



STATE OF ILLINOIS

HEALTH FACILITIES AND SERVICES REVIEW BOARD

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DOCKET NO: H-01	BOARD MEETING: April 17, 2018	PROJECT NO: 17-043	PROJECT COST:
FACILITY NAME: Romeoville Dialysis		CITY: Romeoville	Original: \$4,115,927
TYPE OF PROJECT: Substantive			HSA: IX

PROJECT DESCRIPTION: The Applicants (DaVita Inc. and Tovell Dialysis, LLC d/b/a Romeoville Dialysis) propose to establish a twelve station (12) ESRD facility in 7,000 GSF of leased space located at 480-490 North Independence Boulevard, Romeoville, Illinois. The cost of the project is \$4,115,927 and the completion date is November 30, 2019.

EXECUTIVE SUMMARY

PROJECT DESCRIPTION:

- The Applicants (DaVita Inc. and Tovell Dialysis, LLC) propose to establish a twelve station (12) ESRD facility in 7,000 GSF of leased space located at 480-490 North Independence Boulevard, Romeoville, Illinois. The cost of the project is \$4,115,927 and the completion date is November 30, 2019.
- This project was deferred from the January 2018 State Board Meeting and the State Board Staff review was extended to review additional material received February 8, 2018.
- There are two additional projects on the April 17, 2018 State Board Agenda that are located in HSA IX ESRD Planning Area.
 - Project #17-063-DaVita Hickory Creek to establish a 12-station ESRD facility in Joliet
 - Project #17-065-Fresenius Kidney Care New Lenox to establish a 12-station ESRD facility in New Lenox

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]

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 and those comments are provided in Appendix II at the end of this report.

CONCLUSIONS:

- The State Board is estimating **a need for 17 stations in the HSA IX ESRD Planning Area by 2020**. Additionally, the State Board is estimating a growth of 2.9% compounded annually in the population in this ESRD Planning Area for the period 2015 to 2020. For the period 2013 to 2017, growth in the number of dialysis patients has been 5.75% compounded annually in this planning area.
- 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 nineteen (19) facilities within thirty (30) minutes with an average utilization of approximately 66%. Four of the 19 facilities are not operational or are in “ramp-up” phases of operation. For the 15 remaining facilities, the average utilization is approximately 75%.
- There is a surplus of stations in the 30-minute service area as the ratio of stations to population in the 30-minute service area is 1.5 times the number of stations per population in the State of Illinois. In the State of Illinois, there is 1 station per every 2,760 residents. In this 30-minute service area there is 1 station per every 1,719 residents or 1.6 times the number of stations per population in the State of Illinois.
- The Applicants addressed a total of twenty one (21) criteria and have failed to adequately address the following:

Criteria	Reasons for Non-Compliance
77 ILAC 1110.1430(d)(1), (2) and (3) - Unnecessary Duplication of Service, Mal-distribution of Service, Impact on Other Providers	There appears to be a surplus of ESRD stations (mal-distribution) in the 30-minute service area as the ratio of stations to population in this service area is 1 station per every 1,719 residents compared to the State of Illinois ratio of 1 station per every 2,760 residents. Based upon the surplus stations in this 30-minute service area and the nineteen (19) facilities within thirty (30) minutes with an average utilization of approximately 66%, it would appear the proposed facility will result in an unnecessary duplication of service in this 30-minute service area. <i>“The Applicants stated “Hemodialysis use rates have increased substantially in the HSA 9 planning area and more specifically in the area immediately surrounding the proposed site in Romeoville since the last measurement period, 2015. This growth has resulted in a significant change in the need for additional dialysis services from 17 stations to 67 stations in HSA 9. In just the 10 mile driving radius around the proposed Romeoville Dialysis clinic site there are 11 existing or recently approved dialysis facilities. Excluding facilities that were recently approved or in their two year ramp up, average utilization as of December 31, 2017 was 81 %.”</i>

STATE BOARD STAFF REPORT
Project #17-043
Romeoville Dialysis

APPLICATION/CHRONOLOGY/SUMMARY	
Applicants	DaVita Inc. and Tovell Dialysis, LLC d/b/a Romeoville Dialysis
Facility Name	Romeoville Dialysis
Location	480-490 North Independence Boulevard, Romeoville, Illinois
Permit Holder	DaVita Inc. and Tovell Dialysis, LLC
Operating Entity	Tovell Dialysis, LLC
Owner of Site	TD Romeoville, LLC
Description	Establish a twelve (12) station ESRD facility
Total GSF	7,000 GSF
Application Received	August 23, 2017
Application Deemed Complete	August 25, 2017
Review Period Ends	December 23, 2017
Financial Commitment Date	November 30, 2019
Project Completion Date	November 30, 2019
Review Period Extended by the State Board Staff?	Yes
Can the Applicants request a deferral?	No
Expedited Review?	No

I. Project Description

The Applicants (DaVita Inc. and Tovell Dialysis, LLC) are proposing to establish a twelve station (12) ESRD facility in 7,000 GSF of leased space located at 480-490 North Independence Boulevard, Romeoville, Illinois. The cost of the project is \$4,115,927 and the completion date is November 30, 2019.

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 Tovell Dialysis, LLC d/b/a Romeoville Dialysis. DaVita Inc, a Fortune 500 company, is the parent company of Total Renal Care, Inc. and Tovell Dialysis, LLC. DaVita Inc. is a leading provider of kidney care in the United States, delivering dialysis services to patients with chronic kidney failure and end stage renal disease. DaVita serves patients with low incomes, racial and ethnic minorities, women, handicapped persons, elderly, and other underserved persons in its facilities in the State of Illinois.

Tovell Dialysis, LLC d/b/a as Romeoville Dialysis is a Delaware limited liability corporation jointly owned by:

- DaVita, Inc. (51% Indirect)
- Total Renal Care, Inc. (51% Direct),
- DuPage Medical Group, Ltd. (24.5% Direct),
- Nephron Ventures LLC (24.5% Direct).

Financial commitment will occur after permit issuance. This project is a substantive project subject to a Part 1110 and 1120 review.

