



STATE OF ILLINOIS
HEALTH FACILITIES AND SERVICES REVIEW BOARD

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DOCKET NO: H-06	BOARD MEETING: July 24, 2018	PROJECT NO: 18-006	PROJECT COST:
FACILITY NAME: Fresenius Kidney Care Madison County		CITY: Granite City	Original: \$4,383,915
TYPE OF PROJECT: Substantive			HSA: XI

PROJECT DESCRIPTION: The Applicants (Fresenius Medical Care Holdings, Inc. and Fresenius Medical Care of Illinois, LLC d/b/a Fresenius Kidney Care Madison County) are proposing to establish a nine (9) station ESRD facility in 6,001 GSF of leased space in Granite City, Illinois. The cost of the project is \$4,383,915 and the scheduled completion date is June 30, 2020.

EXECUTIVE SUMMARY

PROJECT DESCRIPTION:

- The Applicants (Fresenius Medical Care Holdings, Inc. and Fresenius Medical Care of Illinois, LLC d/b/a Fresenius Kidney Care Madison County) are proposing to establish a nine (9) station ESRD facility in 6,001 GSF of leased space in Granite City, Illinois. The cost of the project is \$4,383,915, and the scheduled completion date is June 30, 2020.

WHY THE PROJECT IS BEFORE THE STATE BOARD:

- The project is before the State Board because the project proposes to establish a health care facility as defined at 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]

PURPOSE OF THE PROJECT:

- The Applicants stated: “The 9-station Fresenius Kidney Care Madison County ESRD facility will be in Granite City in a Federally Designated Medically Underserved Area (MUA). It is being proposed to address a lack of provider choice in the near Metro East region of the St. Louis Metropolitan Statistical Area. Currently the only clinics reasonably accessible to residents of Granite City are operated by DaVita. The addition of the Madison County facility will give area ESRD patients the ability to participate in the CMS End Stage Renal Disease Seamless Care Organization (ESCO) that only Fresenius participates in for Illinois. Granite City has a somewhat depressed economy, 17% of the residents are living below the poverty level and receive food stamp/SNAP benefits. 8% of residents have no health insurance and 44% are covered by a Public insurance policy. The uninsured/under-insured have greater difficulty accessing needed healthcare services, and preventative care is a struggle. Transportation issues (which are prominent for dialysis patients) also inhibit this population from accessing proper care. The goal of Fresenius Medical Care is to provide patients with a choice of provider as well as the ability to participate in the CMS ESCO, that only Fresenius is participating in for Illinois, by establishing the Madison County facility. There is no direct empirical evidence relating to this project other than that when chronic care patients have adequate access to services, it tends to reduce overall healthcare costs and results in less complications.”

PUBLIC HEARING/COMMENT:

A public hearing was offered but was not requested. Three letters of support were received by the State Board Staff from Dr. Cheema, Dr. Polack, and Dr Mayer.

Dr Mayer stated in part

“We (Dr. Polack and Dr. Mayer) have most of our patients receiving dialysis at Fresenius Kidney Care facilities where our patients have the clinical advantage of participating in the Fresenius CMS ESCO. We feel a need to continue this level of care for our patients across the river in Illinois; however, Fresenius clinic options are severely limited and not accessible to patients in the Granite City area where we spend much of our time. I currently serve as Medical Director of the DaVita Granite City ESRD facility where we have 36 dialysis patients up from 26 patients in 2017. I became medical director of this unit in 2010 long before we realized the direction our practice must take. Davita cannot offer our patients the clinical advantages that can be offered by our ESCO. For this reason, we have no interest in placing any patients at DaVita Foxpoint.”

Fresenius Kidney Care stated in part

“After careful consideration Fresenius decided to proceed with the Madison County project in response to concerns nephrologists based in St. Louis who practice in the near Metro East area who were not able to provide their Illinois patients with a choice of a dialysis provider and more importantly were not able to offer them the advantages of participating in the CMS ESRD Seamless Care Organization (ESCO) that they prefer in St. Louis. This is especially important because of the medically underserved designation of the area. FKC Madison County will participate in the CMS ESCO which not only provides increased patient monitoring, improved quality, and lowers hospitalizations and readmissions but provides significant savings to Medicare.”

“Granite City experiences a depressed economy with 17% of the residents living below the poverty level and receiving Food Stamp/SNAP benefits. 8% of the residents have no health insurance and 41% are covered by public insurance policy. The uninsured underinsured have greater difficulty accessing needed healthcare services, and preventative care is a struggle, Transportation issues (which are prominent for dialysis patients) also inhibit this population from accessing proper care outside of their community if they were to desire a different provider.”

