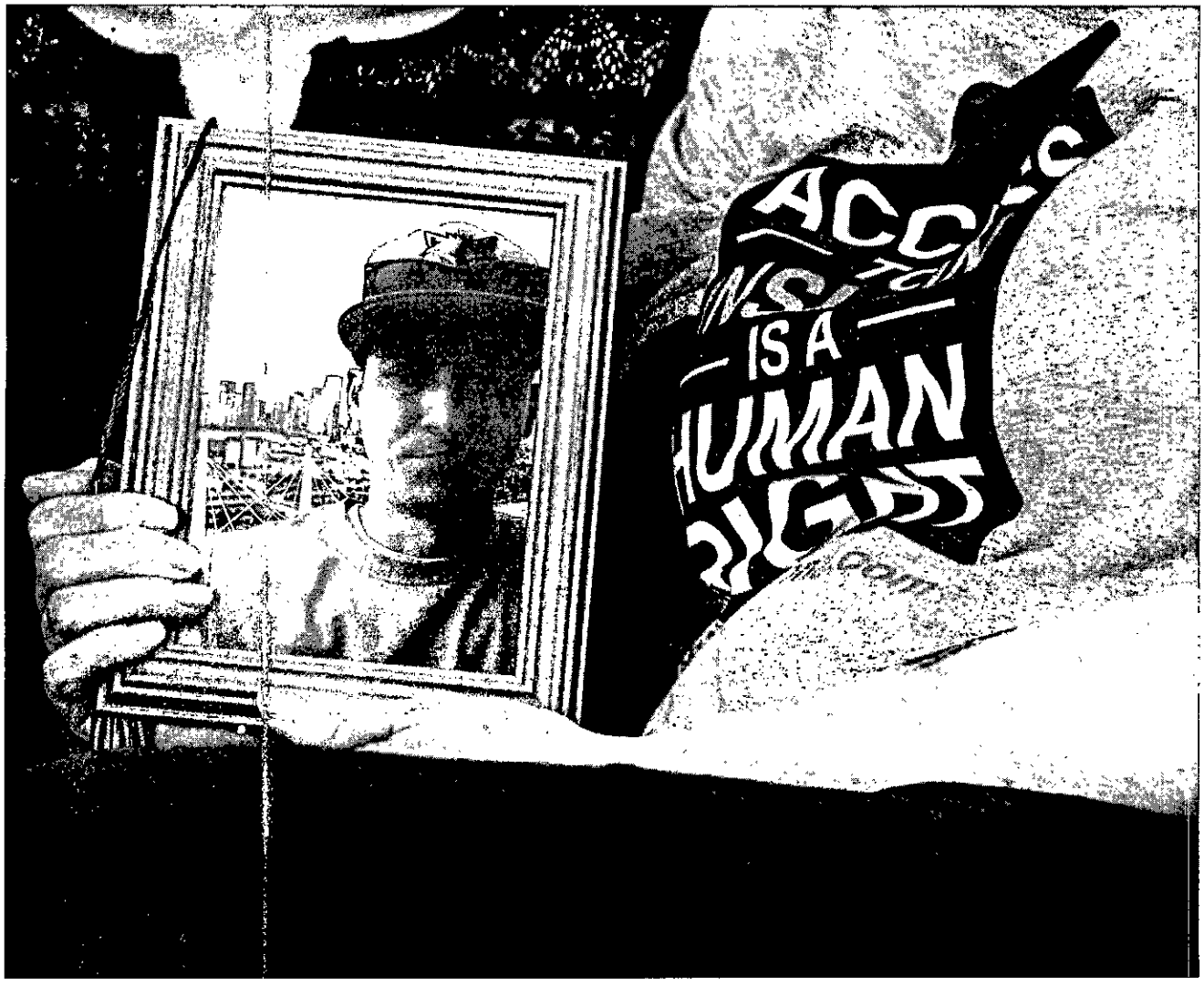
Then Smith-Holt explained it.

SHOTS - HEALTH NEWS

You Can Buy Insulin Without A Prescription, But Should You?

"You have to pay the $7,600 out of pocket before your insurance is even going to kick in," she remembers telling him. Alec decided going uninsured would be more manageable. Although there might have been cheaper alternatives for his insulin supply that Alec could have worked out with his doctor, he never made it that far.

He died less than one month after going off of his mother's insurance. His family thinks he was rationing his insulin — using less than he needed — to try to make it last until he could afford to buy more. He died alone in his apartment three days before payday. The insulin pen he used to give himself shots was empty.



The price of insulin in the U.S. from leading manufacturers has more than doubled since 2012. That's put the life-saving hormone out of reach for some people like Smith-Holt's son Alec.