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

TABLE ONE Current DaVita Projects			
Project Number	Name	Project Type	Completion Date
15-025	South Holland Dialysis	Relocation	04/30/2018
15-048	Park Manor Dialysis	Establishment	02/28/2018
15-049	Huntley Dialysis	Establishment	02/28/2018
15-054	Washington Heights Dialysis	Establishment	03/31/2018
16-015	Forest City Rockford	Establishment	06/30/2018
16-023	Irving Park Dialysis	Establishment	08/31/2018
16-033	Brighton Park Dialysis	Establishment	10/31/2018
16-036	Springfield Central Dialysis	Relocation	03/31/2019
16-037	Foxpoint Dialysis	Establishment	07/31/2018
16-040	Jerseyville Dialysis	Expansion	07/31/2018
16-041	Taylorville Dialysis	Expansion	07/31/2018
16-051	Whiteside Dialysis	Relocation	03/31/2019
17-032	Illini Renal	Relocation/Expansion	05/31/2019

IV. Project Costs and Sources of Funds

The Applicants are funding the project with cash of \$2,212,097 and the FMV of leased space of \$1,903,830. The operating deficit and start-up costs are \$2,511,640. All project costs are classified as clinical.

TABLE TWO			
Project Costs and Sources of Funds			
USE OF FUNDS	Reviewable	Total	% of Total
Modernization Contracts	\$1,354,426	\$1,354,426	32.91%
Contingencies	\$100,000	\$100,000	2.43%
Architectural/Engineering Fees	\$130,500	\$130,500	3.17%
Consulting & Other Fees	\$78,500	\$78,500	1.91%
Movable or Other Equipment (not in construction contracts)	\$548,671	\$548,671	13.33%
Fair Market Value of Leased Space & Equipment	\$1,903,830	\$1,903,830	46.26%
TOTAL USES OF FUNDS	\$4,115,927	\$4,115,927	100.00%
SOURCE OF FUNDS	Reviewable	Total	% of Total
Cash and Securities	\$2,212,097	\$2,212,097	53.74%
Leases (fair market value)	\$1,903,830	\$1,903,830	46.26%
TOTAL SOURCES	\$4,115,927	\$4,115,927	100.00%

V. Health Planning Area

The proposed facility will be located in the HSA IX ESRD Planning Area. The HSA IX ESRD Planning Area includes Kendall, Grundy, Will, and Kankakee counties. As of February 2018 there is a calculated need for 17 ESRD stations in this planning area. There are currently seventeen (17) dialysis facilities in this planning area with 284 ESRD stations. The State Board is estimating a growth of 2.89% compounded annually in the population in this ESRD Planning Area from 2015 to 2020.¹ The State Board reported an increase in the number ESRD patients for the period 2013² thru 2017 of 5.75% compounded annually in this planning area.

¹ Source: 2017 Inventory of Health Care Facilities and Services Need Determinations Other Health Services page A-19.

² Source: 2015 Inventory of Health Care Facilities and Services Need Determination Other Health Services page A-19 and Quarterly Dialysis Report.

TABLE TWO	
Need Methodology HSA IX ESRD Planning Area	
Planning Area Population – 2015	970,600
In Station ESRD patients -2015	1,086
Area Use Rate 2015 ⁽¹⁾	.977
Planning Area Population – 2020 (Est.)	1,111,300
Projected Patients – 2020 ⁽²⁾	1,086
Adjustment	1.33x
Patients Adjusted	1,444
Projected Treatments – 2020 ⁽³⁾	225,323
Existing Stations	284
Stations Needed-2018	301
Number of Stations Needed	17
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

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

- A) A listing of all health care facilities currently owned and/or operated by the applicant in Illinois or elsewhere, including licensing, certification and accreditation identification numbers, as applicable;
- B) A listing of all health care facilities currently owned and/or operated in Illinois, by any corporate officers or directors, LLC members, partners, or owners of at least 5% of the proposed health care facility;
- C) Authorization permitting HFSRB and IDPH access to any documents necessary to verify the information submitted, including, but not limited to: official records of IDPH or other State agencies; the licensing or certification records of other states, when applicable; and the records of nationally recognized accreditation organizations. Failure to provide the authorization shall constitute an abandonment or withdrawal of the application without any further action by HFSRB.
- D) An attestation that the Applicants have not had *adverse action*³ taken against any facility owned or operated that they own.

³ ³ “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)

1. The Applicants have attested that there has been no adverse action taken against any of the facilities owned or operated by DaVita, Inc. and Tovell Dialysis, LLC during the three (3) years prior to filing the application. [Application for Permit page 69-70]
2. The Applicants have authorized the Illinois Health Facilities and Services Review Board and the Illinois Department of Public Health to have access to any documents necessary to verify information submitted in connection to the applicants' certificate of need to establish a twelve-station ESRD facility. The authorization includes, but is not limited to: official records of IDPH or other State agencies; the licensing or certification records of other states, when applicable; and the records of nationally recognized accreditation organizations. [Application for Permit pages 69-70]
3. The site is owned by TD Romeoville LLC and evidence of this can be found at pages 31-41 of the application for permit in the Letter of Intent to lease the property at 480-490 North Independence Boulevard, Romeoville, Illinois.
4. 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 effect in such areas. Such State Agencies shall ensure that proposed development within Special Flood Hazard Areas would meet the requirements of this Order.*
5. 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 the Project, Safety Net Impact, Alternatives

A) Criterion 1110.230 – Purpose of the Project

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

According to the applicants:

“The purpose of the project is to improve access to life sustaining dialysis services to the residents of Romeoville, Illinois, and the surrounding area. There are 19 dialysis facilities within 30 minutes of the proposed Romeoville Dialysis. Excluding recently approved dialysis facilities which are being developed to serve distinct groups of patients, average utilization of area dialysis facilities is 72.8%, or just below the State Board’s utilization standard of 80%. Furthermore, patient census among the existing facilities within the Romeoville Dialysis GSA has increased 6.9% since March 31, 2015. This growth is anticipated to continue to increase for the foreseeable future due to the demographics of the community. Teresa Kravets, M.D., with Northeast Nephrology Consultants, Inc. (NENC), is currently treating 96 late stage CKD patients (Stage4-5), who reside within 30 minutes of the proposed Romeoville Dialysis. Conservatively,

based on attrition due to patient death, transplant, stable disease, or relocation away from the area, and in consideration of other treatment modalities (HHD and peritoneal dialysis), Dr. Kravets anticipates at least 58 of these 96 patients will initiate in-center hemodialysis within 12-24 months following project completion. DuPage Medical Group will also add 12 late-stage CKD patients in support of the application. Conservatively, based on attrition due to patient death, transplant, stable disease, or relocation away from the area and in consideration of other treatment modalities, it is anticipated that 7 of these 12 additional patients will initiate in-center dialysis within 12-24 months following project completion. Thus, a total of 65 patients (58 from NENC, 7 from DMG), will be expected to initiate in-center hemodialysis within 12-24 months following project completion. Based upon historical utilization trends, the existing facilities will not have sufficient capacity to accommodate Dr. Kravet's and DuPage Medical Group's combined projected ESRD patients."