One letter of opposition was received that stated in part

Polsinelli PC *“represents DaVita Inc. ("DaVita") and, on behalf of DaVita, writes this letter to document DaVita's strong objection to the Fresenius Kidney Care ("FKC") Madison County clinic proposal. Davita's objection is very specific and important. With Project No. 18-006, FKC and Dr. Cheema are corrupting one of the core tenets of the Illinois Health Facilities and Services Review Board ("HFSRB") to "promote the orderly and economic development of health care facilities in the State of Illinois Using the same patient data for this impending proposal as Dr. Cheema provided to DaVita under no duress in connection with DaVita' s development of another Granite City facility has resulted in a significant misapplication of the HFSRB's rules by the applicant as described below. Suffice it to say, Dr. Cheema would have this Board believe that it is a part of normal health planning to induce one company to build a facility in reliance on a promise of referrals only to reverse course more than a year after he provided a written commitment and seven months after a CON permit was issued for Foxpoint Dialysis by rescinding the referral letter so that he could attempt to support a competing company using the same patient data. **The Foxpoint Dialysis clinic is complete, operational and Medicare certified.** It is also important to note that DaVita was diligent in putting its Foxpoint Dialysis proposal forward to the HFSRB to demonstrate that the CKD patients which were the basis for the Foxpoint Dialysis clinic development were discrete patients compared to the patients who are anticipated to be cared for in other facilities outside of Granite City and, in fact, deferred its application to further document that fact.”* [Source: Letter of opposition received from Polsinelli dated June 27, 2018]

State Board Staff Notes: Dr. Cheema had originally provided projected referrals for the DaVita Foxpoint facility in Granite City that was approved by the State Board as Permit #16-037 on March 14, 2017. Dr. Cheema notified the State Board on October 17, 2017 that he was no longer associated with the DaVita Foxpoint facility and withdrew his support (referrals) for that facility. Dr Cheema maintains privileges with DaVita and has patients in Granite City.

SUMMARY:

- The State Board is **estimating an excess of 39 stations** in the HSA XI ESRD Planning Area by 2020.
- Board Staff identified 14 ESRD facilities within thirty minutes of the proposed facility. Five facilities have recently been approved and are not completed or in ramp-up. Average utilization of the remaining nine facilities is approximately 76%.
- From the information provided by the Applicants the proposed facility will serve residents of a Medically Underserved Area (MUA) within the HSA XI ESRD Planning Area. Additionally the applicants note the proposed project will allow the projected patient base to participate in Fresenius' End Stage Renal Disease Seamless Care Organization (ESCO), a quality care initiative developed by the applicants to promote better service/health outcomes for its patient base.

CONCLUSION:

- The Applicants addressed a total of 21 criteria and were non-compliant with the following:

State Board Standards Not Met	
Criteria	Reasons for Non-compliance
Criterion 1110.1430 (b) (1) (2) (3) & (5) – Planning Area Need	There is a calculated <u>excess of 39 ESRD stations</u> in the HSA XI ESRD Planning Area.
Criterion 1110.230(c)(1), (2) & (3) – Unnecessary Duplication/Mal-distribution of Service/Impact on Other Providers	There are 14 ESRD facilities within thirty minutes of the proposed facility. Five facilities have recently been approved and are not completed or in ramp-up. Average utilization of the remaining nine facilities is approximately 76%, with only 3 (33%) of these facilities operating in excess of the State standard. The station to patient population indicates a surplus of stations in the 30-minute service area.

STATE BOARD STAFF REPORT
Fresenius Kidney Care Madison County
PROJECT #18-006

APPLICATION SUMMARY/CHRONOLOGY	
Applicants	Fresenius Medical Care Holdings, Inc. Fresenius Medical Care of Illinois, LLC d/b/a Fresenius Kidney Care Madison County
Facility Name	Fresenius Kidney Care Madison County
Location	1938-1946 Grand Avenue, Granite City
Application Received	February 7, 2018
Application Deemed Complete	February 8, 2018
Review Period Ends	June 8, 2018
Permit Holder	Fresenius Medical Care Holdings, Inc. Fresenius Medical Care of Illinois, LLC d/b/a Fresenius Kidney Care Madison County
Operating Entity	Fresenius Medical Care of Illinois, LLC d/b/a Fresenius Kidney Care Madison County
Owner of the Site	Net3 (Granite City), LLC
Project Financial Commitment Date	June 30, 2020
Gross Square Footage	6,001 GSF
Project Completion Date	June 30, 2020
Expedited Review	Yes
Can Applicants Request a Deferral?	Yes
Has the Application been extended by the State Board?	No

I. The Proposed Project

The Applicants (Fresenius Medical Care Holdings, Inc and Fresenius Medical Care of Illinois, LLC d/b/a Fresenius Kidney Care Madison County) are proposing the establishment of a nine (9) station ESRD facility in 6,001 GSF of leased space in Granite City, Illinois. The cost of the project is \$4,383,915, and the scheduled completion date is June 30, 2020.

