



STATE OF ILLINOIS
HEALTH FACILITIES AND SERVICES REVIEW BOARD

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

DOCKET NO: I-04	BOARD MEETING: March 5, 2019	PROJECT NO: 18-039	PROJECT COST:
FACILITY NAME: Fresenius Kidney Care Grayslake		CITY: Grayslake	Original: \$6,113,914
TYPE OF PROJECT: Substantive			HSA: VIII

PROJECT DESCRIPTION: The Applicants (Fresenius Medical Care Holdings, Inc. and Fresenius Medical Care Grayslake, LLC d/b/a Fresenius Kidney Care Grayslake) propose to establish a 10-station facility in Grayslake, Illinois at a cost of \$6,113,914. The anticipated project completion date is March 31, 2021.

EXECUTIVE SUMMARY

PROJECT DESCRIPTION:

- The Applicants (Fresenius Medical Care Holdings, Inc. and Fresenius Medical Care Grayslake, LLC d/b/a Fresenius Kidney Care Grayslake) propose to establish a 10-station facility in Grayslake, Illinois at a cost of \$6,113,914. The anticipated project completion date is March 31, 2021.
- **Note:** For Applicant facilities located in the counties of Lake, Kane and Will, the radius shall be 10 miles. The proposed facility will be located in Lake County. [77 ILAC 1110.230 (b) (5) (C)]
- This project received an Intent to Deny at the January 2019 State Board Meeting. The Applicant provided additional information to address the Intent to Deny on February 13, 2019.
- The Applicants stated in part: *“Fresenius Medical Care came before this Board in 2014 with project #14-029 for a 12-station facility in Grayslake. At that time, two of Fresenius' closest clinics, Gurnee and Round Lake were full. That project was denied by just one vote. Since then we have been diligent in using existing space to address area access issues.*
 - *8 stations were added to FKC Gurnee, which quickly rose back above 80%.*
 - *FKC Round Lake remains above 80% with no room for expansion.*

What is different this time is that the 3rd closest Fresenius facility, Mundelein which opened in 2012, is now also above 80% despite an addition of two stations. We waited and acted upon cost effective strategies to provide access and now five years later we are still in the same predicament. Additional access is needed in Grayslake to alleviate 3 highly utilized Fresenius facilities versus just two when we proposed this project last. We cannot wait another five years with expansion options diminished. The high number of positive votes both in 2014 and at the January 2019 Board meeting support the evident need for access in Grayslake.”

- The additional information along with the transcripts from the January 2019 State Board Meeting are included at the end of this report.

WHY THE PROJECT IS BEFORE THE STATE BOARD:

- The proposed project is before the State Board because it establishes a health care facility as defined at 20 ILCS 3960/3.

PURPOSE OF THE PROJECT:

- The Applicants stated *“The 10-station Fresenius Kidney Care Grayslake End Stage Renal Disease (ESRD) facility is being proposed to provide access centrally located where overall utilization of clinics within a 10-mile radius is at 82%, restricting ESRD patient access and severely limiting access to favored treatment schedule times. Of the 8 facilities within this radius, 6 are above 80%, 1 is just under 80% leaving just one clinic with limited capacity.”*

PUBLIC HEARING/COMMENT:

- No public hearing was requested and no letters of opposition were received by the State Board. Letters of support were received from the following individuals:
- Dr. Thomas McGowan stated in part: *“in Grayslake as of 2017 9% of the population was over age 65 and 41 % were over age 45. Those coming into the age range where the previously mentioned health conditions become more common is rapidly rising. Despite the physician's best efforts to curtail these diseases, I fear we will only see an increase relating to this aging population. With Lake County dialysis patients already being treated in clinics that are quickly approaching capacity, additional options will be needed to meet the demand of the growing elderly population. Area clinics already have seriously restricted choices of treatment times to offer a new patient to dialysis. As my patients begin dialysis, my hope is that they would be offer a time of day that allows them to maintain their family function, employment (if applicable) and the highest quality of life*

possible. I do not want them to start dialysis on an inconvenient shift that severely hampers their personal life any more than it already is with a diagnosis of end stage renal disease.”