A map of the market area was provided, which encompasses an approximate 30-minute radius around the proposed facility. The boundaries of this market area are identified below.

- 30 minutes north to Villa Park, IL (DuPage County)
- 30 minutes northeast to Lyons, IL (Cook County)
- 30 minutes east to Orland Park (Cook County)
- 30 minutes southeast to Mokena, IL (Will County)
- 30 minutes south to Rockdale, IL (Will County)
- 30 minutes southwest to Minooka, IL (Grundy/Kendall/Will Counties)
- 30 minutes west to Oswego, IL (Kendall County)
- 30 minutes northwest to Naperville, IL (DuPage/Will Counties)

B) Criterion 1110.230 (b) - Safety Impact Statement

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

DaVita 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 number 1 in 3 out of 4 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 90-day catheter rates among large dialysis providers. During 2000-2014, DaVita improved its fistula adoption rate by 103%. Its commitment to improving clinical outcomes directly translated into 7% reduction in hospitalizations among DaVita patients. The proposed Romeoville Dialysis will not impact the ability of other health care providers or health care systems to cross-subsidize safety net services. The utilization of existing dialysis facilities within the Romeoville GSA that have been operational for at least 2 years is 72.8%. Further, patient census among the existing facilities within the Romeoville GSA has increased 6.9% since March 31, 2015. The growth is anticipated to increase for the foreseeable future due to demographics of the community and the U.S. Centers for Disease Control and Prevention that estimates that 15% of American adults suffer from CKD. Further, a total of 65 patients (58 from NENC, 7 for DMG), will be expected to initiate in-center hemodialysis within 12-24 months following project completion. Accordingly, the proposed dialysis facility will not impact other general health care providers' ability to cross-subsidize safety net services.

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

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

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

The Applicants considered three (3) alternatives

A) Reducing the Scope and Size of Current Project

The Applicants considered, but ultimately rejected, an 8-station in-center hemodialysis facility. This was rejected due to the expected utilization, as documented throughout this proposal. The Applicants fully expect the facility to reach the required number of patients for a 12-station facility within two years. In order to establish a facility within the HSA proposed, the facility must not have less than eight stations, pursuant to 77 Ill. Adm. Code § 1110.1430(h). The physician's patient data and referral network exhibits a large number of expected patients from within 30 minutes of the proposed location. As a result of the expected referral numbers, the number of patients would quickly overcome the required utilization levels for an 8-station facility. Although the reduced number of stations would have reduced the size and cost of the proposed project, the Applicants came to the decision that a 12-station facility would ultimately better serve the patient population, as it would allow for the expected growth of patients to benefit from the facility. The alternative plan of only establishing an 8-station facility was therefore rejected by the applicants.

B) Utilize Existing Facilities

There are 19 dialysis facilities within Romeoville GSA. Excluding recently approved dialysis facilities which are being developed to serve distinct groups of patients, average utilization of area dialysis facilities is 72.8%, or just below the State standard of 80%. Furthermore, patient census among the existing facilities within the Romeoville GSA has increased 6.9% since March 31, 2015. This growth is anticipated to continue to increase for the foreseeable future due to the demographics of the community and U.S. Centers for Disease Control and Prevention estimates that 15% of Americans adults suffer CKD. Dr. Teresa Kravets, M.D., with Northeast Nephrology Consultants, Inc., anticipates the referral of at least 58 of her 96 patients currently being treated for CKD. This, combined with 7 estimated referrals from DuPage Medical Group, results in an estimated 65 patients who will be expected to require dialysis treatment within 12-24 months after project completion. Based on these referral data, existing facilities will not have sufficient capacity to accommodate Dr. Kravet's and DuPage Medical Group's combined projected ESRD patients. As a result, the Applicants rejected this option. There is no capital cost with this alternative.

C) Pursue a Joint Venture for the Establishment of a New Facility

DaVita, Inc., DuPage Medical Group, Ltd. and Northeast Nephrology Consultants, Inc., 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 Romeoville Dialysis facility is necessary to address this growth and allow existing facilities to operate at an optimum capacity. Further, without any current partnerships with existing in-center hemodialysis facilities, DaVita is seeking to collaborate with DMG and NENC on the proposed facility in order to increase access to care for individuals with ESRD, and address identified issues with care coordination and physician communication in the treatment of patients with kidney disease. The establishment of a 12-station dialysis facility will improve access to life-sustaining dialysis treatment for those individuals in the Romeoville community who suffer from ESRD. ESRD patients are typically chronically ill individuals and adequate access to dialysis services is essential to their well-being. As a result, the Applicants chose this option. The cost of this alternative is \$4,115,927.

D) Empirical Evidence

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 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 a 7 percent reduction in hospitalizations among DaVita patients, which resulted in more than \$1.5 billion in savings to the health care system and the taxpayer from 2010 -2012. Although not quantifiable by empirical data, the Applicants also anticipate the improvement of patient care and experiences through the development of the joint venture facility. Identified issues anticipated to be addressed include maintaining patients' continuum of care and resolving physician communication and care coordination deficiencies that are barriers to optimal care.

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 that the size of the project is in conformance with State Board Standards published in Part 1110 Appendix B.

The Applicants are proposing a twelve (12) station ESRD facility in 7,000 GSF of clinical space or 583.3 GSF per station. This is within the State Board Standard of 650 GSF per station or a total of 7,800 GSF. The Applicants have successfully addressed this criterion.

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

B) Criterion 1110.234(b) – Projected Utilization

To demonstrate compliance with this criterion the Applicants must document that, by the end of the second year of operation, the annual utilization of the clinical service areas or equipment shall meet

or exceed the utilization standards specified in Part 1110 Appendix B. The number of years projected shall not exceed the number of historical years documented.

The Applicants are projecting sixty-five (65) patients by the second year after project completion.