II. Summary of Findings

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

III. General Information

The Applicants are Fresenius Medical Care Holdings, Inc. and Fresenius Medical Care of Illinois, LLC d/b/a Fresenius Kidney Care Madison County. **Fresenius Medical Care Holdings**, operating as Fresenius Medical Care North America or FMCNA, operates a network of some 2,100 dialysis clinics located throughout the continent. One of the largest providers of kidney dialysis services, FMCNA offers outpatient and in-home hemodialysis treatments for chronic kidney disease. The company's operating units also market and sell dialysis machines and related equipment and provide renal research,

laboratory, and patient support services. FMCNA oversees the North American operations of dialysis giant Fresenius Medical Care AG & Co.

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

Substantive Projects means types of projects that are defined in the Act and classified as substantive. *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 a discontinuation of a service; 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]

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

TABLE ONE			
Current Fresenius Projects and Status			
Project Number	Name	Project Type	Completion Date
#15-036	FMC Zion	Establishment	12/31/2018
#15-046	FMC Beverly Ridge	Establishment	10/31/2018
#15-050	FMC Chicago Heights	Establishment	09/30/2018
#15-062	FMC Belleville	Establishment	12/31/2018
#16-024	FMC Kidney Care East Aurora	Establishment	9/30/2018
#16-029	FMC Ross Dialysis – Englewood	Relocation/ Establishment	12/31/2018
#16-034	FKC Woodridge	Establishment	3/31/2019
#16-042	FKC Paris Community	Establishment	09/30/2018
#16-049	FMC Macomb	Relocation/Establishment	12/31/2018
#17-004	FKC Mount Prospect	Establishment	12/31/2018
#17-023	FMC Oswego	Expansion	12/31/2018
#17-024	FKC Springfield East	Establishment	3/31/2019
#17-025	FMC Crestwood	Relocation/Establishment	9/30/2019
#17-027	FMC Sandwich	Expansion	12/31/2018
#17-033	FMC Palatine	Expansion	12/31/2018
#17-065	FKC New Lenox	Establishment	12/31/2019

IV. Health Service Area

The proposed facility will be located in Health Service Area XI. Health Service Area XI is comprised of the Illinois counties of Clinton, Madison, Monroe, and St. Clair. As of June 2018 there is a calculated **excess of 39 ESRD stations** in this planning area.

TABLE ONE	
Need Methodology HSA XI ESRD Planning Area	
Planning Area Population – 2015	599,300
In Station ESRD patients -2015	765
Area Use Rate 2013 ⁽¹⁾	1.246
Planning Area Population – 2020 (Est.)	614,100
Projected Patients – 2020 ⁽²⁾	765
Adjustment	1.33x
Patients Adjusted	1,017
Projected Treatments – 2020 ⁽³⁾	158,722
Existing Stations	251
Stations Needed-2020	212
Number of Stations in Excess	39
<ol style="list-style-type: none"> 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 	

V. Project Costs

The Applicants are funding this project with cash and securities amounting to \$1,596,200 and the fair market value of leased space and equipment of \$2,787,715. The estimated start-up costs and the operating deficit are projected to be \$135,825.

TABLE TWO				
Project Uses and Sources of Funds ⁽¹⁾				
Uses of Funds	Reviewable	Non Reviewable	Total	% of Total
Modernization Contracts	\$810,628	\$281,554	\$1,092,182	24.9%
Contingencies	\$80,172	\$27,846	\$108,018	2.5%
Architectural/Engineering Fees	\$86,580	\$30,420	\$117,000	2.6%
Movable or Other Equipment (not in construction contracts)	\$219,000	\$60,000	\$279,000	6.4%
Fair Market Value of Leased Space or Equipment	\$2,094,259	\$693,456	\$2,787,715	63.6%
TOTAL USES OF FUNDS	\$3,290,639	\$1,093,276	\$4,383,915	100.00%
SOURCE OF FUNDS	Reviewable	Non Reviewable	Total	% of Total
Cash and Securities	\$1,196,380	\$399,820	\$1,596,200	36.4%

TABLE TWO				
Project Uses and Sources of Funds ⁽¹⁾				
Uses of Funds	Reviewable	Non Reviewable	Total	% of Total
Leases (fair market value)	\$2,094,259	\$693,456	\$2,787,715	63.6%
TOTAL SOURCES OF FUNDS	\$3,290,639	\$1,093,276	\$4,383,915	100.00%
1. Itemization of Project Costs can be found at Page 36 of the Application for Permit				

VI. Background of the Applicants

A) Criterion 1110.110(a) – 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 had no *adverse action*¹ taken against any facility they own or operate or a listing of adverse action taken against facilities the Applicants own.