- **Dr. Sergie Shevlyagin stated in part:** *“My name is Dr. Sergei Shevlyagin and I am a board certified Internist in Grayslake. I have a significant number of patients in my care that have declining kidney function, mainly due to diabetes and hypertension, both of which are increasing at alarming rates. Many are already in kidney failure and have had to begin the dialysis treatment regimen. I refer many of these patients to nephrologists Dr. Munir and Dr. Trob because I am confident they will provide high quality compassionate care. I am writing to you because it would be beneficial for my patients to receive dialysis, not only at a high-quality facility, but where their nephrologist will be the Medical Director such as at the proposed Fresenius Kidney Care Grayslake facility.”*
- **Dr. Parag Thakkar stated in part:** *“I am a primary care physician serving Grayslake and the surrounding communities. I have witnessed an increase in the number of patients I see suffering from kidney disease leading to kidney failure. These patients are often extremely ill and require complex health care services. I refer these patients to area nephrologists for specialized care. I am extremely satisfied with the care given to my patients by Dr. Munir of Associates in Nephrology, who will be the Medical Director of this facility. Dialysis services for most of my patients living in Lake County is provided by Fresenius Kidney Care, of which I have been equally satisfied. I am hopeful that this combination of care can be approved for Grayslake, so this model will be continued here. I know that some of the area's dialysis clinics are unable to treat my patients on a schedule that allows them to maintain some of the normalcy of their pre-dialysis life. Additional treatment options in Grayslake will allow them this opportunity.”*
- **Rhett Taylor, Mayor of Grayslake stated in part:** *I am writing to voice my support for the proposed dialysis clinic Fresenius Kidney Care has applied in Grayslake. This facility would be a great benefit for our community by providing quality lifesaving services and creating long-term job opportunities. Fresenius Medical Care has been committed to serve residents of Grayslake for many years at nearby dialysis clinics in Gurnee, Antioch, Round Lake, Mundelein and Waukegan. I can understand how it can be difficult for dialysis patients to maintain a schedule that requires treatment three days out of the week. Having a clinic close-by in Grayslake would greatly enhance the difficult lives of the residents here who suffer from kidney failure. Our population is aging, and rates of kidney failure are constantly on the rise, as evidenced by the high use rates of area clinics. My desire for the residents I serve is to ensure that they have adequate access to all healthcare services including dialysis. The Grayslake facility will be a much-appreciated supplement to the existing services here.*
- **Eugene Pomeranets, MD, Family Care of Lake County stated** *“The purpose of this letter is to state my full support for the long-awaited establishment of the Fresenius Kidney Care Grayslake dialysis center. This facility would answer the current need for accessible dialysis services for residents of Grayslake as well as nearby towns. We have an aging population that is more prone to the diseases that cause kidney failure. Along with kidney disease, these patients deal with a plethora of other chronic conditions.”*
- **Wajahat Mirza, MD stated:** *The purpose of this letter is to express my support for the proposed project submitted by Fresenius Kidney Care and Dr. Jawad Munir to open a dialysis facility in Grayslake. I have practiced in this area for over 15 years. I believe this facility will provide critical access to life-saving services for residents both in Grayslake and surrounding areas of Lake County.*

- Mohammed Kagzi, MD stated *“I write this letter to show my strong support for Project 18-039 – Fresenius Kidney Care Grayslake for a dialysis facility to be established in Grayslake. I am an internist with offices in Grayslake and Gundee and therefore have many patients who live in Grayslake and surrounding communities. As a long time physician here, I know that too often the area clinics are so full that patients have difficulty being place on treatment shift that is best for them.”*
- Joseph H. Mun, MD stated *“Many of my patients suffer from diabetes and hypertension, two of the leading causes of kidney failure, and therefore are in end stage renal disease requiring regular dialysis treatment. What I hear from them in terms of wait time to be moved to an acceptable treatment time is unacceptable. It is clear there is a far greater demand than can be met with the area's current capacity. That is why I urge the Illinois Health Facilities and Services Review Board to approve the application before it for a new dialysis clinic in Grayslake.”*

SUMMARY:

- The proposed facility will be located in the HSA VIII ESRD Planning Area (Kane, Lake, and McHenry counties). There is a calculated excess of 55 stations in the HSA VIII ESRD Planning Area. The Applicants have identified 54 pre-ESRD patients that will utilize the proposed facility within two years after project completion. There is no absence of ESRD services in HSA VIII ESRD Planning Area. No service access issues have been identified. There are eight facilities with 143 stations within the 10-mile radius of the proposed facility. Average utilization of these eight facilities is 82%. Two of these eight facilities are not at target occupancy.

State Board Standards Not Met	
Criteria	Reasons for Non-compliance
77 ILAC 1110.230 (b) – Planning Area Need	For this criterion the Applicants must demonstrate there is a need for ESRD stations in the planning area. The State Board has determined that there is a <u>calculated excess of 55 ESRD stations</u> in the HSA VIII ESRD Planning Area which consists of the counties of Lake, Kane, and McHenry. In response, the Applicants stated <i>““The proposed Fresenius Kidney Care Grayslake facility will maintain access for residents of the Grayslake healthcare market where there is a disproportionate ratio of stations to population demonstrating need and facilities operating at high utilization rates. Average utilization of all area facilities is 82%. Although there is not a determined need for stations in HSA 8, access limitations exist as they pertain to over-utilized existing facilities eliminating shift choice for new patients and the risk of 4th shift initiation as clinics reach capacity.”</i>
77 ILAC 1110.230 (c) – Unnecessary Duplication of Service/Mal-distribution	There are 8 facilities in the 10-mile radius of the proposed facility. Average utilization of these eight facilities is 80%. Three of the eight facilities are not at the target utilization of 80%. In response to this criterion, the Applicants stated <i>“The establishment of the Fresenius Kidney Care Grayslake facility will not create a mal-distribution of services as the station to population ratio indicates a need and area clinics are operating above the State standard at an average 82% Utilization. There is only access for 20 more patients</i>