Sixty-five (65) patients x 156 treatments per year = 10,140 treatments

Twelve (12) stations x 936 treatments available = 11,232 treatments

10,140 treatments/11,232 treatments = 90.2% ⁴

The Applicants have successfully addressed this criterion.

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

C) Criterion 1110.234 (e) - Assurances

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

The necessary attestation is provided at pages 121-122 of the application for permit.

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

IX. In-Center Hemodialysis Projects

A) Criterion 1110.1430(c) - Planning Area Need

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

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

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

There is a calculated need for 17 additional ESRD stations in the HSA IX ESRD Planning Area per the February, 2018 Revised Station Need Determination.

The Applicants provided additional information on February 8, 2018 stating that end-stage renal disease (ESRD) clinic utilization data demonstrates a growth trend in ESRD incidence and prevalence in Romeoville and the area immediately surrounding it and provides more detailed demographic data for the area which helps illustrate why the Romeoville location in Will County was selected for a new clinic site.

⁴ Assumes the proposed facility will operate six (6) days a week fifty-two (52) weeks a year three (3) shifts a day.

The Applicants stated that HSA IX ESRD Planning Area (Kendall, Grundy, Will, and Kankakee County) population has grown by 12.2% from 2013-2018 and the over 65-population has grown by 33.6% for this same time period. The Will County Population (the location of the proposed Romeoville facility) has grown by 12.9% over the same period (2013-2018) and the over age 65 populations by 34.3%. The patient count for the facilities within the patient service area has increased by 9 percent or from 395 patients to 431 since the September 30, 2017 through December 31, 2017. Annualized, this figure represents a 36% increase in patients.

2) Service to Planning Area Residents

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

The primary purpose of the proposed project is to maintain access to life-sustaining dialysis services to the residents of Romeoville, Illinois and the surrounding communities. As evidenced in the physician referral letters, a combined total of one hundred-eight (108) late-stage pre-ESRD patients reside within 30 minutes of the proposed facility. The Applicants are projecting sixty-five (65) patients by the second year after project completion. The sixty-five patients will come from the zip codes identified below. It would appear that the proposed facility will provide dialysis services to the residents of the planning area.

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

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

The Applicants have submitted two (2) referral letters, predicting that 108 patients from the service area will require dialysis services within 2 years of project completion (application for permit, pg. 82). Conservative estimates (based on attrition) has the number of referrals at sixty-five (65) patients requiring dialysis by the second year after project completion.

Zip Code	City	County	Patient #
60446	Romeoville	Will	8
60403	Crest Hill	Will	14
60490	Bolingbrook	Will	6
60544	Plainfield	Will	2
60435	Joliet	Will	15
60441	Lockport	Will	21
60439	Lemont	Cook	7
60586	Plainfield	Will	8
60431	Joliet	Will	4
60432	Joliet	Will	11
60491	Homer Glen	Will	2
60404	Shorewood	Will	10
Total			108

The Applicants provided the necessary information at page 82 of the application for permit. From the referral letter it appears that there is sufficient demand (patient population) to justify the proposed number of stations (12) being requested by this application for permit.

5) Service Accessibility

To demonstrate compliance with this sub-criterion the Applicants must document that the number of stations being established or added for the subject category of service is necessary to improve access for planning area residents. The applicant must document one of the following:

- i) The absence of the proposed service within the planning area;
 - ii) Access limitations due to payor status of patients, including, but not limited to, individuals with health care coverage through Medicare, Medicaid, managed care or charity care;
 - iii) Restrictive admission policies of existing providers;
 - iv) The area population and existing care system exhibit indicators of medical care problems, such as an average family income level below the State average poverty level, high infant mortality, or designation by the Secretary of Health and Human Services as a Health Professional Shortage Area, a Medically Underserved Area, or a Medically Underserved Population;
 - iv) For purposes of this subsection (c)(5) only, all services within the 30-minute normal travel time meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100.
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- 1. There are a total of seventeen (17) dialysis facilities in the HSA IX ESRD Planning Area.
 - 2. There has been no evidence of the access limitations due to payor status of patients.
 - 3. There has been no evidence of restrictive admission policies of existing providers.
 - 4. There are nineteen (19) facilities within thirty (30) minutes with an average utilization of approximately 66%. Four of the nineteen (19) facilities are not operational or are in “ramp-up” stage. For the 15 remaining facilities the average utilization is approximately 75%. Six of the 19 facilities (32%), are operating in excess of the State Board standard (80%). [See Table Below]

The State Board has estimated a need for 17 additional ESRD stations in the planning area by CY 2020 based upon the estimated population and the historical usage rate in the planning area. Based upon the State Board calculated station need the Applicants have successfully addressed this criterion.

TABLE FOUR
Facilities within 30 minutes of the Proposed Project

Name	City	HSA	Stations	Adjusted Time ⁽¹⁾	Utilization ⁽²⁾	Star Rating ⁽³⁾	Meets Standard?
USRC Bolingbrook Dialysis	Bolingbrook	9	13	8.05	80.77%	2	Yes
FMC Bolingbrook Dialysis	Bolingbrook	9	24	11.5	85.42%	4	Yes
FMC Naperville	Naperville	9	18	18.4	70.14%	5	No
FMC Joliet	Joliet	9	16	19.5	70.80%	3	No
FMC Willowbrook	Willowbrook	7	20	19.5	62.50%	3	No
DaVita Renal Center New Lenox	New Lenox	9	19	20.7	93.86%	3	Yes
DaVita Renal Center West Joliet	Joliet	9	29	20.7	74.71%	4	No
FMC Plainfield	Plainfield	9	10	21.8	83.33%	5	Yes
USRC Oak Brook	Downers Grove	7	13	23	84.62%	2	Yes
FMC Downers Grove	Downers Grove	7	16	25.3	70.83%	3	No
FMC Dialysis Center Orland Park	Orland Park	7	18	26.4	60.19%	4	No
Davita Sun Health Joliet	Joliet	9	17	26.4	59.80%	5	No
Fox Valley Dialysis Center	Aurora	8	29	28.7	82.18%	5	Yes
DaVita Palos Park Dialysis	Orland Park	7	12	28.7	68.06%	2	No
FMC Mokena	Mokena	9	14	29.9	65.48%	3	No
Total Stations/Average Utilization			268		74.18%		
FMC Lemont (Completion 05/2016)	Lemont	7	12	11.5	34.72%	N/A	N/A
FMC Woodridge (Completion 03/2019)	Woodridge	7	12	16.1	0.00%	N/A	N/A
FMC Plainfield North (Completion 11/2016)	Plainfield	9	10	20.7	55.00%	3	N/A
FMC Summit (Completion 11/2016)	Summit	7	12	28.75	41.67%	NA	N/A
Total Stations/Average Utilization			314		65.48%		

1. Adjusted time taken from Map Quest and adjusted per 77 ILAC 1100.510 (d)

2. Information as of December 31, 2017

3. Star Rating taken from Medicare Compare Website. An explanation of the Star Rating can be found at Appendix I at the end of this report.

