ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: June 2, 2017
Findings Date: June 2, 2017

Project Analyst: Mike McKillip
Team Leader: Lisa Pittman

Project ID #: J-11312-17
Facility: FMC New Hope Dialysis
FID #: 020868
County: Wake
Applicant: Bio-Medical Applications of North Carolina, Inc.
Project: Add six dialysis stations for a total of 36 stations upon completion of this project and Project I.D. # J-11271-16 (Relocate six stations from FMC New Hope Dialysis to FMC Rock Quarry)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC New Hope Dialysis **[FMC New Hope]** proposes to add six dialysis stations for a total of 36 certified dialysis stations upon completion of this project and Project I.D. # J-11271-16 (Relocate six stations from FMC New Hope Dialysis to FMC Rock Quarry for a total of 10 stations at FMC Rock Quarry).

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need

methodology shows there is no county need determination for Wake County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC New Hope in the January 2017 SDR is 3.3 patients per station per week. This utilization rate was calculated based on 118 in-center dialysis patients and 36 certified dialysis stations as of June 30, 2016 (118 patients / 36 stations = 3.3 patients per station per week). Application of the facility need methodology indicates up to six additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		81.94%
Certified Stations		36
Pending Stations		0
Total Existing and Pending Stations		**36**
In-Center Patients as of 6/30/16 (SDR2)		118
In-Center Patients as of 12/31/15 (SDR1)		104
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	14
	Multiply the difference by 2 for the projected net in-center change	28
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.2692
(ii)	Divide the result of step (i) by 12	0.0224
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.1346
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	133.8846
(v)	Divide the result of step (iv) by 3.2 patients per station	41.8389
	and subtract the number of certified and pending stations to determine the number of stations needed	**6**

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is six stations. Step (C) of the facility need methodology states, *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add six new stations and, therefore, is consistent with the facility need determination for dialysis stations.

<u>Policies</u>

There is one policy in the 2017 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. Policy GEN-3 states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and*

quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 12, Section O, pages 63-67, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), pages 12-13, Section L, pages 55-59, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 13-14, and Section N, pages 61-62. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2017 SDR and Policy GEN-3. 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 New Hope, proposes to add six dialysis stations for a total of 36 certified dialysis stations upon completion of this project and Project I.D. # J-11271-16 (Relocate six stations from FMC New Hope Dialysis to FMC Rock Quarry).

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."* Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 22, the applicant provides the historical patient origin for FMC New Hope patients as of December 31, 2016, which is summarized in the following table:

FMC New Hope Historical Patient Origin

County	In-Center	Home Hemodialysis	Peritoneal Dialysis
Wake	113	20	0
Granville	0	1	0
Johnston	5	1	0
Person	0	1	0
Vance	0	1	0
Wilson	1	0	0
TOTAL	**119**	**24**	**0**

Source: Table on page 22 of the application.

In Section C.1, page 17, the applicant provides the projected patient origin for FMC New Hope for in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

County	Operating Year 1 CY2019			Operating Year 2 CY2020			Percent of Total	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Wake	120.4	23.6	0	127.1	24.9	0	94.1%	94.4%
Granville	0	1	0	0	1	0	0.7%	0.6%
Johnston	4	1	0	4	1	0	3.3%	3.1%
Person	1	1	0	0	1	0	0.7%	0.6%
Vance	0	1	0	0	1	0	0.7%	0.6%
Wilson	1	0	0	1	0	0	0.7%	0.6%
Total*	**125**	**27**	**0**	**132**	**28**	**0**	**100.0%**	**100.0%**

*Rounded to the whole patient

The applicant provides the assumptions and methodology used to project patient origin on pages 17-19. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.2, pages 9-10, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP utilizing data from the January 2017 SDR, and it proposes to add six dialysis stations to FMC New Hope for a total of 36 stations at that facility following completion of this project and Project I.D. # J-11271-16 (Relocate six stations from FMC New Hope Dialysis to FMC Rock Quarry for a total of 10 stations at FMC Rock Quarry). The applicant used the following assumptions:

1. The applicant projects the first two full operating years of the project will be January 1, 2019 – December 31, 2019 (CY2019) and January 1, 2020 – December 31, 2020 (CY2020).

2. On December 31, 2016, FMC New Hope was providing dialysis treatment for 119 in-center patients, including 113 patients who reside in Wake County, five patients who reside in Johnston County, and one patient who resides in Wilson County.

3. FMC New Hope assumes the in-center patient population utilizing the facility who reside in Wake County will increase at the rate of 5.6 percent per year. On page 18, the applicant states,

   "BMA assumes that the FMC New Hope patient population comprised of Wake County residents is a part of the Wake County dialysis population as a whole, and that population will continue to increase at a rate commensurate with the Wake County Five Year Average Annual Change Rate as published in the January 2017 SDR, 5.6%. … BMA assumes that patients from other counties, dialyzing with FMC New Hope, are at the facility by patient choice. BMA assumes these patients will continue to dialyze at the facility. BMA does not project any increase in this patient population. These patients are added into the projections of future patient populations at appropriate points in time."

