

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 23, 2017

Findings Date: May 23, 2017

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: G-11303-17

Facility: Fresenius Kidney Care Garber-Olin

FID #: 170123

County: Guilford

Applicant(s): Bio-Medical Applications of North Carolina, Inc.

Project: Develop a new 28 station dialysis facility by relocating 14 stations from BMA of Greensboro and 14 stations from BMA of South Greensboro

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Kidney Care Garber-Olin (FKC Garber-Olin), proposes to develop a new 28-station dialysis facility in Greensboro by relocating 14 stations from BMA of Greensboro and 14 stations from BMA of South Greensboro. All three facility locations are in Guilford County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, BMA of Greensboro will be certified for 42 dialysis stations and BMA of South Greensboro will be certified for 35 dialysis stations following completion of this project and Project ID #G-11055-15 (relocate ten stations to Fresenius Medical Care High Point).

Need Determination

The applicant is proposing to relocate existing dialysis stations within Guilford County, therefore there are no need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) applicable to this review.

Policies

There are two policies in the 2017 SMFP that are applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 33, and *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure is greater than \$2 million, but less than \$5 million. In Section B.5, pages 18-19, Section K.1, pages 62-63, and Exhibits K-1 and K-2, the applicant describes how it will assure improved energy efficiency and water conservation. Therefore, the application is conforming to Policy GEN-4.

Policy ESRD-2: Relocation of Dialysis Stations states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to develop a new 28-station dialysis facility in Greensboro, by relocating existing dialysis stations from both BMA of Greensboro and BMA of South Greensboro. The two existing facilities and the proposed facility are located in Guilford County, therefore there is no change in the dialysis station inventory in Guilford County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with all applicable policies in the 2017 SMFP.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new 28-station dialysis facility in Greensboro by relocating 14 stations from BMA of Greensboro and 14 stations from BMA of South Greensboro. All three facility locations are in Guilford County.

The following tables, summarized from pages 4-5 of the application, illustrate the proposed FKC Garber-Olin stations, and the current projects under development which impact the number of dialysis stations at BMA of Greensboro and BMA of South Greensboro, the two

facilities from which the applicant plans to relocate stations to develop the proposed new facility.

Fresenius Kidney Care Garber-Olin

Stations	Description	Project ID #
0	Total existing certified stations as of the January 2017 SDR	
+28	Stations to be added as part of this project	G-11303-17
28	Total stations upon completion of above projects	

BMA of Greensboro

Stations	Description	Project ID #
56	Total existing certified stations as of the January 2017 SDR	
-14	Stations to be deleted as part of this project	G-11303-17
42	Total stations upon completion of above projects	

BMA of South Greensboro

Stations	Description	Project ID #
59	Total existing certified stations as of the January 2017 SDR	
-14	Stations to be deleted as part of this project	G-11303-17
-10	Stations previously approved to be deleted but not yet certified	G-11055-15
35	Total stations upon completion of above projects	

As the tables above illustrate, FKC Garber-Olin will be certified for 28 dialysis stations and BMA of Greensboro will be certified for 42 stations at project completion; BMA of South Greensboro will be certified for 35 dialysis stations at completion of this project and Project ID #G-11055-15 (relocate 10 stations from BMA of South Greensboro to develop Fresenius Medical Care High Point).

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* The proposed new facility, FKC Garber-Olin, is located in Guilford County; thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

FKC Garber-Olin will be a new facility in Guilford County and therefore has no existing patient origin.

In Section C.1, page 20, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion for in-center patients, as illustrated in the following table:

**Fresenius Kidney Care Garber-Olin
 Projected Patient Origin by County**

County	Operating Year 1 1/1/19 –12/31/19	Operating Year 2 1/1/20-12/31/20	County Patients as Percent of Total	
	In-Center Patients	In-Center Patients	Year 1	Year 2
Guilford	93.6	97.3	100.0%	100.0%
Total*	93	97	100.0%	100.0%

*Rounded down to the whole patient

As the above table illustrates, the applicant does not propose to serve home hemodialysis or peritoneal dialysis patients.

In Section C.1, pages 20-22, the applicant provides the assumptions and methodology used to project patient origin. The applicant states that projected patient origin is based on 90 of the existing 94 Guilford County patients living in close proximity to the proposed facility who signed letters stating their willingness to transfer their care to the proposed facility. Exhibit C-1 contains copies of the 94 signed letters.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to develop a new 28-station dialysis facility in Greensboro by relocating 14 stations from BMA of Greensboro and 14 stations from BMA of South Greensboro.

In Section C.2, page 22, the applicant states:

“The need methodology for dialysis stations is focused on four patient shifts per week and recognizes that patients will dialyze on a Monday-Wednesday-Friday, morning or afternoon shift schedule, or on a Tuesday-Thursday-Saturday, morning or afternoon shift schedule. Failure to receive dialysis care will ultimately lead to the patient’s demise.”