4. NA – Not Available

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION PLANNING AREA NEEDS (77 ILAC 1110.1430(c) (1), (2), (3) and (5).

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

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

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

1. To determine if there is an unnecessary duplication of service the State Board identifies all facilities within thirty (30) minutes and ascertains if there is existing capacity to accommodate the demand identified in the application for permit. There are nineteen (19) facilities within thirty (30) minutes with an average utilization of approximately 66%. Four of the nineteen (19) facilities are not operational, or are in ramp-up phase. The fifteen remaining facilities the average utilization is approximately 75%. [See Table Above]
2. To determine a mal-distribution (i.e. surplus) of stations in the thirty (30) minute service area the State Board compares the ratio of the number of stations per population in the thirty (30) minute service area to the ratio of the number of stations in the State of Illinois to the population in the State of Illinois. To determine a surplus of stations the number of stations per resident in the thirty (30) minute service area must be 1.5 times the number of stations per resident in the State of Illinois.

	Population	Stations	Ratio
30 Minute Service Area	539,704	314	1 Station per every 1,719 residents
State of Illinois (2015 est.)	12,978,800	4,704	1 Station per every 2,760 residents

The population in the thirty (30) minute service area is 539,704 residents. The number of stations in the (30) minute service area is 314 stations. The ratio of stations to population is one (1) station per every 1,719 residents.

The number of stations in the State of Illinois is 4,704 stations (*as of February 2018*). The 2015 estimated population in the State of Illinois is 12, 978,800 residents (*Illinois Department of Public Health Office of Health Informatics Illinois Center for Health Statistics -2014 Edition*). The ratio of stations to population in the State of Illinois is one (1) station per every 2,760 residents. To have a surplus of stations in this thirty (30) minute service area the number of stations per population would need to be one (1) station per every 1, 840 residents. Based upon this methodology there is a surplus of stations in this service area.

3. The Applicants stated the following regarding the impact on other facilities.
The proposed dialysis facility will not have an adverse impact on existing facilities in the Romeoville GSA. Based on March 2017 data from the Renal Network, 672 ESRD patients live within 30 minutes of the proposed facility. Excluding recently approved dialysis facilities which are being developed to serve distinct groups of patients, average utilization of area dialysis facilities is 72.8%, or just below the State standard of 80%. 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 Romeoville Dialysis facility will not lower the utilization of area providers below the occupancy standards. Further, the three in-center hemodialysis facilities approved by the State Board within the last few years are either in development (FMC Woodridge), or operational less than two years (FMC Plainfield North, FMC Summit). Each facility will serve a distinct patient base within the greater southwest suburban area. As stated in the physician referral letters for these facilities, each physician projects to refer a sufficient number of patients to achieve 80% utilization by the second year after project completion.

There appears to be a surplus of stations in this 30-minute service area and there are currently underutilized facilities in the service area that could accommodate referral population contained in this application.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT NOT IN CONFORMANCE WITH CRITERION UNNECESSARY DUPLICATION OF SERVICE, MALDISTRIBUTION OF SERVICE IMPACT ON OTHER FACILITIES (77 ILAC 1110.1430(d)(1), (2) and (3))

C) Criterion 1110.1430(f) - Staffing

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

The proposed facility will be staffed in accordance with all State and Medicare staffing requirements. The Medical Director will be Dr. Teresa Kravets, M.D. A copy of Dr. Kravets's curriculum vitae has been provided as required. Other Clinical Staff: Initial staffing for the proposed facility will be as follows:

- Administrator (1.04 FTE)
- Registered Nurse (4.53 FTE)
- Patient Care Technician (4.54 FTE)
- Biomedical Technician (0.29 FTE)
- Social Worker (licensed MSW) (0.57 FTE)
- Registered Dietitian (0.58 FTE)
- Administrative Assistant (0.84 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, ARF/CRF, uremia, osteodystrophy and anemia, principles of dialysis; components of hemodialysis system; water treatment; dialyzer reprocessing; hemodialysis treatment; fluid management; nutrition; laboratory; adequacy; pharmacology; patient education, and service excellence. A summary of the training

program has been provided. Romeoville Dialysis will maintain an open medical staff.

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

D) Criterion 1110.1430(g) - Support Services

To demonstrate compliance with this criterion the Applicants must submit a certification from an authorized representative that attests to each of the following:

- 1) Participation in a dialysis data system;
- 2) Availability of support services consisting of clinical laboratory service, blood bank, nutrition, rehabilitation, psychiatric and social services; and
- 3) Provision of training for self-care dialysis, self-care instruction, home and home-assisted dialysis, and home training provided at the proposed facility, or the existence of a signed, written agreement for provision of these services with another facility.

The Applicants have provided the necessary attestation as required at pages 107-108 of the application for permit.

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

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

To demonstrate compliance with this criterion the Applicants must document that the minimum number of in-center hemodialysis stations for an End Stage Renal Disease (ESRD) facility is:

- 1) Four dialysis stations for facilities outside an MSA;
- 2) Eight dialysis stations for a facility within an MSA.

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

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

F) Criterion 1110.1430(i) - Continuity of Care

To demonstrate compliance with this criterion the Applicants document that a signed, written affiliation agreement or arrangement is in effect for the provision of inpatient care and other hospital services. Documentation shall consist of copies of all such agreements.

The Applicants provided the necessary signed affiliation agreement with Silver Cross Hospital, New Lenox, as required at pages 109-120 of the application for permit.

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

G) Criterion 1110.1430(k) - Assurances

To demonstrate compliance with this criterion the representative who signs the CON application shall submit a signed and dated statement attesting to the applicant's understanding that:

- 1) By the second year of operation after the project completion, the applicant will achieve and maintain the utilization standards specified in 77 Ill. Adm. Code 1100 for each category of service involved in the proposal; and
- 2) An applicant proposing to expand or relocate in-center hemodialysis stations will achieve and maintain compliance with the following adequacy of hemodialysis outcome measures for the latest 12-month period for which data are available:
 $\geq 85\%$ of hemodialysis patient population achieves urea reduction ratio (URR) $\geq 65\%$
 and $\geq 85\%$ of hemodialysis patient population achieves Kt/V Daugirdas II 1.2.