1. The Applicants have attested that there has been no adverse action taken against any of the facilities owned or operated by Fresenius Kidney Care during the three (3) years prior to filing the application. [Application for Permit pages 47-48]
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 connections the Applicants' certificate of need to establish a nine 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 47-48]
3. The site is owned by Net3 (Granite City), LLC and evidence of this can be found at pages 27-31 of the application for permit in the Letter of Intent to lease the property in Granite City.

¹Adverse 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)

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).*

VII. Purpose of Project, Safety Net Impact Statement and Alternatives

The following three (3) criteria are informational; no conclusion on the adequacy of the information submitted is being made.

A) Criterion 1110.230 (a) 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 Applicants stated the following:

“The 9-station Fresenius Kidney Care Madison County ESRD facility will be in Granite City in a Federally Designated Medically Underserved Area (MUA). It is being proposed to address a lack of provider choice in the near Metro East region of the St. Louis Metropolitan Statistical Area. Currently the only clinics reasonably accessible to residents of Granite City are operated by DaVita. The addition of the Madison County facility will give area ESRD patients the ability to participate in the CMS End Stage Renal Disease Seamless Care Organization (ESCO) that only Fresenius participates in for Illinois. The goal of Fresenius Medical Care is to provide patients with a choice of provider as well as the ability to participate in the CMS ESCO, that only Fresenius is participating in for Illinois, by establishing the Madison County facility. There is no direct empirical evidence relating to this project other than that when chronic care patients have adequate access to services, it tends to reduce overall healthcare costs and results in less complications.”

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

The Applicants provided a Safety Net Impact Statement as required, which states:

“The establishment of Fresenius Kidney Care Madison County will not have any impact on safety net services in the Granite City area of Madison County. Outpatient dialysis services are not typically considered safety net services, to the best of our knowledge. However, we do provide

care for patients in the community who are economically challenged and/or who are undocumented aliens, who do not qualify for Medicare/Medicaid pursuant to an indigent waiver policy. We assist patients who do not have insurance in enrolling when possible, in Medicaid for ESRD or insurance on the Healthcare Marketplace. Also, our social services department assists patients who have issues regarding transportation and/or who are wheelchair bound or have other disabilities which require assistance with respect to dialysis services and transport to and from the unit. This particular application will not have an impact on any other safety net provider in the area, as no hospital within the area provides dialysis services on an outpatient basis. Fresenius Kidney Care is a for-profit publicly traded company and is not required to provide charity care, nor does it do so, according to the Board's definition. However, Fresenius Kidney Care provides care to patients who do not qualify for any type of coverage for dialysis services. These patients are considered "self-pay" patients. They are billed for services rendered, and after three statement reminders the charges are written off as bad debt. Collection actions are not initiated unless the applicants are aware that the patient has substantial financial resources available and/or the patient has received reimbursement from an insurer for services we have rendered, and has not submitted payment for the same to the applicants. Fresenius notes that as a for-profit entity, it does pay sales tax, real estate, and income taxes. It also does provide community benefit by supporting various medical education activities and associations, such as the Renal Network, National Kidney Foundation, and American Kidney Fund."

Table Three shows the amounts of self-pay care, Medicaid care amounts for three fiscal years prior to the submission of this application.

TABLE THREE ⁽¹⁾			
SAFETY NET INFORMATION			
Fresenius Medical Care Facilities in Illinois			
	2014	2015	2016
Net Revenue	\$411,981,839	\$438,247,352	\$449,611,441
CHARITY			
Charity (# of self-pay patients)	251	195	233
Charity (self-pay) Cost	\$5,211,664	\$3,204,986	\$3,269,127
% of Charity Care to Net Rev.	1.27%	0.73%	.072%
MEDICAID			
Medicaid (Patients)	750	396	320
Medicaid (Revenue)	\$22,027,882	\$7,310,484	\$4,383,383
% of Medicaid to Net Revenue	5.35%	1.67%	.097%
<ol style="list-style-type: none"> 1. Source: Pages 107-108 of the Application for Permit. 2. Charity Care is defined by the State Board as care provided by a health care facility for which the provider does not expect to receive payment from the patient or a third party payer. [20 ILCS 3960/3]. 			

C) Criterion 1110.230 (c) - Alternatives to the Project

To demonstrate compliance with this criterion the Applicants must document all alternatives to the proposed project that were considered.

