ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: November 18, 2016
Findings Date: November 18, 2016

Project Analyst: Mike McKillip
Team Leader: Lisa Pittman

Project ID #: J-11220-16
Facility: Fresenius Medical Care White Oak
FID #: 160405
County: Wake
Applicant: Fresenius Medical Care White Oak, LLC
Project: Develop a new 12-station dialysis facility in Garner by relocating six stations from BMA Raleigh Dialysis and six stations from Wake Dialysis Clinic

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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

Fresenius Medical Care White Oak, LLC **[FMC White Oak]** proposes to develop a new 12-station dialysis facility in Garner (Wake County) by relocating six existing certified dialysis stations from BMA of Raleigh Dialysis and six existing certified dialysis stations from Wake Dialysis Clinic. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The applicant proposes to relocate existing dialysis stations within Wake County; therefore, there are no need determinations in the 2016 State Medical Facilities Plan (2016 SMFP) applicable to this review.

Policies

There is one policy in the 2016 SMFP which is applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations. Policy ESRD-2 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 contiguous counties shall:*
>
> 1. *Demonstrate that the facility losing dialysis stations or moving to a contigous* [sic] *county is currently serving residents of that contigous* [sic] *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 12-station dialysis facility, FMC White Oak, in Wake County, by relocating 12 existing Wake County dialysis stations: six from BMA of Raleigh Dialysis and six from Wake Dialysis Clinic. Because all three facilities are located in Wake County, there is no change in the total dialysis station inventory in Wake County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2 in the 2016 SMFP. Therefore, the application is conforming to this criterion.

(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, FMC White Oak, proposes to develop a new 12-station dialysis facility in Garner (Wake County) by relocating six existing certified dialysis stations from BMA of Raleigh Dialysis and six existing certified dialysis stations from Wake Dialysis Clinic.

Patient Origin

On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the 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."* Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 20, the applicant provides a table showing the projected patient origin for FMC White Oak for in-center (IC), home hemodialysis (HH) and peritoneal (PD) patients for the first two years of operation following completion of the project, FY2019 and FY2020, which is shown below:

	Operating Year (OY) 1			**Operating Year (OY) 2**			**Percent of Total**	
County	**IC**	**HH**	**PD**	**IC**	**HH**	**PD**	**OY1**	**OY2**
Wake	40.1			42.4			91.1%	91.5%
Johnston	2			2			2.2%	2.1%
Total*	**42**			**44**			**100.0%**	**100.0%**

*Rounded down to the whole patient

On page 20, the applicant states,

> *"The facility will not include a home therapies program. Patients who might be candidates for home dialysis will be referred to the Wake Dialysis Clinic."*

On page 21 of the application, the applicant states it has identified 46 in-center patients who are interested in transferring their care to the proposed facility. Exhibit C-1 contains copies of signed letters of support from 46 patients indicating that they would consider transferring their care to the new facility upon certification. The letters state the patients' county of residence, zip code and the facility in which they currently dialyze. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 21, the applicant discusses the necessity to relocate stations to the proposed Garner facility in Wake County, stating:

"The applicant has plotted the residence location of patient dialyzing at BMA facilities within Wake County. It was determined that there are a significant number of dialysis patients residing in eastern areas of Wake County, in the general area of the proposed facility. The applicant has included 46 letters of support (see Exhibit C-1) from in-center patients who reside in close proximity to the proposed facility. Each of these patients could be better served by dialysis in a center located at the FMC White Oak location."

On pages 21-23, the applicant provides the methodology and assumptions used to project utilization, as follows:

1. Based on letters of support from 46 current in-center dialysis patients, the applicant assumes that 40 of those in-center patients will transfer their care to the proposed new facility in Garner. Also, the applicant assumes that 38 of those patients will reside in Wake County and two patients will reside in Johnston County.

2. The project is scheduled for completion June 30, 2018.

   Operating Year 1 (OY1) is Fiscal Year 2019, July 1, 2018 through June 30, 2019.
   Operating Year 2 (OY2) is Fiscal Year 2020, July 1, 2019 through June 30, 2020.