State Board Standards Not Met	
Criteria	Reasons for Non-compliance
	<p><i>until all clinics are operating above 80%. While there may be excess stations in the HSA Planning area, there exists a "need" for additional stations in the 10-mile distance radius of the proposed Grayslake facility." Fresenius Kidney Care Grayslake 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 of Associates in Nephrology (AIN). No patients have been identified to be transferred from any other facility. As well, the overall utilization of area clinics is above the State standard of 80%. The applicant is not a hospital; however, the utilization will not be lowered at any other ESRD facility due to the establishment of the Grayslake facility. No patients have been identified to transfer to the new facility and the physicians supporting this project will continue to refer patients to nearby clinics per the patient's choice."</i></p>

STATE BOARD STAFF REPORT
Project #18-039
Fresenius Kidney Care Grayslake

APPLICATION/ CHRONOLOGY/SUMMARY	
Applicants(s)	Fresenius Medical Care Holdings, Inc. Fresenius Medical Care Grayslake, LLC d/b/a Fresenius Kidney Care Grayslake
Facility Name	Fresenius Kidney Care Grayslake
Location	Lot 2. SEC Rt. 120 at Rt. 45, PIN # 07631106006 (approximately 1817-1863 Belvidere Rd, Grayslake, Illinois)
Permit Holder	Fresenius Medical Care Holdings, Inc. Fresenius Medical Care Grayslake, LLC d/b/a Fresenius Kidney Care Grayslake
Operating Entity/Licensee	Fresenius Medical Care Grayslake, LLC d/b/a Fresenius Kidney Care Grayslake
Owner of Site	Health Property Services, Inc.
Proposed Gross Square Feet	7,659 GSF
Application Received	October 16, 2018
Application Deemed Complete	October 19, 2018
Financial Commitment Date	March 5, 2021
Anticipated Completion Date	March 31, 2021
Review Period Ends	February 17, 2019
Review Period Extended by the State Board Staff?	No
Can the Applicants request a deferral?	Yes

I. Project Description

The Applicants (Fresenius Medical Care Holdings, Inc. and Fresenius Kidney Care, LLC d/b/a Fresenius Kidney Care Grayslake) propose to establish a 10-station facility in Grayslake, Illinois at a cost of \$6,113,914. The anticipated project completion date is March 31, 2021.

II. Summary of Findings

- A. State Board Staff finds the proposed project not in conformance with all relevant provisions of Part 1110.
- B. State Board Staff finds the proposed project is in conformance with all relevant provisions of Part 1120.

III. General Information

The Applicants are Fresenius Medical Care Holdings, Inc. and Fresenius Medical Care Grayslake, LLC d/b/a Fresenius Kidney Care Grayslake. **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.

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

IV. Health Service Area

The proposed project is located in the HSA VIII ESRD Planning Area. HSA VIII consists of the Illinois counties of Kane, Lake, and McHenry. As of January 2019, there is a calculated excess of 55 stations in this planning area.

TABLE ONE

Need Methodology HSA VIII ESRD Planning Area	
Planning Area Population – 2015 (Est)	1,540,100
In Station ESRD patients -2015	1,541
Area Use Rate 2015	.910
Planning Area Population – 2020 (Est.)	1,692,900
Projected Patients – 2020	1,541
Adjustment	1.33
Patients Adjusted	2,050
Projected Treatments – 2020	319,727
Existing Stations	482
Stations Needed-2020	427
Number of Stations in Excess	55

V. Project Uses and Sources of Funds

The Applicants are funding this project with cash in the amount of \$2,096,374 and the Fair Market Value of Lease Expense of \$4,017,540.

**TABLE TWO
Project Uses and Sources of Funds**

Uses of Funds	Reviewable	Non-reviewable	Total	% of Total
Modernization Contracts	\$1,132,512	\$307,380	\$1,439,892	23.55%
Contingencies	\$108,432	\$29,430	\$137,862	2.25%
Architectural/Engineering Fees	\$122,150	\$32,470	\$154,620	2.53%
Movable or Other Equipment (not in construction contracts)	\$288,000	\$76,000	\$364,000	5.95%
Fair Market Value of Leased Space or Equipment	\$3,199,686	\$817,854	\$4,017,540	65.71%
Total Uses of Funds	\$4,850,780	\$1,263,134	\$6,113,914	100.00%
Sources of Funds				
Cash and Securities	\$1,651,094	\$445,280	\$2,096,374	34.29%
Leases (fair market value)	\$3,199,686	\$817,854	\$4,017,540	65.71%
Total Sources of Funds	\$4,850,780	\$1,263,134	\$6,113,914	100.00%