The applicant has included 94 in-center patient letters of support, which indicate the patient would consider transferring their care to the new facility. The applicant states that each of these patients resides in close proximity to the proposed facility location, is currently receiving dialysis care at a Fresenius-affiliated dialysis facility in Guilford County, and has expressed a willingness to transfer to the proposed location because it is more convenient and closer to their homes. The applicant provides a table on page 21 of the application showing at

which Fresenius-affiliated facility the 94 Guilford County patients are currently dialyzing, as summarized below.

Facility	Number of Patients
BMA Burlington	1
FMC of East Greensboro	30
BMA of Greensboro	39
BMA of South Greensboro	22
BMA of Southwest Greensboro	2
Total	94

The applicant further states that the need this population has for the proposed service is a function of the individual patient need for dialysis care, and the stated desire of the patients to have dialysis at the proposed facility.

Projected Utilization

In Section C.1, pages 20-22, the applicant provides the following assumptions used to project utilization:

- The applicant plotted the residence location of patients dialyzing at Fresenius-affiliated facilities within Guilford County. The applicant includes 94 letters (Exhibit C-1) from patients who reside in close proximity to the proposed facility, who could be better served by the proposed location.
- The applicant projects, based on the patient letters, that 90 in-center dialysis patients will transfer their care to the new facility upon project certification. This is 96% of the patients who signed letters stating willingness to consider transferring their care to the proposed facility.
- The applicant states that the project will be completed on December 31, 2018. Operating Year 1 (OY1) is the period from January 1 through December 31, 2019. Operating Year 2 (OY2) is the period from January 1 through December 31, 2020.
- The applicant assumes that the Guilford County dialysis patients transferring to the new facility are part of the Guilford County ESRD patient population as a whole, and that this population will increase at a rate commensurate with the Guilford County Five Year Average Annual Change Rate (AACR) of 4.0%, as published in the January 2017 Semiannual Dialysis Report (SDR).

In Section C.1, page 21, the applicant provides a methodology table used to project utilization, as summarized below:

FKC Garber-Olin	In-Center
Begin with 90 in-center dialysis patients projected to transfer their care to the new facility upon certification of the project, December 31, 2018.	90
The applicant projects the patient population forward to December 31, 2019, the end of OY1, using the Guilford County Five Year AACR of 4.0%.	$(90 \times 0.040) + 90 = 93.6$
The applicant projects the patient population forward to December 31, 2020, the end of OY2, using the Guilford County Five Year AACR of 4.0%.	$(93.6 \times 0.04) + 93.6 = 97.3$

The applicant states on page 20, that it rounds down to the whole patient. Therefore, the applicant projects that at the end of OY1, 93 patients will be dialyzing on 28 stations for a projected utilization rate of 3.3 patients per station per week (93 in-center patients / 28 stations = 3.321) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C.2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need the projected population has for the proposed facility.

Access

In Section L.1, page 69, the applicant states:

“It is policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L.1, page 70, the applicant projects that over 87% of its in-center patients will be covered by some combination of Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population projected to be served has for the proposed services based on reasonable and supported utilization projections and assumptions, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect

of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new 28-station dialysis facility in Greensboro by relocating 14 dialysis stations each, from both BMA of Greensboro and BMA of South Greensboro. The two existing facilities and the proposed facility are located in Guilford County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, FKC Garber-Olin will be certified for 28 dialysis stations, BMA of Greensboro will be certified for 42 dialysis stations ($56 - 14 = 42$), and BMA of South Greensboro will be certified for 35 dialysis stations following completion of this project and Project ID #G-11055-15 (relocate ten stations to develop Fresenius Medical Care High Point, a new facility) ($59 - 14 - 10 = 35$).

The following table shows the proposed relocation of stations and transfer of Guilford County dialysis patients projected for the proposed FKC Garber-Olin project.

Facility	Number of Stations to be Relocated	Number of Patients Transferring
BMA of Greensboro	14	39
BMA of South Greensboro	14	24
BMA of Southwest Greensboro	0	27
Total	28	90

BMA of Greensboro

In Section D.1, pages 32-34, the applicant states that as of December 31, 2016, as reported to DHSR Healthcare Planning as part of the ESRD Data Collection reporting for the period ended December 31, 2016, there were 179 patients dialyzing at BMA of Greensboro on 56 dialysis stations, for a utilization rate of 79.9%. In addition, the applicant states that 175 of the 179 in-center patients lived in Guilford County, with two patients from Randolph County and two from other states and considered transient.

In Project ID #G-11055-15, BMA projected that six patients from BMA of Greensboro would transfer to FMC High Point, upon completion of that project on June 30, 2017. Based on letters of support, the applicant assumes 39 Guilford County patients will transfer to the proposed facility, upon completion of this project at December 31, 2018.