3. The applicant assumes the Wake County dialysis patients transferring to the proposed FMC White Oak facility are a part of the Wake County ESRD patient population as a whole, and that this population will increase at the Wake County Five Year Average Annual Change Rate (AACR) of 5.6%, as published in the July 2016 SDR.

<u>Projected Utilization</u>

The applicant's methodology is shown in the following table.

FMC White Oak	In-Center
Begin the facility census with the in-center patients projected to transfer care to the proposed facility upon certification on June 30, 2018.	38 Wake County patients 2 Johnston County patients
Project growth of the Wake County patient census by the Wake County Five Year Average Annual Change Rate for one year to June 30, 2019.	(38 X 0.056) + 38 = 40.1
Add the two Johnston County patients. This is the census at the end of OY1, June 30, 2019.	40.1 + 2 = 42.1
Project growth of the census by the Wake County Five Year Average Annual Change Rate for one year to December 31, 2019.	(40.1 X 0.056) + 40.1 = 42.4
Add the two Johnston County patients. This is the census at the end of OY2, June 30, 2020.	42.4 + 2 = 44.4

The applicants project to serve 42 in-center patients or 3.5 patients per station (42/12 = 3.5) by the end of Operating Year 1 and 44 in-center patients or 3.7 patients per station (44/12 = 3.7) by the end of Operating Year 2 for the proposed 12-station facility. This satisfies the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). In this application, the applicant assumes a projected annual rate of growth of 5.6% for the Wake County dialysis patient census, which is consistent with the Wake County Five Year Average Annual Change Rate (2010-2014). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1(a), pages 75-76, the applicant states that each of BMA's 102 facilities in 42 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. In Section L.1(b), page 76, the applicant projects over 83% of its in-center patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that this population has for the proposed project, and adequately demonstrates the extent to which all residents, including underserved groups, will 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 relocate six existing dialysis stations from the BMA of Raleigh Dialysis facility and six existing dialysis stations from the Wake Dialysis Clinic facility, both in Wake County, to develop a new 12-station dialysis facility, FMC White Oak, also in Wake County. In Section D.1, on pages 34-38, the applicant discusses how the needs of dialysis patients at BMA of Raleigh Dialysis and Wake Dialysis Clinic will continue to be met after the relocation of stations to the proposed FMC White Oak dialysis facility.

BMA of Raleigh Dialysis

In Section D.1, pages 34-36, the applicant describes the impact of the proposed transfer of six stations from BMA of Raleigh Dialysis as follows:

> *"The BMA of Raleigh Dialysis facility is certified for 50 dialysis stations at the time this application is filed. Thus, FMC White Oak will be relocating six of 50 stations, leaving a net of 44 stations at the facility, effective June 30, 2018….*
>
> *There were 174 patients dialyzing at BMA of Raleigh Dialysis on June 30, 2016; 172 patients were residents of Wake County (Source: ESRD Data Collection Forms for June 30, 2016). FMC White Oak will project the Wake County patient population forward at the Wake County Five Year Average Annual Change Rate as published in the July 2016 SDR; that rate is 5.6%. The patients from Johnston County will be added at the end of the calculations.*
>
> *Based on the letters of support from the facility, FMC White Oak projects that three Wake County patients will transfer their care to the new location. These patients will be subtracted from projections of future patient populations to be served….*
>
> *Thus, at June 30, 2018, BMA of Raleigh Dialysis is projected to have 44 certified dialysis stations with a patient population of 190.8 in-center patients rounded to 191. Utilization is calculated to be 4.34 patients per station. … In this case, Bio-Medical Applications of North Carolina, Inc., d/b/a BMA of Raleigh Dialysis will be filing a CON application on September 15, 2016 seeking to add six dialysis stations at BMA of Raleigh Dialysis upon completion of this project (FMC White Oak).*
>
> *Assuming approval of the application to add six dialysis stations at BMA of Raleigh Dialysis, the facility would have a census of 191 patients dialyzing on 50 stations the day following relocation of the six stations to FMC White Oak. This would equate to a utilization rate of 3.82 patients per station."*

On September 15, 2016, the applicant submitted an application (Project I.D. # J-11237-16) to add six dialysis stations to BMA of Raleigh Dialysis. That application is currently under review. As described above, assuming that Project I.D. # J-11237-16 is approved, the applicant projects to be serving 191 in-center patients on 50 dialysis stations as of June 30, 2018, for a utilization rate of 96%. The applicant demonstrates that the needs of the population presently served at the BMA of Raleigh Dialysis facility will continue to be adequately met.