The Applicants provided the following project alternatives:

1. Proposing a project of greater or lesser scope and cost.

The only option that would entail a lesser scope and cost than the project proposed in this application would be to do nothing. Doing nothing would deny the patient the options of choosing a service provider, and deny the Medicare patient base the opportunity to participate in the End Stage Renal Disease Seamless Care Organization (ESCO). Dr. Cheema's and Dr. Polack's patients in the Granite City area have no access to Fresenius facilities/services, and the only Fresenius facility in the service area is approximately 30 minutes away and operates in excess of the State standard (80%). There is no cost to this alternative.

2. Pursuing a joint venture or similar arrangement with one or more providers of entities to meet all or a portion of the project's intended purposes' developing alternative settings to meet all or a portion of the project's intended purposes.

The preferred Fresenius model of ownership is for our facilities to be wholly owned, however we do enter into joint ventures on occasion. Fresenius Medical Care always maintains control of the governance, assets and operations of a facility it enters into a joint venture agreement with to ensure financial stability. Our healthy financial position and abundant liquidity indicate that that we have the ability to support the development of additional dialysis centers. Fresenius Medical Care has more than adequate capability to meet all of its expected financial obligations and does not require any additional funds to meet expected project costs. This facility will not be a joint venture because there is no physician interest at this time. The cost of a joint venture would be the same as the current project, however split amongst joint venture partners.

3. Utilizing other health care resources that are available to serve all or a portion of the population proposed to be served by the project

Drs. Cheema and Polack currently admit patients to Fresenius and DaVita facilities in Missouri, but are limited to their referral choice in the Granite City area. While the patient base has access to DaVita facilities/services at the clinics in Granite City, no other referral options exist. The three nearest Fresenius facilities are approximately 15-19 miles from Granite City, which presents accessibility issues for Dr. Cheema's and Dr. Polack's patients. The cost of a joint venture would be the same as the cost for the current project.

4. Reasons why the chosen alternative was selected

The most efficient long-term solution to maintaining access and patient choice for dialysis services in the Granite City market is to establish Fresenius Kidney Care Granite City. The proposed 9-station ESRD facility will increase patient satisfaction

through the provision of choice in dialysis care services. The cost of this project is \$4,383,915.

VIII. Project Scope and Size, Utilization and Assurances

A) Criterion 1110.234(a) - Size of Project

To demonstrate compliance with this criterion the Applicants must document that the proposed size of the project is in compliance with the State Board Standard in Part 1110 Appendix B.

The Applicants propose to lease 6,001 GSF of space in which 4,454 GSF of space will be reviewable space. The State Board standard is 650 GSF per station or 5,850 GSF (9 stations x 650 GSF = 5,850 GSF). The Applicants have met the requirements of this criterion.

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

B) Criterion 1110.120(b) – Projected Utilization

To demonstrate compliance with this criterion the Applicants must document that the 12-station facility will be at target occupancy as specified in Part 1100. 630.

The Applicants project 59 patients will utilize the proposed 9-station facility within 2-years after project completion.

$$\begin{aligned} 59 \text{ patients} \times 156 \text{ treatment per year} &= 9,204 \text{ treatments} \\ 9 \text{ stations} \times 936 \text{ treatments per year per station} &= 8,424 \text{ treatments} \\ 9,204 \text{ treatments} \div 8,424 \text{ treatments} &= 109.2\% \end{aligned}$$

The Applicants have met the requirements of this criterion,

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

C) Criterion 1110.120(e) – Assurances

To demonstrate compliance with this criterion the Applicants must attest that the proposed facility will be at target occupancy (80%) within two (2) years after project completion.

The Applicants have provided the necessary attestation as required at page 94 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 Hemo-dialysis Projects

A) Criterion 1110.1430(b)(1), (2), (3) & (5) - Planning Area Need

To demonstrate compliance with this criterion the Applicants must document the number of stations to be established for in-center hemodialysis is in conformance with the projected station deficit specified in 77 Ill. Adm. Code 1100, as reflected in the latest updates to the Inventory.

1. Planning Area Need

To demonstrate compliance with this sub-criterion the Applicants must document that there is a calculated need in the ESRD Planning Area.

The State Board is estimating an excess of 39 stations in the HSA XI ESRD Planning Area as of June 2018 Revised Station Need Determination.

2. Service to Area Residents

To demonstrate compliance with this sub-criterion the Applicants must document that the proposed ESRD service will serve the residents of the ESRD Planning Area.

A review of the number of patients by zip code indicates that one hundred percent (100%) of the patients will come from the HSA XI ESRD Planning Area.

Zip Code	City	County	Health Service Area (HSA)	Number Of Pre-ESRD Patients
62040	Granite City	Madison	11	46
62060	Madison	Madison	11	3
62025	Edwardsville	Madison	11	2
62207	East St. Louis	St. Clair	11	4
62034	Glen Carbon	Madison	11	4
TOTAL				59

3. Service Demand

To demonstrate compliance with this sub-criterion the Applicants must document that there is sufficient demand for the number of stations being proposed.