The applicant assumes that the number of in-center patients at BMA of Greensboro who live in Guilford County will increase at 4.0% per year based on the Five Year AACR for Guilford County, as reported in Table B of the January 2017 SDR. The applicant assumes that no growth will occur for the 2 in-center patients from Randolph County and the two transient patients will not be projected forward. In Section D.1, page 34, the applicant calculates the

in-center patient census for BMA of Greensboro starting December 31, 2016 through OY1 (CY2019) and OY2 (CY2020), illustrated as follows:

BMA of Greensboro	In-Center Patients
Begin with the ESRD patient population of Guilford County, as of December 31, 2016.	175
Project this population forward for 6 months to June 30, 2017, using the Five Year AACR for Guilford County.	$[175 \times (0.04 / 12 \times 6)] + 175 = 178.5$
Subtract 6 patients projected to transfer their care to FMC High Point on June 30, 2017.	$178.5 - 6 = 172.5$
Project this population forward for 6 months to December 31, 2017, using the Five Year AACR for Guilford County.	$[172.5 \times (0.04 / 12 \times 6)] + 172.5 = 176.0$
Project this population forward for 12 months to December 31, 2018, using the Five Year AACR for Guilford County.	$(176 \times 0.04) + 176 = 183.0$
Subtract 39 Guilford County patients projected to transfer their care to FKC Garber-Olin.	$183 - 39 = 144.0$
Add 2 patients from Randolph County	$144.0 + 2.0 = 146.0$

Thus, at December 31, 2018, BMA of Greensboro is projected to have 42 (56 - 14 = 42) certified dialysis stations with a patient population of 146 in-center dialysis patients. Utilization is calculated to be 3.48 patients per station ($146 / 42 = 3.476$). Therefore, the applicant states that no patients will be adversely impacted by this application to relocate 14 stations and transfer 39 patients from BMA of Greensboro to FKC Garber-Olin.

BMA of South Greensboro

In Section D.1, pages 34-36, the applicant states that as of December 31, 2016, as reported to DHSR Healthcare Planning as part of the ESRD Data Collection reporting for the period ended December 31, 2016, there were 182 patients dialyzing at BMA of South Greensboro on 59 dialysis stations, for a utilization rate of 77.1%. In addition, the applicant states that 173 of the 182 in-center patients lived in Guilford County.

In Project ID #G-11287-17, BMA projected that six patients from BMA of South Greensboro would transfer to Northwest Kidney Center with the relocation of four stations from BMA of South Greensboro, upon completion of that project on December 31, 2017. Based on letters of support, the applicant assumes 24 Guilford County patients will transfer from BMA of South Greensboro to the proposed facility, upon completion of this project at December 31, 2018.

The applicant assumes that the number of in-center patients at BMA of South Greensboro who live in Guilford County will increase at 4.0% per year based on the Five Year AACR for Guilford County, as reported in Table B of the January 2017 SDR. The applicant assumes that no growth will occur for the four in-center patients from Randolph County and the one in-center patient from Rockingham County. The other non-Guilford County patients are

considered to be transient patients and will not be projected forward. In Section D.1, page 36, the applicant calculates the in-center patient census for BMA of South Greensboro starting December 31, 2016 through OY1 and OY2, illustrated as follows:

BMA of South Greensboro	In-Center Patients
Begin with the ESRD patient population of Guilford County, as of December 31, 2016.	173
Project this population forward for 6 months to June 30, 2017, using the Five Year AACR for Guilford County.	$[173 \times (0.04 / 12 \times 6)] + 173 = 176.5$
Subtract 6 patients projected to transfer their care to FMC High Point on June 30, 2017.	$176.5 - 6 = 170.5$
Project this population forward for 6 months to December 31, 2017, using the Five Year AACR for Guilford County.	$[170.5 \times (0.04 / 12 \times 6)] + 170.5 = 173.9$
Subtract 6 patients projected to transfer their care to Northwest Greensboro Kidney Center on December 31, 2017.	$173.9 - 6 = 167.9$
Project this population forward for 12 months to December 31, 2018, using the Five Year AACR for Guilford County.	$(167.9 \times 0.04) + 167.9 = 174.6$
Subtract 24 Guilford County patients projected to transfer their care to FKC Garber-Olin.	$174.6 - 24 = 150.6$
Add 5 patients from Randolph and Rockingham counties	$150.6 + 5.0 = 155.6$

Thus, at December 31, 2018, BMA of South Greensboro is projected to have 35 (59 -10 -14 = 35) certified dialysis stations with a patient population of 155 (rounded down per the applicant's methodology as stated on page 20) in-center dialysis patients. Utilization is calculated to be 4.43 patients per station ($155 / 35 = 4.429$).