Wake Dialysis Clinic

In Section D.1, pages 37-39, the applicant describes the impact of the proposed transfer of six stations from Wake Dialysis Clinic as follows:

> *"Wake Dialysis Clinic is certified for 50 dialysis stations at the time this application is filed. Thus, FMC White Oak will be relocating six of 50 stations, leaving a net of 44 stations at the facility, effective June 30, 2018….*

There were 204 patients dialyzing at Wake Dialysis Clinic on June 30, 2016; 200 patients were residents of Wake County (Source: ESRD Data Collection Forms for June 30, 2016). FMC White Oak will project the Wake County patient population forward at the Wake County Five Year Average Annual Change Rate as published in the July 2016 SDR; that rate is 5.6%. The patients from Franklin and Johnston Counties will be added at the end of the calculations.

Based on the letters of support from the facility, FMC White Oak projects that five Wake County resident and two Johnston County patients will transfer their care to the new location. These patients will be subtracted from projections of future patient populations to be served….

Thus, at June 30, 2018, Wake Dialysis Clinic is projected to have 44 certified dialysis stations with a patient population of 220 in-center dialysis patients. Utilization is calculated to be 5.00 patients per station. … In this case, Bio-Medical Applications of North Carolina, Inc., d/b/a Wake Dialysis Clinic will be filing a CON application on September 15, 2016 seeking to add six dialysis stations [sic] *Wake Dialysis Clinic upon completion of this project (FMC White Oak).*

Assuming approval of the application to add six dialysis stations at BMA of Raleigh Dialysis [sic]*, the facility would have a census of 220 patients dialyzing on 50 stations the day following relocation of the six stations to FMC White Oak. This would equate to a utilization rate of 4.4 patients per statin* [sic].

As noted, utilization rates above 4.0 patients per station necessarily mean the facility will operate a third, or evening shift. It is not uncommon for facilities such as Wake Dialysis Clinic to operate the third shift. The July 2016 SDR reports the utilization at Wake Dialysis Clinic was 102.5%, or 4.1 patients per station as of December 31, 2015.
Wake Dialysis Clinic operates a third, or evening shift, as well as a nocturnal – overnight – dialysis shift. At the time this application is prepared, there are 12 patients dialyzing on the nocturnal dialysis shift, and 20 dialysis patients dialyzing on the third, or evening dialysis shift. … Assuming these 32 patients are dialyzing on these shifts by choice, and assuming the number of patients on the non-traditional dialysis shifts remains constant through the date of certification of this project, it is reasonable to conclude that the 'effective' utilization at Wake Dialysis Clinic on June 30, 2018 would be 188 patients dialyzing on 50 stations [220 – 32 = 188]. *The 'effective' utilization rate is projected to be 3.76 patients per station."*

On September 15, 2016, the applicant submitted an application (Project I.D. # J-11240-16) to add six dialysis stations to Wake Dialysis Clinic. That application is currently under review. As described above, assuming that Project I.D. # J-11240-16 is approved, the applicant projects to be serving 220 in-center patients on 50 dialysis stations as of June 30, 2018, for a utilization rate of 110%. However, the applicant projects that 32 of the 220 patients will be served on a third shift or *"nocturnal dialysis shift,"* resulting in an effective utilization rate of

3.76 patients per station, or 94%. The applicant demonstrates that the needs of the population presently served at the Wake Dialysis Clinic facility will continue to be adequately met.