Dr. Anahit Cheema, M.D. (Gateway Nephrology, St. Louis) and Dr. Donovan Polack, M.D. (St. Louis Kidney Care, St. Louis) are the referring nephrologists and the referring physician practices for the proposed ESRD facility. Dr. Cheema (Gateway Nephrology), was treating 37 Pre-ESRD patients by September 2017, and expects to refer 33 of these patients to be referred to the proposed facility by the second year of operation. Dr. Polack (St. Louis Kidney Care), was treating 36 Pre-ESRD patients by September 2017, and expects to refer 26 of these patients to the proposed facility by the second year of operation. In total, the physicians expect to refer a total of 59 patients to the proposed facility, resulting in operations exceeding the 100th percentile.

5. Service Accessibility

To demonstrate compliance with this sub-criterion the Applicants must document at least 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;
- v) 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 in the proposed HSA XI ESRD Planning Area. The applicants provided proof of access limitations, based on the service area's designation as a Federally Designated Medically Underserved Area (MUA). The applicants also cite a lack of access to their choice of providers. However, a lack of provider choice does not constitute a service accessibility issue. The applicants identified 14 ESRD facilities within thirty minutes of the proposed facility (See Table Five). Five facilities have recently been approved and are not completed or in ramp-up. Average utilization of the remaining nine facilities is approximately 76%. (See Table Below)

Summary

The applicants have identified a sufficient number of patients that will need dialysis within two years after project completion (59 pre-ESRD patients) to justify the proposed 9-station facility. It also appears that the patients will come from within the ESRD planning area. The proposed facility will be located in a designated Federally Medically Underserved Area (MUA)², based on the socioeconomic status of its patient base. However, the State Board is estimating an excess of 39 stations in the HSA XI ESRD Planning Area by 2020. Based upon this excess of stations in the planning area the Applicants have not successfully addressed this criterion.

² Medically Underserved Areas (MUAs) and Medically Underserved Populations (MUPs) identify geographic areas and populations with a lack of access to primary care services MUAs have a shortage of primary care health services for residents within a geographic area such as: a whole county; a group of neighboring counties; a group of urban census tracts; or a group of county or civil divisions. MUPs are specific sub-groups of people living in a defined geographic area with a shortage of primary care health services. These groups may face economic, cultural, or linguistic barriers to health care. Examples include, but are not limited to, those who are: homeless; low-income; Medicaid-eligible; Native American; or migrant farm workers. MUA/P designations are based on the Index of Medical Under service (IMU). IMU is calculated based on four criteria: the population to provider ratio; the percent of the population below the federal poverty level; the percent of the population over age 65; and the infant mortality rate. IMU can range from 0 to 100, where zero represents the completely underserved. Areas or populations with IMUs of 62.0 or less qualify for designation as an MUA/P.

**TABLE FIVE
Facilities within 30-minutes of the Proposed Facility**

Facility	City	Time (1)	Star Rating (2)	Stations	Utilization (3)	Met Standard?
DaVita Granite City	Granite City	8	4	20	79.1%	No
DaVita Maryville	Maryville	22	3	14	73.8%	No
DaVita Sauget	Sauget	22	2	24	57.6%	No
FKC Regency Park	O'Fallon	24	3	20	89.1%	Yes
DaVita Metro East	Belleville	27	3	36	81.9%	Yes
FKC Southwestern IL	Alton	27	2	19	70.1%	No
DaVita Shiloh	Belleville	29	2	12	86.1%	Yes
DaVita Edwardsville	Edwardsville	30	3	8	77%	No
DaVita Alton	Alton	30	2	16	67.7%	No
Total Stations/Patients				169	75.82%	
Average Utilization						
DaVita Foxpoint	Granite City	9	NA	12	0.0%*	N/A
DaVita Collinsville	Collinsville	14	NA	8	22.9%>	N/A
DaVita Edgemont	E. St. Louis	19	NA	12	0.0%*	N/A
FKC Belleville	Belleville	25	NA	12	0.0%*	N/A
DaVita O'Fallon	O'Fallon	27	NA	12	30.5%	N/A
Total Stations/Patients				225	56.60%	
Average Utilization						
<ol style="list-style-type: none"> 1. Time Based upon MapQuest. 2. Star Rating from Medicare ESRD Compare Website. 3. Stations as of June 2018 4. Utilization as of March 31, 2018 						

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

B) Criterion 1110.1430(c)(1), (2) and (3) - Unnecessary Duplication/Mal-distribution/ Impact on Other Facilities

- 1) The applicant shall document that the project will not result in an unnecessary duplication of service.
- 2) The applicant shall document that the project will not result in maldistribution of services.
- 3) The applicant shall document that, within 24 months after project completion, the proposed project will not lower the utilization of other area providers below the occupancy standards specified in 77 Ill. Adm. Code 1100 and will not lower, to a further extent, the utilization of other area providers that are currently (during the latest 12-month period) operating below the occupancy standards.