The Applicants provided a comment on the cost of project:

“While the cost of this project may appear higher than average for a 10-station facility, it should be noted that 62%, or \$4,017,540, are costs related directly to the lease of the space which is for 15 years. When Fresenius enters into a lease for space in a build-to-suit structure the developer/bank require a longer term lease to ensure they can amortize the costs. We engage in 10-year leases for space in an existing building. One is not necessarily more cost effective than the other. The 15-year lease just inflates the lease expense item line in the above costs. All construction, architecture and equipment costs always remain within Board standards. Fresenius does not generally enter into short-term leases, such as 5 years, because of our long-term commitment to the communities we serve. Fresenius' project costs are in line with other major dialysis provider's applications in Illinois. There is no corporate overhead or executive offices located in our clinics or included in any cost estimates of our clinics as it has been suggested by another provider. Spaces in the facility are either mandatory or necessary for the operation of the clinic and are standard across the industry.”

VI. Background of the Applicants, Purpose of the Project, Safety Net Impact, Alternatives

A) Criterion 1110.110(a) - Background of the Applicant

To address this criterion the applicants must provide a list of all facilities currently owned in the State of Illinois and an attestation documenting that no adverse actions¹ have been taken against any applicant's facility by either Medicare or Medicaid, or any State or Federal regulatory authority during the 3 years prior to the filing of the Application with the Illinois Health Facilities and Services Review Board or a certified listing of adverse action taken against any applicant's facility; and authorization to the State Board and Agency access to information in order to verify any documentation or information submitted in response to the requirements of the application for permit.

1. A listing of Fresenius Medical Care Dialysis Facilities has been provided at pages 42-43 of the Application for Permit.
2. The Applicants provided the necessary attestation that no adverse action has been taken against any facility owned or operated by the Applicants and authorization allowing the State Board and IDPH access to all information to verify information in the application for permit. [Application for Permit pages 44-45]
3. Evidence of ownership (Copy of the Letter of Intent to Lease the Property) of the site has been provided as required at pages 28-31 of the Application for Permit. Organizational relationships can be found at pages 33 of the Application for Permit.
4. A Certificate of Good Standing has been provided as required for Fresenius Medical Care Grayslake, LLC, as a foreign entity with permission to transact business in the State of Illinois. An Illinois Certificate of Good Standing is evidence that an Illinois business franchise (i.e. Illinois Corporation, LLC or LP) is in existence, is authorized to transact business in the state of Illinois, and complies with all state of Illinois business requirements and therefore is in "Good Standing" in the State of Illinois. [Application for Permit page 26]
5. The Applicants provided evidence that they were in compliance with Executive Order #2006-05 that requires *all State Agencies responsible for regulating or permitting development within Special Flood Hazard Areas shall take all steps within their authority to ensure that such development meets the requirements of this 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.* [Application for Permit page 34]

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

6. The proposed location of the 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). [Application for Permit page 35]

B) Criterion 1110.110(b) – 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 shall define the planning area or market area, or other area, per the applicant's definition. The Applicants shall address the purpose of the project, i.e., identify the issues or problems that the project is proposing to address or solve. Information to be provided shall include, but is not limited to, identification of existing problems or issues that need to be addressed, as applicable and appropriate for the project.

The Applicants stated in part that *“the 10-station Fresenius Kidney Care Grayslake End Stage Renal Disease (ESRD) facility is being proposed to provide access centrally located where overall utilization of clinics within a 10-mile radius is at 82%, restricting ESRD patient access and severely limiting access to favored treatment schedule times. Of the 8 facilities within this radius, 6 are above 80%, 1 is just under 80% leaving just one clinic with limited capacity. Using data as of June 30, 2018, only 20 more patients will bring all clinics above 80%.”* [Application for Permit page 46]

C) Criterion 1110.110(c) Safety Net Impact

All health care facilities, with the exception of skilled and intermediate long term care facilities licensed under the Nursing Home Care Act, shall provide a safety net impact statement, which shall be filed with an application for a substantive project (see Section 1110.40). *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]

This is a substantive project. The Applicants provided the required safety net information at pages 94-96 of the Application for Permit.

TABLE THREE
Safety Net Information ⁽¹⁾

Year	2015	2016	2017
#Charity Care/Self Pay Patients	195	233	280
Net Patient Revenue	\$438,247,352	\$449,611,441	\$460,678,799
Amount of Charity Care/Self Pay	\$3,204,986	\$3,269,127	\$4,552,654
Cost of Charity Care/Self Pay	\$3,204,986	\$3,269,127	\$4,552,654
# Medicaid Patients	396	320	328
Medicaid Revenue	\$7,310,484	\$4,383,383	\$6,630,014

1. As a for-profit corporation Fresenius does not provide charity care per the Board's definition. Numbers reported are self-pay. Self-pay balances are written off to bad debt. Medicare may reimburse a portion of bad debt as part of cost reporting.