In Section D.2, page 40, the applicant states, *"The relocation of stations from BMA of Raleigh Dialysis and Wake Dialysis Clinic will not alter or affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care."*

Conclusion

The applicant adequately demonstrated that the needs of the population presently served will continue to be adequately met following the proposed relocation of six dialysis stations from BMA of Raleigh Dialysis and six dialysis stations from Wake Dialysis Clinic to FMC White Oak 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 41-42, the applicant describes the alternatives considered prior to submitting the application for the proposed project, which include:

- Maintain the status quo – The applicant states that maintaining the status quo is not an effective alternative due to the projected future ESRD patient population of Wake County within its existing BMA facilities. Therefore, this alternative was rejected.
- Develop a facility in another area of Wake County - The applicant states that evaluation of the existing patient populations served by BMA, and projections of future patient populations, indicate that the patient population in eastern Wake County in the Garner area might be better served by a new facility. Therefore, this alternative was rejected.
- Develop a larger facility – The applicant states it considered applying for more stations but rejected the alternative because the 12-station facility will meet the needs of the projected patients who will transfer their care to the proposed facility upon certification, and will also meet the performance standards at 10A NCAC 14C .2203.
- Expand at existing facilities – The applicant states that the existing Wake County BMA facilities cannot be expanded due to physical plant capacity; therefore this alternative was rejected.
- Relocate stations from existing BMA facilities with low utilization rates - The applicant states that this alternative was rejected because the facilities with low utilization rates are projected to have increasing utilization over the near future.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served and the physical plant capacity issues, the project represented in the application is the most effective alternative to meet the identified need.

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

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

1. **Fresenius Medical Care White Oak, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Fresenius Medical Care White Oak, LLC shall relocate no more than 6 dialysis stations from BMA of Raleigh Dialysis and no more than 6 dialysis stations from Wake Dialysis Clinic.**

3. **Fresenius Medical Care White Oak, LLC shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations, which shall include any isolation or home hemodialysis stations.**

4. **Fresenius Medical Care White Oak, LLC shall take the necessary steps to decertify 6 dialysis stations at BMA of Raleigh Dialysis for a total of no more than 44 dialysis stations at BMA of Raleigh Dialysis upon project completion.**

5. **Fresenius Medical Care White Oak, LLC shall take the necessary steps to decertify 6 dialysis stations at Wake Dialysis Clinic for a total of no more than 44 dialysis stations at Wake Dialysis Clinic upon project completion.**

6. **Fresenius Medical Care White Oak, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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

FMC White Oak proposes to develop a new 12-station dialysis facility in Garner by relocating six stations from BMA of Raleigh Dialysis and six stations from Wake Dialysis Clinic.

<u>**Capital and Working Capital Costs**</u>

In Section F.1, page 44, the applicant states that it projects $1,790,117 in capital costs to develop this project. In Sections F.10-F.12, pages 47-49, the applicant states there will be

$168,354 in start-up expenses and $1,554,439 in initial operating expenses, for total working capital required of $1,722,793.

	Total Capital Costs
Construction Contract	$1,194,429
Miscellaneous Project Costs	$595,688
Total Capital Costs	**$1,790,117**

Availability of Funds

In Section F.2, page 45, the applicant states it will finance the capital costs with accumulated reserves. Exhibit F-1 contains a letter dated August 15, 2016 from the Senior Vice President & Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), the parent company for the applicant, which states the applicant has adequate funds for the capital and working capital costs for the proposed project. Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had $249 million in cash and cash equivalents as of December 31, 2015. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	FY2019	FY2020
Total Net Revenue	$2,896,751	$3,037,869
Total Operating Expenses	$2,323,531	$2,415,866
Net Income	$573,219	$622,003

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs 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 the availability of sufficient funds for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