1. Unnecessary Duplication of Service

In response to all existing facilities not being at target occupancy the Applicants stated the following:

“The ratio shows an excess of stations, however, what this ratio does not show is that patients in Granite City area are restricted to dialyzing at a DaVita clinic leaving them no choice of provider unless they want to travel out of State or long distances outside of their community and health care market, diminishing the continuity of care and raising patient travel issues and costs. There is not an absence of dialysis services in Granite City. However, there is an absence of providers for patients to choose from. DaVita Granite City is at 80%, and DaVita will be opening the Foxpoint facility soon, also in Granite City. Dr. Cheema as well as Dr. Polack, from a separate practice, are supporting the FKC Madison County facility to give their patients a choice of providers for their dialysis treatments. Providing access to a choice of provider and a FKC facility will not create a maldistribution of services or unnecessary duplication but will eliminate the current maldistribution and duplication of services by only one provider and will give patients a much-needed choice not only of provider but the option to participate in the CMS ESRD Seamless Care Organization of which Fresenius is the only dialysis participant in Illinois.”

2. Mal-distribution of Service

The ratio of ESRD stations to population in the zip codes within a 30-minute radius of Fresenius Kidney Care Madison County is 1 station per 1,715 residents. The State ratio is 1 station per 2,694 residents (based on 2015 US Census estimates and the June 2018 State Board Station Inventory). To have a surplus of stations in this 30-minute service area the number of stations per population would need to be one station per every 1,796 residents. Based upon this methodology there is a surplus of stations in this service area.

	State of Illinois	30-minute Service Area
Population	12,978,800	380,752
Stations	4,818	225
Ratio	1 Station per 2,694 residents	1 Station per 1,715 residents

3. Impact on Other Facilities

The Applicants stated the following:

“Fresenius Kidney Care Madison County will not have an adverse effect on any other area ESRD provider in that the new patients identified for this facility are pre-ESRD patients from two separate practices and will be referred to a facility of choice, No patients have been identified to be transferred from any other facility.”

Summary

There are 14 ESRD facilities within thirty minutes of the proposed facility. Five facilities have recently been approved and are not completed or in ramp-up. Average utilization of the remaining nine facilities is approximately 76%, with only 3 (33%) of these facilities operating in excess of the State standard. The station to patient population indicates a surplus of stations in the service area, and a negative finding results for this criterion.

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

C) Criterion 1110.1430(e) - 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. Dr. Anahit Cheema, M.D. will be the Medical Director for Fresenius Kidney Care Madison County. Dr. Cheema’s curriculum vitae has been provided. A complete narrative of the staffing for the proposed facility has been provided at pages 82-86 of the Application for Permit. Based upon the information provided in the Application for Permit, the Applicants have met the requirements of this criterion.

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

D) Criterion 1110.1430(f) - 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 page 87 of the application for permit.

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

E) Criterion 1110.1430(g) - 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 9-station facility will be located in the St. Louis-St. Charles-Farmington 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(g))

F) Criterion 1110.1430(h) - Continuity of Care

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

The Applicants have provided the necessary signed affiliation agreement with Gateway Regional Medical Center located in Granite City as required at pages 89-93 of the Application for Permit.

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

G) Criterion 1110.1430(j) - Assurances

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

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

The necessary attestation has been provided at page 94 of the application for permit.

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

X. FINANCIAL VIABILITY

- A) Criterion 1120.120 – Availability of Funds**
- B) Criterion 1120.130 – Financial Viability**

The Applicants are funding this project with cash and securities of \$1,596,200 and the fair market value of leased space of \$2,787,715. The lease will be an operating lease³. A review of the 2014/2015/2016 audited financial statements indicates there is sufficient cash to fund the project. Because the project will be funded with cash no viability ratios need to be provided and the Applicants have qualified for the financial viability waiver.⁴