Bram Sable-Smith for NPR

"It's just not even enough time to really test whether [going without insurance] was working or not," Smith-Holt says.

A miracle discovery

Insulin is an unlikely symbol of America's problem with rising prescription costs.

Before the early 1920s, Type 1 diabetes was a death sentence for patients. Then, researchers at the University of Toronto — notably Frederick Banting, Charles Best and J.J.R. Macleod — discovered a method of extracting and purifying insulin that

could be used to treat the condition. Banting and Macleod were awarded a Nobel Prize for the discovery in 1923.

For patients, it was nothing short of a miracle. The patent for the discovery was sold to the University of Toronto for only $1 so that live-saving insulin would be available to everyone who needed it.

Today, however, the list price for a single vial of insulin is more than $250. Most patients use two to four vials per month (I personally use two). Without insurance or other forms of medical assistance, those prices can get out of hand quickly, as they did for Alec.

Depending on whom you ask, you'll get a different response for why insulin prices have risen so high. Some blame middlemen — such as pharmacy benefit managers, like Express Scripts and CVS Health — for negotiating lower prices with pharmaceutical companies without passing savings on to customers. Others say patents on incremental changes to insulin have kept cheaper generic versions out of the market.

SHOTS - HEALTH NEWS

Why Is Insulin So Expensive In The U.S.?

For Nicole Holt-Smith, as well as a growing number of online activists who tweet under the hashtag #insulin4all, much of the blame should fall on the three main manufacturers of insulin today: Sanofi of France, Novo Nordisk of Denmark and Eli Lilly and Co. in the U.S.

The three companies are being sued in the U.S. federal court by diabetic patients in Massachusetts who allege the prices are rising at the expense of patients' health.

The Eli Lilly did not make anyone available for an interview for this story. But a company spokesman noted in an email that high-deductible health insurance plans — like the one Alec found — are exposing more patients to higher prices. In August, Eli

Lilly opened a help line that patients can call for assistance in finding discounted or even free insulin.

A dangerous solution

Rationing insulin, as Nicole Smith-Holt's son Alec did, is a dangerous solution. Still, 1 in 4 people with diabetes admits to having done it. I've done it. Actually, there's a lot of Alec's story that feels familiar to me.

We were both born and raised in the Midwest, just two states apart. We were both diagnosed at age 23 — pretty old to develop a condition that used to be called "juvenile diabetes." I even used to use the same sort of insulin pens that Alec was using when he died. They're more expensive, but they make management a lot easier.

"My story is not so different from what I hear from other families," Smith-Holt recently told a panel of U.S. Senate Democrats in Washington D.C., in a hearing on the high price of prescription drugs.

"Young adults are dropping out of college," she told the lawmakers. "They're getting married just to have insurance or not getting married to the love of their lives because they'll lose their state-funded insurance."

I can relate to that, too. My fiancé moved to a different state recently, and soon I'll be joining her. I'll be freelancing and won't have health benefits, though she will via her job. We're getting married — one year before our actual wedding — so I can get insured, too.

This story is part of NPR's reporting partnership with Side Effects Public Media and Kaiser Health News. A version of this story appears in The Workaround podcast.

prescription drug insulin type 1 diabetes drug prices' diabetes

More Stories From NPR

YOUR HEALTH

Can't Get Comfortable In Your Chair? Here's What You Can Do

American Diabetes Association®

Kidney Disease (Nephropathy)

Kidneys are remarkable organs. Inside them are millions of tiny blood vessels that act as filters. Their job is to remove waste products from the blood.

Sometimes this filtering system breaks down. Diabetes can damage the kidneys and cause them to fail. Failing kidneys lose their ability to filter out waste products, resulting in kidney disease.

How Does Diabetes Cause Kidney Disease?

When our bodies digest the protein we eat, the process creates waste products. In the kidneys, millions of tiny blood vessels (capillaries) with even tinier holes in them act as filters. As blood flows through the blood vessels, small molecules such as waste products squeeze through the holes. These waste products become part of the urine. Useful substances, such as protein and red blood cells, are too big to pass through the holes in the filter and stay in the blood.

Diabetes can damage this system. High levels of blood glucose make the kidneys filter too much blood. All this extra work is hard on the filters. After many years, they start to leak and useful protein is lost in the urine. Having small amounts of protein in the urine is called microalbuminuria.

When kidney disease is diagnosed early, during microalbuminuria, several treatments may keep kidney disease from getting worse. Having larger amounts of protein in the urine is called macroalbuminuria. When kidney disease is caught later during macroalbuminuria, end-stage renal disease, or ESRD, usually follows.