(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

FMC White Oak proposes to develop a new 12-station dialysis facility in Garner by relocating six stations from BMA of Raleigh Dialysis and six stations from Wake Dialysis Clinic.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the 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."* Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates eleven dialysis centers in Wake County. Also, BMA has been approved to develop two additional facilities in Wake County, FMC Northern Wake and FMC Morrisville, but the facilities were not yet operational on December 31, 2015. Wake Forest Dialysis Center (DaVita) is the only other provider of dialysis services in Wake County, and currently operates just one dialysis center. DaVita has been approved to develop one additional facility in Wake County, Oak City Dialysis, but the facility was not yet operational on December 31, 2015. The existing and approved Wake County dialysis facilities are shown below:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/15	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	22	0	95.45%	3.8
BMA of Raleigh Dialysis	50	0	92.50%	3.7
Cary Kidney Center (BMA)	28	-4	75.89%	3.0
FMC Apex (BMA)	20	0	58.75%	2.4
FMC Central Raleigh (BMA)	19	0	75.00%	3.0
FMC Eastern Wake (BMA)	14	3	110.71%	4.4
FMC Millbrook (BMA)	17	0	82.35%	3.3
FMC Morrisville (BMA)	0	10	NA	NA
FMC New Hope (BMA)	36	0	72.22%	2.9
FMC Northern Wake (BMA)	0	3	NA	NA
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake (BMA)	31	-6	95.16%	3.8
Wake Dialysis Clinic (BMA)	50	0	102.50%	4.1
Wake Forest Dialysis (DaVita)	20	12	93.75%	3.8
Zebulon Kidney Center (BMA)	30	-2	81.67%	3.3

Source: July 2016 SDR, Table A.

As shown in the table above, eight of the twelve operational Wake County dialysis facilities were operating above 80% utilization (3.2 patients per station), and ten of the twelve operational facilities were operating at or above 75% utilization (3.0 patients per station) as of December 31, 2015.

The applicant proposes to develop a new 12-station dialysis facility in Garner by relocating six stations from BMA of Raleigh Dialysis and six stations from Wake Dialysis Clinic. The applicant does not propose to increase the inventory of dialysis stations in Wake County. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 20-22 of the application. The growth projections are based on a projected 5.6% average annual growth rate in the number of in-center dialysis patients at the proposed BMA White Oak facility. At the end of Operating Year Two, BMA White Oak projects utilization will be 3.7 in-center patients per station per week (44 patients / 12 dialysis stations = 3.7), which is 93% of capacity. The applicant adequately demonstrates the need to develop a new 12-station dialysis facility based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, 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 58, the applicant provides the proposed staffing for the new facility in the second operating year (FY2020), which includes 11.85 full-time equivalent (FTE) employee positions, as shown below.

Position	Projected # of FTE Positions
Medical Director*	NA
RN	2.00
Technician	6.00
Clinical Manager	1.00
Administrator	0.15
Dietitian	0.50
Social Worker	0.50
Chief Technician	0.15
Equipment Technician	0.60
In-Service	0.15
Clerical	0.80
Total FTE Positions	**11.85**

*The applicant states the Medical Director is a contract position, not an employee of the facility.

In Section H.3, page 59, the applicant describes its experience and process for recruiting and retaining staff. Exhibit I-5 contains a copy of a letter from Michael Casey, M.D., expressing his interest in serving as the Medical Director for the facility. 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 62, the applicant includes a list of providers of the necessary ancillary and support services. Exhibits I-2, 3 and 4 contain documentation for laboratory, hospital and transplant services, respectively. Exhibit I-5 contains a letter from the proposed medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 63-65. 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 health care 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

The applicant proposes to develop the new facility in 7,776 square feet of space in a building to be located on Timber Drive East in Garner. In Section F.1, page 44, the applicant lists the project costs, including $1,194,429 for construction and $595,688 in miscellaneous project costs. In Section K.1, pages 67-69, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application, beginning on page 94. 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

In Section L.1, page 75, the applicant states that Fresenius has a long history of providing dialysis services to the underserved populations of North Carolina. FMC, BMA's parent company, currently operates 102 facilities in 42 North Carolina Counties. 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 which would classify a patient as underserved. On page 76, the applicant states:

"Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. For example, Medicare (includes Medicare Advantage treatments) represented 81.38% of North Carolina dialysis treatments in BMA facilities in FY 2015; Medicaid treatments represented an additional 4.87% of treatments in BMA facilities for FY 2015."