The necessary attestation has been provided at pages 121-122 of the application for permit.

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

IX. Financial Viability

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

A) **Criterion 1120.120 – Availability of Funds**

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

The Applicants are funding this project with cash in the amount of \$2,212,097 and a lease with a FMV of \$1,903,830. 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	2015
Cash	\$508,234	\$674,776	\$1,499,116
Current Assets	\$8,744,358	\$3,994,748	\$4,503,280
Total Assets	\$18,948,193	\$18,755,776	\$18,514,875
Current Liabilities	\$3,041,177	\$2,710,964	\$2,399,138
LTD	\$9,158,018	\$8,944,676	\$9,001,308
Patient Service Revenue	\$9,608,272	\$9,269,052	\$9,480,279
Total Net Revenues	\$10,876,634	\$10,707,467	\$13,781,837
Total Operating Expenses	\$9,063,879	\$8,677,757	\$12,611,142
Operating Income	\$1,812,755	\$2,029,710	\$1,170,695
Net Income	\$830,555	\$1,033,082	\$427,440

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 \$2,212,097 and a lease with a FMV of \$1,903,830. The Applicants have qualified for the financial waiver.

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

X. 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 \$2,212,097 and a lease with a FMV of \$1,903,830. The lease is for fifteen (15) years at a base rent of \$29.50/gsf for the first five (5) years, with a ten percent (10%) increase every five (5) years. It appears the lease is reasonable when compared to previously approved projects.

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

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

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

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

New Construction and Contingencies Costs are \$1,454,426 or \$207.77 per GSF for 7,000 GSF of clinical space. This appears reasonable when compared to the State Board Standard of \$278.19 per GSF, with 2018 listed as mid-point of construction.

Contingencies – These costs total \$100,000 and are 7.3% of the new construction costs identified for this project. This is in compliance with the State standard of 10%.

Architectural/Engineering Fees are \$130,500 and are 8.9% of new construction and contingencies. This appears reasonable when compared to the State Board Standard of 6.64% to 9.98%.

Consulting and Other Fees are \$78,500. The State Board does not have a standard for these costs.

Movable or Other Equipment – These costs are \$548,671 or \$45,722 per station (12 stations). This appears reasonable when compared to the State Board Standard of \$53,682 per station.

Fair Market Value of Leased Space and Equipment – These costs are \$1,903,830. The State Board does not have a standard for these costs.

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

D) Criterion 1120.140(d) – Projected Operating Costs

To demonstrate compliance with this criterion the Applicants must document 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 \$247.70 operating expense per treatment.

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

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

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

The Applicants are projecting capital costs of \$19.20 per treatment.

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

Appendix I

Star Rating System

Centers for Medicare & Medicaid Services (CMS) Star Ratings

“The star ratings are part of Medicare’s efforts to make data on dialysis centers easier to understand and use. The star ratings show whether your dialysis center provides quality dialysis care - that is, care known to get the best results for most dialysis patients. The rating ranges from 1 to 5 stars. A facility with a 5-star rating has quality of care that is considered ‘much above average’ compared to other dialysis facilities. A 1- or 2- star rating does not mean that you will receive poor care from a facility. It only indicates that measured outcomes were below average compared to those for other facilities. Star ratings on Dialysis Facility Compare are updated annually to align with the annual updates of the standardized measures.”

CMS assigns a one to five ‘star rating’ in two separate categories: best treatment practices and hospitalizations and deaths. The more stars, the better the rating. Below is a summary of the data within the two categories.

➤ Best Treatment Practices

This is a measure of the facility’s treatment practices in the areas of anemia management; dialysis adequacy, vascular access, and mineral & bone disorder. This category reviews both adult and child dialysis patients.

➤ Hospitalization and Deaths

This measure takes a facility's expected total number of hospital admissions and compares it to the actual total number of hospital admissions among its Medicare dialysis patients. It also takes a facility's expected patient death ratio and compares it to the actual patient death ratio taking into consideration the patient’s age, race, sex, diabetes, years on dialysis, and any co-morbidities.

The Dialysis Facility Compare website currently reports on 9 measures of quality of care for facilities. These measures are used to develop the star rating. Based on the star rating in each of the two categories, CMS then compiles an ‘overall rating’ for the facility. As with the separate categories: the more stars, the better the rating.

Appendix II

Support and Opposition Comments

Northeast Nephrology Consultants stated in support

“I am writing to express support of the Certificate of Need request for the development of new In-Center Hemodialysis facility located at 480 - 490 North Independence Boulevard, Romeoville, Illinois 60446 to provide life-sustaining dialysis treatment, education, and support for patients with kidney disease. I am a physician that is board certified in Nephrology and currently practicing within the market area for this facility. As related within the application, there is an identified need for additional dialysis stations to serve an identified patient population. In-center hemodialysis care is a burdensome and time intensive process for patients. Through this facility, we can transform the lives of patients and their families by having more options in their dialysis care providers, locations, and treatment times. As you know, it is not a simple matter of having one time slot available for a patient, as patients often cannot receive dialysis at the times dictated by limited facility openings. The utilization rate of area facilities is over 72% and it is projected to continue increasing on an annual basis. This will lead to even more competition for dialysis stations by patients and complicate their already difficult lives. Ensuring patients have practical access to dialysis care is a mission we all have a responsibility to support within the community. In partnership with DaVita, DuPage Medical Group, and other minority investors, we can bring high- quality, integrated, and necessary care to the Romeoville and surrounding community. By leveraging the latest technology and care platforms, we will be offering patient-centered care on the forefront of dialysis care. With well-resourced partners, a local focus, and a care model seeking coordination across the metropolitan area, the proposed facility will be a positive step for patients suffering from renal disease and the providers that care for them. For these reasons, I ask that the Illinois Health Facilities & Services Review Board approve the dialysis facility application for the proposed Romeoville Dialysis facility.”