The applicant states that based on the facility need methodology, BMA of South Greensboro is expected to qualify for expansion in March 2018, as would be reported in the January 2018 SDR (June 30, 2017 data: 176.5 Guilford County patients + 5.0 Randolph and Rockingham patients = 180.5 patients dialyzing on 49 stations for a utilization rate of 3.684 patients per station). The applicant states that BMA will apply for seven stations for an April 2018 review and provides the facility need supporting calculations on page 37. Assuming approval of the application to add seven stations, the facility would have a census of 156 patients dialyzing on 42 stations the day following relocation of the stations and transfer of patients to FKC Garber-Olin, equating to a utilization rate of 3.71 patients per station.

Therefore, the applicant states that the relocation of stations and transfer of patients to FKC Garber-Olin will not create any undue hardship or impair admissions to BMA of Greensboro or BMA of South Greensboro.

In Section L.1(b), page 70, the applicant states that the projected payor mix at the proposed facility is based on the payor mix of BMA of Greensboro and BMA of South Greensboro, the facilities which are contributing the stations to the project. Thus, the proposed relocation of

stations will not have an adverse impact on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

Thus, the applicant demonstrates that the needs of the populations presently served at BMA of Greensboro and BMA of South Greensboro will continue to be adequately met following the proposed relocation of 14 dialysis stations and the transfer of patients from each facility to FKC Garber-Olin; and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E.1, pages 39-40, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

1. Maintain the Status Quo – the applicant dismissed this alternative based on the fact that there is a significant number of patients dialyzing with BMA and residing in close proximity to the proposed FKC Garber-Olin facility, who can be more conveniently served by the development of the proposed facility. Therefore, the applicant determined this would not be the most effective alternative.
2. Develop Facility in Another Area in Guilford County – the applicant states that based on its evaluation of existing patients served by Fresenius-affiliated facilities, coupled with projections of future patient populations, a significant number of patients would be better served in the proposed location. Thus, the applicant determined any other location would be less effective at this time.
3. Develop a Larger Facility with More Stations – after evaluation of the patient population served, the applicant states that it determined that FKC Garber-Olin should only have 28 stations to open the facility with a patient population of sufficient size to meet the Performance Standards at 10A NCAC 14C .2203. Thus, the applicant determined a larger facility would be more costly and therefore, not the most effective alternative.
4. Expand Existing Facilities - the applicant states that existing Fresenius-affiliated related facilities have very little opportunity for physical plant expansion. The applicant states that all of the existing BMA facilities in Guilford County are essentially at physical plant capacity and that in order to serve patients of the proposed area in a convenient setting, a new facility is required; therefore, the applicant rejected this alternative.

5. Apply to Offer Home Therapies – the applicant states that it could have proposed to provide home therapies at this location, however BMA has a centralized home therapies program in Greensboro. The applicant states that utilization of a consolidated home therapies program will reduce development costs for the proposed facility. Therefore, the applicant rejected this alternative as more costly.

Thus, after considering the above alternatives, the applicant concluded that its proposal to develop a new 28-station dialysis center by relocating stations from BMA of Greensboro and BMA of South Greensboro is the most cost effective alternative.

Furthermore, the application is conforming or conditionally conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Garber-Olin shall materially comply with all representations made in the certificate of need application.**
2. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Garber-Olin shall relocate no more than 14 dialysis stations from BMA of Greensboro and no more than 14 dialysis stations from BMA of South Greensboro.**
3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Garber-Olin shall install plumbing and electrical wiring through the walls for no more than 28 dialysis stations, which shall include any isolation or home hemodialysis stations.**
4. **Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 14 dialysis stations at BMA of Greensboro for a total of no more than 42 dialysis stations at BMA of Greensboro upon completion of this project and to decertify 14 dialysis stations at BMA of South Greensboro for a total of no more than 35 dialysis stations at BMA of South Greensboro upon completion of this project and Project ID #G-11055-15 (relocate 10 stations to Northwest Kidney Center).**
5. **The approved capital expenditure is \$2,868,546.**
6. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Garber-Olin shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 28-station dialysis facility in Greensboro by relocating 14 stations from BMA of Greensboro and 14 stations from BMA of South Greensboro.

Capital and Working Capital Costs

In Section F.1, page 42, the applicant provides the capital cost of the project as summarized in the following table:

**FKC Garber-Olin
 Project Capital Costs**

		Total Capital Costs
Construction Project Costs		
Construction Contract	\$2,182,186	
Sub-Total Construction Costs		\$2,182,186
Miscellaneous Project Costs		
Water Treatment Equipment	\$225,000	
Equipment/Furniture	\$214,970	
Architect & Engineering Fees	\$137,279	
Other: Contingency	\$109,109	
Generator	\$78,852	
Sub-Total Miscellaneous Costs		\$686,359 [\$765,210]
Total Capital Cost		\$2,868,546 [\$2,947,396]

Totals may not sum due to rounding

The applicant's sub-total for miscellaneous costs is incorrectly summed, therefore the total project capital cost is incorrectly summed. The Project Analyst includes the correct sum in [brackets], a difference of \$78,850.