D) Criterion 1110.110(d) - 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 alternatives to the proposed project

1. A project of greater or lesser scope
2. A joint venture project
3. Utilize other health care facilities in the 10-mile radius.

The Applicants rejected all three alternatives because they did not “provide access to a market where access is severely restricted due to high clinic utilization is to establish the 10-station Grayslake facility, which is centrally located to help alleviate over-utilization at Fresenius Round Lake and Gurnee, that have been over utilized for years despite station additions, and at Fresenius Mundelein that is just under 80% utilization. It will be approximately 2 years before the Grayslake facility is operating and the current high utilization will only increase, thereby eliminating access altogether. The cost of this project is \$6,113,914.” [See Application for Permit pages 47-49 for complete discussion]

VII. Project Scope and Size, Utilization and Unfinished/Shell Space

A) Criterion 1110. 120(a) - Size of Project

To demonstrate compliance with this criterion the Applicants must document that that the physical space proposed for the project is necessary and appropriate. The proposed square footage cannot deviate from the square footage range indicated in Appendix B, or exceed the square footage standard in Appendix B if the standard is a single number, unless square footage can be justified by documenting, as described in subsection (a)(2).

The Applicants are proposing 10 stations in 6,024 GSF of reviewable space or 603 GSF per station. The State Board Standard is 650 GSF per station. The Applicants have met this criterion.

B) Criterion 1110.120(b) - Project Services 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 Appendix B. The number of years projected shall not exceed the number of historical years documented. All Diagnostic and Treatment utilization numbers are the minimums per unit for establishing more than one unit, except where noted in 77 Ill. Adm. Code 1100. [Part 1110 Appendix B]

The Applicants are have identified 54 pre-ESRD patients that will require dialysis within 24 months of project completion. Should these patients require dialysis the Applicants will be at the target occupancy of 80% or more. The Applicants have successfully addressed this criterion.

$$\begin{aligned} 54 \text{ patients} \times 156 \text{ treatments per year} &= 8,424 \text{ treatments} \\ 10 \text{ stations} \times 936 \text{ treatments per year} &= 9,360 \text{ treatments} \\ 8,424 \text{ treatment} \div 9,360 \text{ treatments} &= 90\% \end{aligned}$$

C) Criterion 1110.120(e) - Assurances

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

The Applicants have provided the necessary attestation at page 82 of the Application for Permit

STATE BOARD STAFF FINDS THE PROPOSED PROJECT TO BE IN CONFORMANCE WITH CRITERION SIZE OF THE PROJECT, PROJECTED UTILIZATION, ASSURANCES (77 ILAC 1110.120(a), (b) & (e))

VIII. Establishment of ESRD Facility

A) Criterion 1110.230(b) - Planning Area Need

The applicant shall document that the number of stations to be established or added is necessary to serve the planning area's population, based on the following:

1) 77 Ill. Adm. Code 1100

- A) 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.
- B) The number of stations proposed shall not exceed the number of the projected deficit, to meet the health care needs of the population served, in compliance with the utilization standard specified in 77 Ill. Adm. Code 1100.

The State Board is estimating as of January 2019 that there will be an excess of 55 stations in the HSA VIII Planning Area by 2020.

2) Service to Planning Area Residents

- A) Applicants proposing to establish or add stations shall document that the primary purpose of the project will be to provide necessary health care to the residents of the area in which the proposed project will be physically located (i.e., the planning or geographical service area, as applicable), for each category of service included in the project.

All of the 54 pre-ESRD patients will be from the HSA VIII ESRD Planning Area as shown in the table below.

**TABLE FOUR
Pre-ESRD Patients**

Zip Code	Planning Area	County	City	Patients
60030	VIII	Lake	Grayslake	12
60031	VIII	Lake	Gurnee	7
60046	VIII	Lake	Lake Villa	7
60048	VIII	Lake	Libertyville	9
60060	VIII	Lake	Mundelein	9
60073	VIII	Lake	Round Lake	8
60084	VIII	Lake	Wauconda	3
Total				54

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

The number of stations proposed to establish a new in-center hemodialysis service is necessary to accommodate the service demand experienced annually by the existing applicant facility over the latest 2-year period, as evidenced by historical and projected referrals, or, if the applicant proposes to establish a new facility, the applicant shall submit projected referrals. The applicant shall document subsection (b)(3)(A) and either subsection (b)(3)(B) or (C).