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 & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Wake	10%	51%	39%	12%	5%	14%
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 *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	**% of Dialysis Population**
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: http://www.esrdnetwork6.org/utils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf

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

The applicant demonstrates that it currently provides adequate 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, page 78, the applicant states:

> *"Fresenius related facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status."*

In Section L.6, page 79, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facilities within the past five years. Therefore, 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(b), page 76, the applicant projects that 83% of the in-center patients who will receive treatments at FMC White Oak in the second operating year (FY2020) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected Year 2 payment source for the facility for in-center patients:

Payment Source	In-Center Patients by Percent of Total
Medicare	65.37%
Medicaid	3.76%
Commercial Insurance	10.58%
Medicare/Commercial	13.88%
Miscellaneous (VA)	2.15%
Self/Indigent/Charity	4.25%
Total	**100.00%**

In Section L.1, page 76, the applicant provides the assumptions used to project payer mix. The applicant's projected payment sources are consistent with the historical (CY2015) payment sources for BMA of Raleigh Dialysis and Wake Dialysis Clinic as reported by the applicant in Section L.7, page 80. The applicant demonstrated that medically underserved groups will have adequate access to the services offered at FMC White Oak. 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 79, the applicant describes the range of means by which a person will have access to the dialysis services at FMC White Oak, including referrals from nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates the facility will offer a range of means by which patients will have access to dialysis 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 81, the applicant states that BMA facilities routinely work with local community training programs and students, and that the proposed facility will also offer the same opportunities to local health professional training programs. Exhibit M-1 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicant to offer the facility as a clinical training site. The information provided is reasonable and adequately supports a determination that the application is conforming 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

FMC White Oak proposes to develop a new 12-station dialysis facility in Garner by relocating six stations from BMA of Raleigh Dialysis and six stations from Wake Dialysis Clinic.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the 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."* Thus, the service

area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates eleven dialysis centers in Wake County. Also, BMA has been approved to develop two additional facilities in Wake County, FMC Northern Wake and FMC Morrisville, but the facilities were not yet operational on December 31, 2015. Wake Forest Dialysis Center (DaVita) is the only other provider of dialysis services in Wake County, and currently operates just one dialysis center. DaVita has been approved to develop one additional facility in Wake County, Oak City Dialysis, but the facility was not yet operational on December 31, 2015. The existing and approved Wake County dialysis facilities are shown below:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/15	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	22	0	95.45%	3.8
BMA of Raleigh Dialysis	50	0	92.50%	3.7
Cary Kidney Center (BMA)	28	-4	75.89%	3.0
FMC Apex (BMA)	20	0	58.75%	2.4
FMC Central Raleigh (BMA)	19	0	75.00%	3.0
FMC Eastern Wake (BMA)	14	3	110.71%	4.4
FMC Millbrook (BMA)	17	0	82.35%	3.3
FMC Morrisville (BMA)	0	10	NA	NA
FMC New Hope (BMA)	36	0	72.22%	2.9
FMC Northern Wake (BMA)	0	3	NA	NA
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake (BMA)	31	-6	95.16%	3.8
Wake Dialysis Clinic (BMA)	50	0	102.50%	4.1
Wake Forest Dialysis (DaVita)	20	12	93.75%	3.8
Zebulon Kidney Center (BMA)	30	-2	81.67%	3.3

Source: July 2016 SDR, Table A.

As shown in the table above, eight of the twelve operational Wake County dialysis facilities were operating above 80% utilization (3.2 patients per station), and ten of the twelve operational facilities were operating at or above 75% utilization (3.0 patients per station) as of December 31, 2015.

In Section N.1, pages 82-83, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

> *"BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 83% of the In-center treatments will be*

reimbursed at government payors (Medicare / Medicaid / VA) rates. The facility must capitalize upon every opportunity for efficiency.

Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ... This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."

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

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

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) 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 Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. In Section O.3, pages 88-90, the applicant identifies three of its 102 Fresenius affiliated North Carolina facilities, BMA Lumberton, BMA East Charlotte, and RAI West College, as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that the facilities are back in full compliance with CMS Guidelines as of the date of submission of this 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. 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(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, the applicant adequately demonstrates the need to establish the proposed 12-station FMC White Oak dialysis facility by relocating 12 existing Wake County dialysis stations to the proposed facility. At the end of the first operating year, the applicant projects FMC White Oak will serve 42 patients for a utilization of 3.5 patients per station per week. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

.2203(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 not 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. The applicant is seeking to develop a new 12-station dialysis facility.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which*

patient utilization is projected.

-C- In Section C.1, pages 20-22, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.