In Section F.10, pages 45-46, Section F.11, page 46, and Section F.12, page 46, the applicant estimates start-up expenses of \$288,974 and initial operating expenses of \$2,777,426, respectively, for a total working capital \$3,066,400.

Availability of Funds

In Exhibit F-1, the applicant provides a letter dated March 15, 2017 from the Senior Vice President & Treasurer of the parent company, Fresenius Medical Care Holdings, Inc. (FMC), authorizing the project and committing cash reserves for the capital expenditure in the amount of \$2,868,546. The letter also authorizes additional funds as necessary for start-up costs. Exhibit F-2 contains the FMC and Subsidiaries Consolidated Financial Statements, as of December 31, 2015, showing cash and cash equivalents of \$249,300,000, total assets of \$19,332,539,000 and net assets (total assets less total liabilities) of \$8,915,722,000. The applicant adequately demonstrates the availability of funds for the capital, working capital, and operating needs of the project, as conditioned by Condition (5) in Criterion (4).

Financial Feasibility

In Section R, Form C, page 90, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

Allowable Charges

Payor	In-Center Charge
Self Pay/Indigent/ Charity	\$224.22
Medicare	\$237.17
Medicaid	\$209.64
Commercial Insurance	\$990.02
Medicare/Commercial	\$293.80
Miscellaneous, including VA	\$314.10

In Section R, page 91, the applicant states that it calculates an average number of in-center patients (number of patients at the beginning of the year + number of patients at the end of the year / 2), rounded down to the nearest whole number, to calculate its revenues for the first and second operating years of the project. Therefore, the number of in-center patients used in operating year one was 91, and the number of in-center patients used in operating year two was 95.

In Section R, page 89, the applicant projects operating expenses and revenues, summarized as follows:

FKC Garber-Olin

	Operating Year 1	Operating Year 2
Average # of In-Center Patients	91	95
Projected Treatments ((156 / Pt) - 5%)	13,486	14,079
Projected Average Charge (Gross Patient Revenue / Projected # Treatments)	\$3,988	\$3,988
Gross Patient Revenue	\$53,782,168	\$56,147,052
Deductions from Gross Patient Revenue	\$49,579,753	\$51,759,850
Net Patient Revenue	\$4,202,415	\$4,387,202
Total Expenses	\$4,166,139	\$4,294,393
Net Income	\$36,276	\$92,808

Totals may not sum due to rounding

The applicant projects that revenues will exceed operating expenses in each of the first two operating years of the project. However, the staffing expense related to Dietary and Social Services was under-reported on Form A by a total of \$3,708 in OY2, when compared to the staffing chart of budgeted salary in Section F.14(d), page 48, and Section H.1, page 53. Both Sections F and H project salary expense for Dietary and Social Services in OY2 as \$65,913 and \$61,368, respectively. Form A, page 86, does not show the “OY2” amounts from Sections F and H, the OY2 column in Form A reflects the amounts for the “OY1” salary expense for Dietary and Social Services from Sections F and H, \$63,993 and 59,580, respectively. Therefore, the expense shown on Form A for Dietary and Social Services in OY2 is under-reported by a total of \$3,708, an insignificant amount when compared to the projected Net Income for OY2 of \$92,808. The assumptions used in preparation of the pro forma financial statements are reasonable, including projected utilization, cost and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital, working capital, and operating needs of the project, as conditioned by Condition (5) in Criterion (4). Furthermore, the applicant demonstrates the financial feasibility of the proposal is based on reasonable projections of cost and charges. Therefore, the application is conforming to this criterion, as conditioned.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new 28-station dialysis facility in Greensboro by relocating 14 stations from BMA of Greensboro and 14 stations from BMA of South Greensboro. All three facility locations are in Guilford County. The applicant does not

propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, FKC Garber-Olin will be certified for 28 stations, BMA of Greensboro will be certified for 42 dialysis stations and BMA of South Greensboro will be certified for 35 dialysis stations following completion of this project and Project ID #G-11055-15 (relocate ten stations to Fresenius Medical Care High Point).

On page 373, the 2017 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* The proposed new facility, FKC Garber-Olin, is located in Guilford County; thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR, there are eight dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	79.91%	3.1964
BMA of South Greensboro (FMC)*	59	76.69%	3.0678
BMA of Southwest Greensboro (FMC)	33	88.64%	3.5455
FMC of East Greensboro (FMC)	35	92.86%	3.7143
FMC High Point (FMC Proposed Site)*	0	0.00%	0.0000
High Point Kidney Center (WFUHS)**	42	91.07%	3.6429
Northwest Greensboro Kidney Center (FMC)	33	75.00%	3.0000
Triad Dialysis Center (WFUHS)	22	94.32%	3.7727

Source: January 2017 SDR, Table A.