The Applicants provided a signed and notarized referral letter from Jawad Munir, M.D., a nephrologist with Associates in Nephrology S.C., that states the practice (Associates in Nephrology S.C.) is caring for 454 Stage 3 and Stage 4 patients who live in the Grayslake Area. The Applicants have identified 54 patients by zip code of residence that live within the 10-mile radius that will utilize the proposed facility should the proposed project be approved. The number of projected referrals do not exceed the historical referrals as required.

5) Service Accessibility

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 shall document the following:

A) Service Restrictions

The applicant shall document that at least one of the following factors exists in the planning area:

- 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 (b)(5) only, all services within the established radii outlined in subsection (b)(5)(C) meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100.

The proposed facility will be located in the HSA VIII ESRD Planning Area (Kane, Lake, and McHenry counties). There is a calculated excess of 55 stations in the HSA VIII ESRD Planning Area. The Applicants have identified 54 pre-ESRD patients that will utilize the proposed facility within two years after completion. There is no absence of ESRD services in HSA VIII ESRD Planning Area. The existing providers do not have restrictive admission policies. There has been no access limitations due to the payor status of patients and there has been no indication of medical care problems of the population. The proposed facility will not be located in a health professional shortage area, or a medically underserved area or be providing services to a medically underserved population. Average utilization of facilities within the 5-mile radius is 82% with two of the facilities not at target occupancy.

The Applicants state

“The proposed Fresenius Kidney Care Grayslake facility will maintain access for residents of the Grayslake healthcare market where there is a disproportionate ratio of stations to population demonstrating need and facilities operating at high utilization rates. Average utilization of all area facilities is 82%. Although there is not a determined need for stations in HSA 8, access limitations exist as they pertain to over-utilized existing facilities eliminating shift choice for new patients and the risk of 4th shift initiation as clinics reach capacity.”

“Grayslake is centrally located between Fresenius Gurnee and Round Lake, both of which have been operating at average utilizations beyond 80% for 5 years or more. (The Gurnee facility just opened 8 additional stations to reduce over utilization and remains only 4 patients away from an 80% utilization rate). It will also be central to Fresenius Mundelein which just added two stations yet is at 82% utilization. Patients in Grayslake will need to travel well beyond their market past several full clinics to find shift choice availability. This creates a loss of continuity of care as some may have to change physicians and, in an emergency, may end up at a hospital where their healthcare team does not round. Numerous transportation problems will also arise since most patients are dependent on either family members for rides to and from treatment or medical car transportation companies that do not operate past 4 p.m.”

“Between 2000 and 2010 the Lake County population grew at 9% and projections to 2020 are remaining at 9%. This is higher than the State of Illinois overall rate of 3% and 2% projected. The elderly population more than doubled during this time. The elderly are more likely to require dialysis services as incidence of diabetes and hypertension increase with age. There were significant increases in minority populations who are also at a greater risk of kidney failure than the general population. There was an average 7% growth of ESRD in Lake County from 2013-2017. The Illinois ESRD Growth rate was only 3%.”[Application for Permit page 61]

Facility	City	Star Rating (1)	Miles (2)	Stations (3)	Patients (4)	Utilization	Met Standard?
FKC Round Lake	Round Lake	5	4.65	16	79	82.29%	Yes
FKC Gurnee	Gurnee	5	5.6	24	111	77.08%	No
DaVita Waukegan	Waukegan	3	6.4	24	132	91.67%	Yes
FKC Mundelein	Mundelein	5	6.84	14	68	80.95%	Yes
DaVita Lake County	Vernon Hills	5	7.73	16	57	59.38%	No
DaVita Lake Villa	Vernon Hills	5	8	12	58	80.56%	Yes
FKC Lake Bluff	Lake Bluff	4	8	16	69	71.88%	No
FKC Waukegan Harbor	Waukegan Harbor	4	8.76	21	110	87.30%	Yes
Total Stations/Patients/ Average Utilization				143	684	79.72%	

1. Star Rating taken from Medicare ESRD Compare Website
2. For facilities located in Lake County the GSA is 10-miles per 1110.230 (b) (5) (C)
3. Stations as of January 2019
4. Patients as of December 31, 2018

STATE BOARD STAFF FINDS THE PROPOSED PROJECT NOT IN CONFORMANCE WITH CRITERION PLANNING AREA NEED (77 ILAC 1110.230(b))

B) Criterion 1110.230(c) - Unnecessary Duplication/Mal-distribution

1) The applicant shall document that the project will not result in an unnecessary duplication.