Troutman & Dams LLC stated in support

“We offer our enthusiastic support for the DaVita Dialysis Project. Our firm, Troutman & Dams, has been working closely with the Village of Romeoville in the development of the Village's "Uptown" area. We have similarly worked with DaVita in finding a location for its facility that will be accessible and convenient for its patients. In working with DaVita we have come to understand that most dialysis patients receive treatment three times each week. This means traveling to the facility over 150 times per year. Obviously, access to transportation becomes very important to DaVita and its patients. What is particularly attractive about this site is the abundant availability of multiple modes of convenient transportation. The proposed facility is located on Illinois Route 53. For patients who drive, this major highway is the primary north/south route serving this area. The route links Joliet with Downers Grove, and communities in between such as Lockport, Romeoville and Bolingbrook. The proposed site will have ample free parking for patients. For those patients using mass transit, there is a Pace bus stop located only 900 feet from the DaVita site and accessed with a new 8 foot wide sidewalk. Metra has also recently opened a new station within one mile that can similarly serve this area. The site is also easily accessible through the Village's very affordable "Ride Around Town" program for residents. For those patients who desire, the facility is also located directly on a wide bike path that would go right past the DaVita door.”

Appendix II

Support and Opposition Comments

Presence Saint Joseph Medical Center stated in support

“Presence Saint Joseph Medical Center has proudly served Romeoville and the southern suburbs area for over 100 years. The Romeoville community has grown significantly in recent years. Unfortunately, the percentage of people with chronic kidney disease is also rising. The population growth combined with the increased incident in kidney disease is creating greater need for dialysis services in the area. We are seeing an increased number of patients with kidney disease in our hospital as almost 15% of American adults suffer chronic kidney disease (CKD). We are fortunate to collaborate with many excellent nephrologists on our staff in caring for our patients with kidney disease. We are pleased that Dr. Teresa Kravets, the medical director of the proposed DaVita Romeoville facility, and many of the other nephrologists involved are members of our medical staff. We would value continuing to work with them in this new facility. An optimal care plan for patients with CKD includes strategies to slow the loss of kidney function, manage comorbidities, 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 end-stage renal disease (ESRD) by multidisciplinary teams leads to improved disease management and care, mitigating the risk of disease advancement and patient mortality. We believe we can work well with Dr. Kravets and DaVita in caring for their patients with kidney disease, and we support the Review Board's approval of DaVita Romeoville ESRD facility.”

Nephrology Associates of Northern Illinois, LTD stated in opposition

“Never in this history of the planning board have so many unnecessary dialysis stations been approved for a single operator in a defined geographic at one time. At the January Board meeting the Board will consider two applications by the Applicants for the first time, and will consider four other applications which already received an Intent to Deny. However, all of the applications have three things in common: (1) the lack of referral letters to justify the patient population for the facilities; (2) overlapping service areas; and (3) emphasis on market share instead of patient care. It is inexplicable that the Applicants would provide no new information to the Board regarding projects: #17-014 Rutgers Park Dialysis, #17-15 Stone Quarry, and #17-06 Salt Creek Dialysis. There are still substantial deficiencies that remain as evidenced by this letter and the staff report released for the November Board meeting and that justified the indent-to-deny that the applications received. Further, applications for project #17-029 Melrose Village Dialysis and 17-043 DaVita Romeoville Dialysis have identical deficiencies and introduce even more new problems that Board members cannot overlook. As simply as can be put - approving these projects would adversely alter the healthcare delivery system in this HSA in a way that is entirely inconsistent with the HFSRB at its rules. In an effort to help Board members visualize the issue with the applicant's proposal for 72 stations, we have created a map (Attachment A) which plots out each of the proposed facilities and creates a circle around a 10-mile service area per the Board's rule (77 Ill. Admin. 1110.1430.). This picture certainly is worth 1,000 words. You can clearly see how each of the proposed facility service areas completely overlaps with one another. There is only one way an applicant could explain this sort of unnecessary duplication of services. An applicant would have to be able to identify patients to fill these stations. But the Applicants cannot do that and have refused to comply with the Board's rules.

The applicant's referral letter included in these applications and referenced in the SBSR by the applicant's own admission do **not** meet HFSRB standards and serve as an indictment of the applicant's disregard for the HFSRB planning process. The HFSRB has in its possession six copies of the exact same letter (with the date changed on each), that word for word regurgitates the same flawed understanding the HFSRB planning process. It would alter longstanding practice to require referrals sufficient to justify a project - and even more so the express prohibition of utilizing the same patients to justify multiple projects. It is not

Appendix II

Support and Opposition Comments

clear how these "referrals" were accepted by Board staff- but they certainly should not be accepted by this Board. There have been instances in the past when the HFSRB has approved applications for new dialysis facilities with negative findings in an application. In many of those instances the applicant provided context for why they received a negative finding. After several public commenters's noted this important issue for the Board at the September Meeting, the Applicants responded to the elephant in the room but in the process only obfuscated the truth. The applicant's only explanation was that they expected to fill the facilities with "DMG patients and they are not patients of other providers at this time." With this one statement the Applicants managed to not only admit their inability to identify patients for these facilities but they also neglected to mention that some of the "DMG patients" are already seen by other area nephrologists, and those same patients receive dialysis treatments at facilities with excess capacity. The applicant's "innovative" approach for these stations is to plant a flags and siphon patients from existing providers. If you approve it, we will build it, and they will come is not innovative and certainly is not responsible health planning. This will undoubtedly put great strain on other area providers who currently have excess capacity in HSA 7, and undermine the cost savings achieved through the area's End Stage Renal Disease (ESRD) Seamless Care Organization (ESCO). This planning process is designed to protect against the very ill-conceived market saturation that the Applicants propose. A more practicable approach would be for the Applicants to withdraw their applications and assess where there is a true need in the HSA and then submit only necessary applications to this Board. For these reasons, we pray the HFSRB continue to deny these applications and allow for more organized development of ESRD services within these communities."