* Project ID #G-11055-15 approved the relocation of 10 stations from BMA of South Greensboro to develop FMC High Point in Guilford County, leaving a total of 49 stations at BMA of South Greensboro upon project completion.

** Approved to relocate 10 stations to North Randolph Dialysis Center in Randolph County in Project ID #G-10262-14, leaving a total of 32 stations at High Point Kidney Center upon project completion.

As illustrated above, FMC or Fresenius-affiliated entities own five of the seven operational dialysis facilities in Guilford County. FMC High Point is an approved Fresenius-affiliated 10-station facility, which is not yet operational. Wake Forest University Health Sciences operates the other two Guilford County dialysis facilities. All of the Guilford County dialysis facilities are reasonably well-utilized, operating at or above 75% utilization or three patients per station.

According to Table B in the January 2017 SDR, there is a surplus of six dialysis stations in Guilford County. However, the applicant is not increasing the number of dialysis stations in Guilford County, rather it is proposing to relocate 28 existing Guilford County stations to

develop a new facility that is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, rather it is proposing to create a new facility to better serve existing patients using existing stations.

In Section C.1, page 20, the applicant demonstrates that FKC Garber-Olin will serve a total of 93 in-center patients on 28 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 83.0% ($93 / 28 = 3.32$; $3.32 / 4 = 0.830$). The applicant provides documentation in Exhibit C-1 from 94 Guilford County in-center patients dialyzing at Fresenius-affiliated facilities indicating their willingness to consider transferring to FKC Garber-Olin because its location would be more convenient. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the need to relocate existing Guilford County Fresenius-affiliated dialysis stations to develop a new Fresenius dialysis facility in Guilford County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on the needs of the population presently served at both BMA of Greensboro and BMA of South Greensboro, found in Criterion (3a), is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Guilford County. Consequently, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section H.1, page 53, the applicant provides the projected staffing for FKC Garber-Olin in OY2 by FTE position, as shown in the table below:

FKC Garber-Olin Proposed FTE Positions OY2	
Position	Total
Registered Nurse	6.00
Patient Care Technician	12.00
Clinical Manager	1.00
Administrator	0.25
Dietitian	1.00
Social Worker	1.00
Chief Tech	0.25
Equipment Tech	1.00
In-Service	0.25
Clerical	1.00
Total FTEs	23.75

Note: The Medical Director is an independent contractor, not an employee.

In Exhibit I.5, the applicant provides a letter from Dr. James Deterding, dated March 7, 2017, indicating his support for the project and his willingness to serve as Medical Director of the facility. In Section H.3, page 54, the applicant states it does not anticipate any difficulties in filling staff positions as it provides a range of benefits and competitive salaries to attract qualified staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I.1, page 57, the applicant lists the providers of the necessary ancillary and support services for the proposed project. The table states that acute dialysis in an acute care setting, blood bank services, diagnostic/evaluation, and X-ray services will be referred to Cone Health. Exhibit I-3 includes a letter of support from Cone Health affirming a willingness to provide those services to FKC Garber-Olin patients. Exhibit I-4 contains a letter from UNC Hospitals agreeing to enter in to an agreement with FKC Garber-Olin to provide its patients with transplant services. Exhibit I-1 contains an agreement for home training services at BMA of Greensboro. Exhibit I-2 contains an agreement for lab services between Spectra and FMC. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 58-60, stating that Fresenius has relationships with the medical community in the area, including area physicians and hospitals. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable

and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K.2, page 64, the applicant states that the proposed facility has 4,854 square feet of treatment area, which includes isolation space. The applicant provides the proposed facility's line drawings in Exhibit K-1. The drawing depicts a 10,214 square foot facility, with 27 main floor dialysis stations and an isolation dialysis station, for a total of 28 stations. In Section F.1, page 41, the applicant states that it relies upon the Fresenius Facility Design and Maintenance Department to develop anticipated project development costs. On page 42, the applicant provides the proposed costs, including \$2,182,186 for construction, \$686,359 [\$765,210] in miscellaneous costs, including water treatment equipment, furniture, architect/engineering fees, and contingency for a total project cost of \$2,868,546 [2,947,396]. (Sums correctly calculated by the Project Analyst are shown in [brackets]). In Section K.1, pages 62-64, the applicant describes its plans for energy-efficiency, including water conservation. The applicant states its plans for implementing applicable energy saving features and water conservation methods, include the following:

- The building plumbing systems will be designed to ensure conservation of water.
- The exterior roof, walls and glass systems will meet current requirements for energy conservation.
- HVAC system operating efficiency "will equal current industry standards for high seasonal efficiency." In addition, the system will be controlled via 7 day/24 hour set back time clock and maintained and serviced quarterly.
- Energy efficient exit signs, water flow restrictors at sink faucets, water conserving flush toilets, optical sensor water switches and external insulation wrap for hot water heaters will be used for energy and water conservation.