The applicant shall provide the following information:

- A) A list of all zip code areas that are located, in total or in part, within the established radii outlined in subsection (c)(4) of the project's site;
 - B) The total population of the identified zip code areas (based upon the most recent population numbers available for the State of Illinois population); and
 - C) The names and locations of all existing or approved health care facilities located within the established radii outlined in subsection (c)(4) of the project site that provides the categories of station service that are proposed by the project.
- 2) The applicant shall document that the project will not result in maldistribution of services. Mal-distribution exists when the identified area (within the planning area) has an excess supply of facilities, stations and services characterized by such factors as, but not limited to:
- A) A ratio of stations to population that exceeds one and one-half times the State average;
 - B) Historical utilization (for the latest 12-month period prior to submission of the application) for existing facilities and services that is below the utilization standard established pursuant to 77 Ill. Adm. Code 1100; or
 - C) Insufficient population to provide the volume or caseload necessary to utilize the services proposed by the project at or above utilization standards.
- 3) The applicant shall document that, within 24 months after project completion, the proposed project:
- A) Will not lower the utilization of other area providers below the occupancy standards specified in 77 Ill. Adm. Code 1100; and
 - B) Will not lower, to a further extent, the utilization of other area hospitals that are currently (during the latest 12-month period) operating below the occupancy standards.

1. There are eight facilities with 143 stations within the 10-mile radius operating at an average of 80% utilization. Three (FKC Gurnee, DaVita Lake County, and FKC Lake Bluff with an average utilization of 70%) of the eight facilities are not at target occupancy of 80%. It appears that the proposed facility will result in an unnecessary duplication of service in this 10-mile GSA. See Table Five above.
2. There are 608,277 individuals that reside in the 10-mile radius of the proposed facility. There are 143 stations within this 10-mile radius. The ratio in this 10-mile radius is 1 station per 4,254 residents. The estimated population in the State of Illinois is 12,978,800 (2015 estimated) and the number of ESRD stations is 4,923. The ratio is 1 station per 2,637 residents in the State of Illinois. There is no surplus of stations in this 10-mile radius.
3. The Applicants have stated *“The establishment of the Fresenius Kidney Care Grayslake facility will not create a mal-distribution of services as the station to population ratio indicates a need and area clinics are operating above the State standard at an average 82% Utilization. There is only access for 20 more patients until all clinics are operating above 80%. While there may be excess stations in the HSA Planning area, there exists a "need" for additional stations in the 10-mile distance radius of the proposed Grayslake facility.”* Fresenius Kidney Care Grayslake 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 of Associates in Nephrology (AIN). No patients have been identified to be transferred from any other facility. As well, the overall utilization of area clinics is above the State standard of 80%. The applicant is not a hospital; however, the utilization will not be lowered at any other ESRD facility due to the establishment of the Grayslake facility. No patients have been identified to transfer to the new facility and the physicians supporting this project will continue to refer patients to nearby clinics per the patient's choice.”

STATE BOARD STAFF FINDS THE PROPOSED PROJECT NOT IN CONFORMANCE WITH CRITERION UNNECESSARY DUPLICATION/MALDISTRIBUTION/IMPACT TO AREA PROVIDERS (77 ILAC 1110.230(c))

C) Criterion 1110.230(e) - Staffing

The applicant shall document that relevant clinical and professional staffing needs for the proposed project were considered and that licensure and The Joint Commission staffing requirements can be met. In addition, the applicant shall document that necessary staffing is available by providing letters of interest from prospective staff members, completed applications for employment, or a narrative explanation of how the proposed staffing will be achieved.

The Applicants have provided the necessary information as required by this criterion at pages 66-75 of the Application for Permit. The Applicants have successfully addressed this criterion.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION STAFFING (77 ILAC 1110.230(e))

D) Criterion 1110.230(f) - Support Services

An applicant proposing to establish an in-center hemodialysis category of service 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 information as required by this criterion at page 76 of the Application for Permit. The Applicants have successfully addressed this criterion.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION SUPPORT SERVICES (77 ILAC 1110.230(f))

E) Criterion 1110.230(g) - Minimum Number of Stations

The minimum number of in-center hemodialysis stations for an End Stage Renal Disease (ESRD)

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

The proposed facility will be located in the Chicago-Naperville-Joliet-Gary, IL-IN-WI Metropolitan Statistical Area (MSA). The Applicants have met the requirements of this criterion as the proposed facility is for 10 stations.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION CONTINUITY OF CARE (77 ILAC 1110.230(g))

F) Criterion 1110.230(h) - Continuity of Care

An applicant proposing to establish an in-center hemodialysis category of service shall 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 a sign copy of the Affiliation Agreement with Advocate Condell Medical Center. See Additional information provided by the Applicants on 11/27/2018. The Applicants have met the requirements of this criterion.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION CONTINUITY OF CARE (77 ILAC 1110.230(h))

G) Criterion 1110.230(i) - Relocation of Facilities

This criterion may only be used to justify the relocation of a facility from one location in the planning area to another in the same planning area and may not be used to justify any additional stations. A request for relocation of a facility requires the discontinuation of the current category of service at the existing site and the establishment of a new category of service at the proposed location. The applicant shall document the following:

- 1) That the existing facility has met the utilization targets detailed in 77 Ill. Adm. Code 1100.630 for the latest 12-month period for which data is available; and

- 2) That the proposed facility will improve access for care to the existing patient population.