In time, the stress of overwork causes the kidneys to lose their filtering ability. Waste products then start to build up in the blood. Finally, the kidneys fail. This failure, ESRD, is very serious. A person with ESRD needs to have a kidney transplant or to have the blood filtered by machine (dialysis).

Who Gets Kidney Disease?

Not everyone with diabetes develops kidney disease. Factors that can influence kidney disease development include genetics, blood glucose control, and blood pressure.

The better a person keeps diabetes and blood pressure under control, the lower the chance of getting kidney disease.

What are the Symptoms?

The kidneys work hard to make up for the failing capillaries so kidney disease produces no symptoms until almost all function is gone. Also, the symptoms of kidney disease are not specific. The first symptom of kidney disease is often fluid buildup. Other symptoms of kidney disease include loss of sleep, poor appetite, upset stomach, weakness, and difficulty concentrating.

It is vital to see a doctor regularly. The doctor can check blood pressure, urine (for protein), blood (for waste products), and organs for other complications of diabetes.

How Can I Prevent It?

Diabetic kidney disease can be prevented by keeping blood glucose in your target range. Research has shown that tight blood glucose control reduces the risk of microalbuminuria by one third. In people who already had microalbuminuria, the risk of progressing to macroalbuminuria was cut in half. Other studies have suggested that tight control can reverse microalbuminuria.

Treatments for Kidney Disease

Self-care

Important treatments for kidney disease are tight control of blood glucose and blood pressure. Blood pressure has a dramatic effect on the rate at which the disease progresses. Even a mild rise in blood pressure can quickly make kidney disease worsen. Four ways to lower your blood pressure are losing weight, eating less salt, avoiding alcohol and tobacco, and getting regular exercise.

Drugs

When these methods fail, certain medicines may be able to lower blood pressure. There are several kinds of blood pressure drugs, however, not all are equally good for people with diabetes. Some raise blood glucose levels or mask some of the symptoms of low blood glucose. Doctors usually prefer people with diabetes to take blood pressure drugs called ACE inhibitors.

ACE inhibitors are recommended for most people with diabetes, high blood pressure and kidney disease. Recent studies suggest that ACE inhibitors, which include captopril and enalapril, slow kidney disease in addition to lowering blood pressure. In fact, these drugs are helpful even in people who do not have high blood pressure.

Diet

Another treatment some doctors use with macroalbuminuria is a low-protein diet. Protein seems to increase how hard the kidneys must work. A low-protein diet can decrease protein loss in the

urine and increase protein levels in the blood. Never start a low-protein diet without talking to your health care team.

Kidney Failure

Once kidneys fail, dialysis is necessary. The person must choose whether to continue with dialysis or to get a kidney transplant. This choice should be made as a team effort. The team should include the doctor and diabetes educator, a nephrologist (kidney doctor), a kidney transplant surgeon, a social worker, and a psychologist.

Read more about dialysis and transplantation (http://www.diabetes.org/living-with-diabetes/treatment-and-care/transplantation/) .

Last Reviewed: August 21, 2013
Last Edited: February 9, 2017

Articles from *Diabetes Forecast® magazine: (http://www.diabetesforecast.org)*

(http://www.diabetes.org/in-my-community/become-a-member/?loc=articles)
Your Kidneys and Your Health (http://www.diabetesforecast.org/2018/03-may-jun/your-kidneys-and-your-health.html?loc=morefrom)

Cranberrys Help Cut UTI Risk (http://www.diabetesforecast.org/2018/02-mar-apr/cranberrys-help-cut-uti-risk.html?loc=morefrom)

Belly Fat Raises Your Risk of Diabetic Kidney Disease (http://www.diabetesforecast.org/diabetes-discovery/pi/belly-fat-raises-your-risk-of-diabetic-kidney-disease.html?loc=morefrom)

Jardiance May Slow Kidney Disease Development (http://www.diabetesforecast.org/2016/sep-oct/kidney-care.html?loc=morefrom)

Protect Your Kidneys (http://www.diabetesforecast.org/2016/mar-apr/renal-rules.html?loc=morefrom)

Connect With Us

Register for diabetes news, research and food & fitness tips.

Email

United States

☑ **Yes, I would like to receive e-mail from the American Diabetes Association.**

To identify that you are a real human, please solve below problem:

0 – 10 =

insert answer here

American Diabetes Association
2451 Crystal Drive, Suite 900
Arlington, VA 22202
1-800-DIABETES (800-342-2383)

Exhibit D

Melrose Village Dialysis 17-029 5 mile radius