- Water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors which run cooler and use less amperage.

Costs and charges are described by the applicant in Section F, pages 42-50, and in Section R proforma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

FKC Garber-Olin is not an existing facility; thus, it has no historical payor mix. However, in Section L.7, page 73, the applicant provides the payor mix for both BMA of Greensboro and BMA of South Greensboro for CY2016. These are the facilities that will be contributing 14 dialysis stations each to develop the proposed 28-station facility and from which approximately 67% of the patients will transfer (See Exhibit C-1 for patients' letters of support). The historical payor mix is illustrated as follows:

Payor Source	Percentage of In-Center Patients	
	BMA of Greensboro	BMA of South Greensboro
Private Pay/Indigent/ Charity	0.82%	0.34%
Medicare	63.25%	61.38%
Medicaid	5.30%	3.67%
Commercial Insurance	11.67%	4.50%
Medicare/Commercial	16.52%	25.49%
Miscellaneous, including VA	2.44%	4.62%
Total	100.00%	100.00%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Guilford	14%	53%	48%	17%	7%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015>.

*Excludes "White alone" who are "not Hispanic or Latino"

***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 provides prevalence data on ESRD Network 6 dialysis patients by age, race, and gender on pages 27-28¹. The ESRD Network 6 service area contract, previously managed by Alliant Healthcare Solutions’ Southeastern Kidney Council, was awarded to IPRO in April 2016 and is now called the IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6). IPRO SA Network 6 is still comprised of North Carolina, South Carolina and Georgia. The 2015 Annual Report, submitted in November 2016 by IPRO differs somewhat from the reports submitted in the past by The Southeastern Kidney Council.

The statistics on number and percent of dialysis patients by age, gender and race are now shown only in total for Network 6; the statistics are no longer separately shown for North Carolina in the report. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*² percentages for North Carolina and the total Network shows very little variance; therefore the statistics for the total Network 6 are representative of North Carolina’s statistics. One would also assume the 2015 percentages for the total Network 6 should also very closely reflect North Carolina percentages by age, gender and race. The following table shows the North Carolina and total Network data for 2014 as provided by the Southeastern Kidney Council, and compared with the IPRO 2015 Network totals.

¹http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

²<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014 and 2015						
	2014 Patients and Percentages*				2015 Patients and Percentages**	
	NC Patients	NC Percentage	Total Network 6 Patients	Total Network 6 Percentage	Total Network 6 Patients	Total Network 6 Percentage
Age						
0-19	52	0.3%	137	0.3%	137	0.3%
20-34	770	4.8%	2,173	4.9%	2,142	4.7%
35-44	1,547	9.7%	4,385	9.9%	4,493	9.8%
45-54	2,853	17.8%	8,070	18.3%	8,422	18.3%
55-64	4,175	26.1%	11,706	26.5%	12,024	26.1%
65+	6,601	41.3%	17,716	40.1%	18,817	40.9%
Gender						
Female	7,064	44.2%	19,923	45.1%	20,805	45.2%
Male	8,934	55.8%	24,264	54.9%	25,230	54.8%
Race						
African-American	9,855	61.6%	29,191	66.1%	30,092	65.4%
White	5,778	36.1%	14,222	32.2%	15,049	32.7%
Other	365	2.3%	774	1.8%	894	1.9%

*2014 Calendar Year data from the Southeastern Kidney Council Network 6 2014 annual Report at <http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

**2015 Calendar Year data from the IPRO ESRD Network of the South Atlantic at http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian comparing with 85% of Network 6 patients being 45 and over and 69% being non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*). In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older and over 67% were non-Caucasian. (IPRO SA Network 6).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3(e), page 72, the applicant states,

“Fresenius related facilities in North Carolina do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L.6, page 72, the applicant states that no civil rights complaints have been lodged against any BMA North Carolina facilities in the past five years.

The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.1, page 70, the applicant provides the projected payor mix for the proposed services at FKC Garber-Olin as shown in the table below:

**Projected Payor Mix, OY2
1/1/20-12/31/20**

Payor Source	Percentage
Private Pay/Indigent/Charity	0.58%
Medicare	62.33%
Medicaid	4.50%
Commercial Insurance	8.13%
Medicare/Commercial	20.95%
Miscellaneous, including VA	3.51%
Total	100.00%

Totals may not sum due to rounding

As shown in the table above, the applicant projects that over 87% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. In Section L.1, page 70, the applicant states that the projected payor mix is calculated based upon the current payor mix of BMA of Greensboro and BMA of South Greensboro, the two facilities contributing the 28 stations for the development of the proposed facility. The applicant adequately demonstrates that medically underserved

populations would have access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.4, page 72, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FKC Garber-Olin will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