TABLE SIX			
FMC Holdings Inc. Audited Financial Statements			
(Dollars in Thousands 000)			
December 31st			
	2014	2015	2016
Cash & Investments	\$195,280	\$249,300	\$357,899
Current Assets	\$4,027,091	\$4,823,714	\$5,208,339
Total Assets	\$18,489,619	\$19,332,539	\$20,135,661
Current Liabilities	\$2,058,123	\$2,586,607	\$2,799,192
Long Term Debt	\$2,669,500	\$2,170,018	\$2,085,331
Total Liabilities	\$9,029,351	\$9,188,251	\$9,602,364
Total Revenues	\$10,373,232	\$11,691,408	\$12,806,949
Expenses	\$9,186,489	\$10,419,012	\$11,185,474
Income Before Tax	\$1,186,743	\$1,272,396	\$1,621,175
Income Tax	\$399,108	\$389,050	\$490,932
<i>Net Income</i>	\$787,635	\$883,346	\$1,130,243
Source: 2014/2015/2016 Audited Financial Statements			

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION AVAILABILITY OF FUNDS AND FINANCIAL VIABILITY (77 ILAC 1120.120 and 77 ILAC 1120.130)

³ Operating lease is a contract wherein the owner, called the Lessor, permits the user, called the Lessee, to use of an asset for a particular period which is shorter than the economic life of the asset without any transfer of ownership rights. The Lessor gives the right to the Lessee in return for regular payments for an agreed period of time.

⁴ Financial Viability Waiver: 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.

XI. ECONOMIC FEASIBILITY

- A) Criterion 1120.140(a) – Reasonableness of Financing Arrangements**
- B) Criterion 1120.140(b) – Terms of Debt Financing**

The State Board considers leasing a form of debt financing⁵. The Applicants provided a copy of a letter of intent to lease 6,001 GSF rentable contiguous square feet with an initial lease term of fifteen (15) years with three (3) five (5) year renewal options. The annual base rental rate shall be \$25.77 per SF, which shall escalate on an annual basis by three percent (1.7%) per year, beginning at the beginning of year two. (See Application for Permit page 95-99)

The Applicants have attested that entering into of a lease (borrowing) is less costly than the liquidation of existing investments which would be required for the applicant to buy the property and build a structure itself to house a dialysis clinic. (See Application for Permit page 103)

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

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

Only the reviewable costs are being reviewed for this criterion. The Applicants are proposing 4,454 GSF of reviewable space for the proposed facility.

**TABLE SEVEN
Reasonableness of Project Costs**

Description	Project Costs		State Standard		Difference	Met Standard?
	Total	Unit	Total	Unit		
Modernization and Contingency Cost ⁽²⁾	\$890,800	\$200 GSF	\$895,254	\$201.GSF	-\$4,454	Yes
Contingencies	\$80,172	9.0%	\$133,620	15.00%	-\$53,448	Yes
Architectural/Engineering Fees	\$86,580	9.71%	\$91,974	10.59%	-\$5,394	Yes
Movable or Other Equipment (not in construction contracts) ⁽³⁾	\$219,000	\$24,333 per Station	\$497,637	\$55,293 per station	-\$278,637	Yes
Fair Market Value of Leased Space or Equipment ⁽¹⁾	\$2,094,259	No Standard				

1. Modernization includes the build out of leased space and shall include the cost of capital equipment included in the terms of the lease.
2. Modernization and Contingency Costs are \$178.33 per GSF (2015) and inflated by 3% to 2019.
3. Station cost is \$39,945 per station (2008) and inflated by 3% to 2019.

⁵ "Debt Financing" means all or any portion of project costs financed through borrowing. Leasing, for purposes of this Part, is considered borrowing. Portions of lease payments that are for service, insurance, or other noncapital costs are not considered borrowing. 77 ILAC 1120.10

D) Criterion 1120.140(d) - Direct Operating Costs

To demonstrate compliance with this criterion the Applicants must document the projected direct annual operating costs (in current dollars per equivalent patient day or unit of service) for the first full fiscal year at target utilization but no more than two years following project completion. Direct cost means the fully allocated costs of salaries, benefits and supplies for the service.

The Applicants are estimating \$195.31 per treatment in direct operating costs. This appears reasonable when compared to previously approved projects of this type.

Estimated Personnel Expense:	\$787,968
Estimated Medical Supplies:	\$160,165
Estimated Other Supplies	\$671,846
Exc: Depreciation and Amortization	
Total	\$1,619,979
Estimated Annual Treatments:	8,294
Direct Operating Cost Per Treatment:	\$195.31

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

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

To demonstrate compliance with the criterion the Applicants must document the capital costs (in current dollars per equivalent patient day or unit of service) for the first full fiscal year at target utilization but no more than two years following project completion. Direct cost means the fully allocated costs of salaries, benefits and supplies for the service.

The Applicants are estimating \$19.29 in capital costs. This appears reasonable when compared to previously approved projects of this type.

Depreciation/Amortization:	\$160,000
Interest	\$0
Capital Costs:	\$160,000
Treatments:	8,294
Capital Cost per Treatment	\$19.29

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

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