Juan Morado, Jr. Benesch, Friedlander, Coplan & Aronoff, LLP stated in part

The applicant's project reflects the continuation of a poorly planned hostile take-over of dialysis care in Illinois. This duo of Applicants has filed eight applications proposing to establish ESRD services in a Health Service Area already served by an abundance of providers. This signifies an all-out assault which would undermine the Board's mission with regards to health planning in our state. The reason for this is that these applications do not reflect a desire to serve patients that are without access to care, but rather to manipulate the service of those patients from quality existing providers to serve the financial needs of the applicants. This is exactly what the Certificate of Need program was designed to prevent. This application will greatly undermine the cost savings achieved by the nation's first ESRD Seamless Care Organization ("ESCO"), and the quality of patient care by oversaturating a planning area where the average utilization rate is a meager 67%. This project was originally slated for consideration by the Board at your January 2018 meeting, but was deferred by the Applicants in an effort to delay what would have surely been an intent-to-deny by this Board. As you may recall during the January 2018 meeting, this Board was provided with a full and honest assessment of the applicant's quest to increase their market share. We would ask that the abundance of public comment, both in written form and in oral testimony before the Board, be incorporated by reference into this application file. This application would contribute to the unnecessary duplication of service and have a severe impact on other providers in violation of ILL. Admin. Code 1110.1430(d) (1) (3). You have heard the testimony from several of them. The greatest indication of this imbalance is evidenced by reviewing the utilization rate of other area facilities.

- There are nineteen (19) facilities in the planning area and only 30% or six (6) of those facilities are at the state's target utilization rate.
- Four (4) of the nineteen (19) area facilities are still ramping up, and have only been in service for a couple of months.

Appendix II Support and Opposition Comments

When taking a comprehensive review of the planning area where this project is proposed, it is clear that there are simply not enough patients to fill the existing stations in the planning area. The only way this project will succeed is to syphon patients from existing providers to the benefit of the applicants. Nothing exhibits this better than the fact that these Applicants had patients testify to support related projects, and the only available patients were those already being provided with care by those existing providers who are opposing these projects. The applicant's also continue use the same stale "referral" letter for several projects that was submitted to support their other projects. This letter cites unidentified patients from the same zip code multiple times- in a clear violation of Board rules that prohibit the same referral to support multiple projects. This project proposes to serve patients in the same overlapping geographic area that the applicant's five (5) other projects propose to serve. The Applicants have already admitted before the Board that they do not know where their patients will come from and they are asking the Board to abandon rational health planning in favor of an "if you build it they will come" mentality. This was not enough for the Board members to approve the applicant's project in September, it wasn't enough in January, and it should certainly not be enough in February. As noted above, this application is part of a larger bundle of applications filed by the applicant, to have this Board approve the largest number of dialysis stations at one time to a single provider in Illinois CON history. There is something wrong with these proposals and the applicant knows it. The five (5) other applications were deferred again by the Applicants to the April 2018 agenda in a pointless attempt to delay their inevitable final denial by this Board. Nothing has changed since this application was last slated to be considered by the Board. The obvious is still true. There is **NO** need for these stations in HSA 9. It is not problematic for these Applicants to repeatedly come before this Board to propose ESRD facilities, because they do not have ESRD patients they are busy caring for. The providers opposing these projects do have to care for such patients. The fact that the dozens of people previously opposing these projects may not make every meeting to which these projects are strategically deferred should not undermine the opposition, its validity, and the prior denials of these projects. For these reasons, we pray that the Board continue to deny this application and allow for a more organized development of ESRD services within this community.

- There are nineteen (19) facilities in the planning area and only 30% or six (6) of those facilities are at the state's target utilization rate.
- Four (4) of the nineteen (19) area facilities are still ramping up, and have only been in service for a couple of months.

When taking a comprehensive review of the planning area where this project is proposed, it is clear that there are simply not enough patients to fill the existing stations in the planning area. The only way this project will succeed is to syphon patients from existing providers to the benefit of the applicants. Nothing exhibits this better than the fact that these Applicants had patients testify to support related projects, and the only available patients were those already being provided with care by those existing providers who are opposing these projects. The applicant's also continue use the same stale "referral" letter for several projects that was submitted to support their other projects. This letter cites unidentified patients from the same zip code multiple times- in a clear violation of Board rules that prohibit the same referral to support multiple projects. This project proposes to serve patients in the same overlapping geographic area that the applicant's five (5) other projects propose to serve. The Applicants have already admitted before the Board that they do not

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Support and Opposition Comments

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Section XI, Safety Net Impact Statement

1. 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.

DaVita accepts and dialyzes patients with renal failure needing a regular course of hemodialysis without regard to race, color, national origin, gender, sexual orientation, age, religion, disability or ability to pay. Because of the life sustaining nature of dialysis, federal government guidelines define renal failure as a condition that qualifies an individual for Medicare benefits eligibility regardless of their age and subject to having met certain minimum eligibility requirements including having earned the necessary number of work credits. Indigent ESRD patients who are not eligible for Medicare and who are not covered by commercial insurance are eligible for Medicaid benefits. If there are gaps in coverage under these programs during coordination of benefits periods or prior to having qualified for program benefits, grants are available to these patients from both the American Kidney Foundation and the National Kidney Foundation. If none of these reimbursement mechanisms are available, financially needy patients may qualify for assistance from DaVita in the form of free care.

2. The proposed Romeoville Dialysis will not impact the ability of other health care providers or health care systems to cross-subsidize safety net services. The utilization of existing dialysis facilities within the Romeoville GSA that have been operational for at least 2 years is 72.8%. Further, patient census among the existing facilities within the Romeoville GSA has increased 6.9% since March 31, 2015. This growth is anticipated to continue to increase for the foreseeable future due to the demographics of the community and U.S. Centers for Disease Control and Prevention estimates that 15% of American adults suffer from CKD. Further, a total of 65 patients (58 from NENC and 7 from DMG) will be expected to initiate in-center hemodialysis within 12 to 24 months following project completion. Accordingly, the proposed dialysis facility will not impact other general health care providers' ability to cross-subsidize safety net services.
3. The proposed project is for the establishment of Romeoville Dialysis. As such, this criterion is not applicable. A table showing the charity care and Medicaid care provided by the Applicants for the most recent three calendar years is provided below.

Safety Net Information per PA 96-0031			
CHARITY CARE			
	2014	2015	2016
Charity (# of patients)	146	109	110
Charity (cost in dollars)	\$2,477,363	\$2,791,566	\$2,400,299
MEDICAID			
	2014	2015	2016
Medicaid (# of patients)	708	422	297
Medicaid (revenue)	\$8,603,971	\$7,381,390	\$4,692,716

Section XII, Charity Care Information

The table below provides charity care information for all dialysis facilities located in the State of Illinois that are owned or operated by the Applicants.

CHARITY CARE			
	2014	2015	2016
Net Patient Revenue	\$266,319,949	\$311,351,089	\$353,226,322
Amount 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

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