The applicant adequately demonstrates that FKC Garber-Olin will provide a range of means by which a person can access its services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M.1, page 74, the applicant states that health related education programs will be welcomed at the facility. Exhibit M-1 includes a letter from the applicant to the nursing program at Guilford Technical Community College, dated March 14, 2017, inviting the school to include FKC Garber-Olin in its clinical rotations for its nursing students. The information provided in Section M.1 and Exhibit M-1 is reasonable and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new 28-station dialysis facility in Greensboro by relocating 14 stations from BMA of Greensboro and 14 stations from BMA of South Greensboro. All three facility locations are in Guilford County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, FKC Garber-Olin will be certified for 28 stations, BMA of Greensboro will be certified for 42 dialysis stations and BMA of South Greensboro will be certified for 35 dialysis stations following completion of this project and Project ID #G-11055-15 (relocate ten stations to Fresenius Medical Care High Point).

On page 373, the 2017 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* The proposed new facility, FKC Garber-Olin, is located in Guilford County; thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR, there are seven operational dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	79.91%	3.1964
BMA of South Greensboro (FMC)*	59	76.69%	3.0678
BMA of Southwest Greensboro (FMC)	33	88.64%	3.5455
FMC of East Greensboro (FMC)	35	92.86%	3.7143
FMC High Point (FMC Proposed Site)*	0	0.00%	0.0000
High Point Kidney Center (WFUHS)**	42	91.07%	3.6429
Northwest Greensboro Kidney Center (FMC)	33	75.00%	3.0000
Triad Dialysis Center (WFUHS)	22	94.32%	3.7727

Source: January 2017 SDR, Table A.

* Project ID #G-11055-15 approved the relocation of 10 stations from BMA of South Greensboro to develop FMC High Point in Guilford County, leaving a total of 49 stations at BMA of South Greensboro upon project completion.

** Approved to relocate 10 stations to North Randolph Dialysis Center in Randolph County in Project ID #G-10262-14, leaving a total of 32 stations at High Point Kidney Center upon project completion.

As illustrated above, FMC or Fresenius related entities own five of the seven operational dialysis facilities in Guilford County. FMC High Point is an approved Fresenius-affiliated 10-station facility, which is not yet operational. Wake Forest University Health Sciences operates the other two Guilford County dialysis facilities. All of the Guilford County dialysis facilities

are reasonably well-utilized, operating at or above 75% utilization or three patients per station.

According to Table B in the January 2017 SDR, there is a surplus of six dialysis stations in Guilford County. However, the applicant is not increasing the number of dialysis stations in Guilford County, rather it is relocating 28 existing Guilford County dialysis stations to develop a new facility that is closer to patients living in the area where the new facility will be located.

In Section N.1, page 76, the applicant discusses the expected effects of the proposed project on competition, including cost-effectiveness, quality and access, stating,

“BMA does not expect this proposal to have effect on the competitive climate in Guilford County. According to the January 2017 SDR there are currently seven dialysis facilities operating within Guilford County. Five facilities are operated by BMA and two facilities are operated by Wake Forest Baptist Hospital. The two Wake Forest Facilities are located in the southwest corner of Guilford County, essentially in the High Point area. Due to the geographic location of this facility it does not seem probable that the facilities are serving the same patient population.”

The applicant further states that the physicians with privileges at Wake Forest facilities do not have privileges at BMA facilities and vice versa. The applicant states that the proposal is seeking to continue to provide dialysis care and treatment to BMA patients of the area.

In addition, the applicant states that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that greater than 87% of the patients at FKC Garber-Olin will have their services covered by Medicare or Medicaid. Moreover, the applicant states, on page 76, that its proposal will *“enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”*

See also Sections B, C, E, F, H, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates it will continue to provide quality services. The discussion regarding quality found in Criterion (20), is incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a), and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section A.11, page 5, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc., which owns and operates 108 existing kidney disease treatment centers in North Carolina. In Exhibit A-4, the applicant provides a listing of the FMC-affiliated, owned and operated ESRD facilities in North Carolina. In Section O, pages 80-81, the applicant provides information on quality of care provided at its sister facilities, including citations received during the 18 months immediately preceding the submittal of the application, and their resolution. Two FMC facilities had immediate jeopardy citations: RAI West College-Warsaw and BMA East Rocky Mount. The applicant summarizes the deficiencies cited, the resolutions, and provides documentation in Exhibit O-3, including correspondence from Licensure and the Centers for Medicare and Medicaid Services. On page 81, the applicant states that both facilities were back in full compliance with all CMS Guidelines upon the submittal of the application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-C- In Section C.1, pages 20-22, the applicant documents the need for the project and demonstrates that it will serve a total of 93 in-center patients on 28 stations at the end of the first operating year, which is 3.32 patients per station per week, or a utilization rate of 83% (93 patients / 28 stations = 3.32; $3.32 / 4 = 0.830$). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-NA- The applicant is seeking to develop a new 28-station dialysis facility.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 20-22. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.