The Applicants are not proposing a relocation of an existing facility.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION RELOCATION OF FACILITIES (77 ILAC 1110.230(i))

H) Criterion 1110.230(j) - Assurances

The applicant 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 Applicants have provided the necessary assurance as required at page 82 of the Application for Permit.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION ASSURANCES (77 ILAC 1110.230 (j))

IX. 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 \$2,096,374 and the fair market value of leased space totaling \$4,017,540. 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.²

TABLE SIX
FMC Holdings Inc. Audited Financial Statements
(Dollars in Thousands 000)
December 31st

	2014	2015	2016	2017
Cash & Investments	\$195,280	\$249,300	\$357,899	\$569,818
Current Assets	\$4,027,091	\$4,823,714	\$5,208,339	\$4,519,571
Total Assets	\$18,489,619	\$19,332,539	\$20,135,661	\$19,822,127
Current Liabilities	\$2,058,123	\$2,586,607	\$2,799,192	\$2,900,783
Long Term Debt	\$2,669,500	\$2,170,018	\$2,085,331	\$1,755,960
Total Liabilities	\$9,029,351	\$9,188,251	\$9,602,364	\$9,279,633
Total Revenues	\$10,373,232	\$11,691,408	\$12,806,949	\$13,919,204
Expenses	\$9,186,489	\$10,419,012	\$11,185,474	\$12,003,776
Income Before Tax	\$1,186,743	\$1,272,396	\$1,621,175	\$1,915,428
Income Tax	\$399,108	\$389,050	\$490,932	\$407,606
<i>Net Income</i>	\$787,635	\$883,346	\$1,130,243	\$1,507,822

Source: 2014/2015/2016/2017 Audited Financial Statements

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

² 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.

X. ECONOMIC FEASIBILITY

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

The Applicants provided a copy of a letter of intent to lease 7,659 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 \$30.00 per SF, which shall escalate on an annual basis by two percent (2%) per year, beginning at the beginning of year three.

The Applicants attested that entering into a lease (borrowing) is less costly than liquidating existing investments which would be required for the Applicants to buy the property and build a structure itself to house a dialysis clinic. (See Application for Permit pages 91-92)

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) & 77 ILAC 1120.140(b))

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

Only Reviewable Costs are reviewed in this criterion. As illustrated in Table Seven, the Applicants are in compliance with the Standards in Part 1120 Appendix A.

**TABLE SEVEN
REASONABLENESS OF PROJECT COSTS**

	Project Costs		State Standard		Difference		Met Standard?	
	Total	GSF/%	Total	GSF/%/Station	Total	GSF/%/Station		
Modernization Contracts & Contingencies	\$1,240,944	\$206/GSF	\$1,360,822	\$225.90/GSF	-\$119,878	-\$19.90/GSF	Yes	
Contingencies	\$108,432	9.57%	\$169,877	15.00%	-\$61,445	-5.43%	Yes	
Architectural/Engineering Fees	\$122,150	9.84%	\$133,774	10.78%	-\$11,624	-0.94%	Yes	
Movable or Other Equipment (not in construction contracts)	\$288,000	\$28,800	\$622,330	\$62,233 Station	\$334,330	-33,433/Station	Yes	
Fair Market Value of Leased Space or Equipment	\$3,199,686		No Standard					

Calculation of State Board Standards for Modernization and Contingency Costs and ESRD Cost per Station

Year	2015	2016	2017	2018	2019	2020	2021	2022	2023
Modernization & Contingency Costs	\$178.33	\$183.68	\$189.19	\$194.87	\$200.71	\$206.73	\$212.94	\$219.32	\$225.90
Cost Per Station	\$49,127	\$50,601	\$52,119	\$53,683	\$55,293	\$56,952	\$58,661	\$60,420	\$62,233

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) - Direct Operating Costs

The Applicants shall provide 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 costs means the fully allocated costs of salaries, benefits and supplies for the service.

The Applicants are estimating \$231.83 per treatment in direct operating costs. The State Board does not have a standard for this cost.

Estimated Personnel Expense:	\$932,745
Estimated Medical Supplies:	\$168,483
Estimated Other Supplies (Exc. Dep/Amort):	\$821,648
Total	\$1,922,876
Estimated Annual Treatments:	8,294
Direct Cost Per Treatment:	\$231.83

STATE BOARD STAFF FINDS THE PROPOSED PROJECT 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

The Applicants shall provide the total projected annual capital costs (in current dollars per equivalent patient day) for the first full fiscal year at target utilization but no more than two years following project completion.

The Applicants are estimating \$12.06 in capital costs. The State Board does not have a standard for this cost.

Depreciation/Amortization:	\$100,050
Interest	\$0
Capital Costs:	\$100,050
Treatments:	8,294
Capital Cost per Treatment:	\$12.06

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