Projected Utilization

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

	In-Center
The applicant begins with the facility census of Wake County in-center residents as of December 31, 2016.	113
The census of Wake County in-center patients is increased by 5.6% to project the census forward one year to December 31, 2017.	[113 X 0.056] + 113 = 119.3
The census of Wake County in-center patients is increased by 2.8% to project the census forward six months to June 30, 2018.	[119.3 X (0.056/12X6)] + 119.3 = 122.7
The applicant subtracts four patients from the projected in-center census who are projected to transfer to FMC White Oak.	122.7 – 4 = 118.7
The census of Wake County in-center patients is increased by 2.8% to project the census forward six months to December 31, 2018.	[118.7 X (0.056/12X6)] + 118.7 = 122.0
The applicant subtracts eight patients who are projected to transfer to FMC Rock Quarry.	122.0 – 8 = 114.0
The census of Wake County in-center patients is increased by 5.6% to project the census forward one year to December 31, 2019.	(114 X 0.056) +114 = 120.4
The applicant adds five patients who reside in other counties. This is the projected ending census for Operating Year 1.	120.4 + 5 = 125.4
The census of Wake County in-center patients is increased by 5.6% to project the census forward one year to December 31, 2020.	(120.4 X 0.056) +120.4 = 127.1
The applicant adds five patients who reside in other counties. This is the projected ending census for Operating Year 2.	127.1 + 5 = 132.1

The applicant projects to serve 125 in-center patients or 3.5 patients per station per week (125/36 = 3.5) by the end of Operating Year 1 and 132 in-center patients or 3.7 patients per station per week (132/36 = 3.7) by the end of Operating Year 2 for the proposed 36-station facility. This exceeds 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). The January 2017 SDR indicates that FMC New Hope operated at a utilization rate of 82 percent (3.3 patients per station) as of June 30, 2016. Based on data reported in the SDR, during the period from June 30, 2015 to June 30, 2016, the in-center census at FMC New Hope increased from 110 to 118 patients, which is an annual rate of growth of 7.3 percent. In this application, the applicant

assumes a projected annual rate of growth of 5.6 percent for the in-center patient census (Wake County residents only) at FMC New Hope, which is equal to the Wake County Five Year Average Annual Change Rate (2011-2015). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Home Dialysis

On page 19, the applicant provides the following table showing its projections of home hemodialysis (HH) patients through the first two operating years of the project.

	Home Dialysis
The applicant begins with the facility census of Wake County home therapy patients as of December 31, 2016.	20 Wake County HH patients
The census of Wake County patients is increased by 5.6% to project the census forward one year to December 31, 2017.	(20 X 0.056) + 20= 21.1
The census of Wake County patients is increased by 5.6% to project the census forward one year to December 31, 2018.	(21.1 X 0.056) + 21.1 = 22.3
The census of Wake County patients is increased by 5.6% to project the census forward one year to December 31, 2019.	(22.3 X 0.056) + 22.3 = 23.6
The applicant adds four out-of-county patients. This is the census at the end of Operating Year 1.	23.6 + 4 = 27.6
The census of Wake County patients is increased by 5.6% to project the census forward one year to December 31, 2020.	(23.6 X 0.056) + 23.6 = 24.9
The applicant adds four out-of-county patients. This is the census at the end of Operating Year 2.	24.9 + 4 = 28.9

Source: Table on page 19 of the application.

On page 19, the applicant describes its assumptions as follows:

> *""BMA assumes that the FMC New Hope patient population comprised of Wake County residents is a part of the Wake County dialysis population as a whole, and that population will continue to increase at a rate commensurate with the Wake County Five Year Average Annual Change Rate as published in the January 2017 SDR, 5.6%. … BMA assumes that patients from other counties, dialyzing with FMC New Hope, are at the facility by patient choice. BMA assumes these patients will continue to dialyze at the facility. BMA does not project any increase in this patient population. These patients are added into the projections of future patient*

populations at appropriate points in time. ... No home patients are projected to transfer to another facility."

As shown above, the applicant assumes a projected annual rate of growth of 5.6 percent for the home dialysis patient census (Wake County residents only) at FMC New Hope, which is equal to the Wake County Five Year Average Annual Change Rate (2011-2015). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1(a), pages 55-56, the applicant states that each of BMA's 108 facilities in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.7, page 59, the applicant reports that 85% of the in-center patients who received treatments at FMC New Hope had some or all of their services paid for by Medicare or Medicaid in CY2016. The applicant projects 84% of its patients will be Medicare or Medicaid recipients in the second operating year of the project (CY2020). The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for six additional stations at FMC New Hope, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. 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.

NA

(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 26-27, the applicant describes the alternatives considered prior to submitting this 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 fact that FMC New Hope would not have adequate capacity to meet the projected need for dialysis services.
- Relocate Stations from an Existing BMA Facility – The applicant states it considered relocating stations from an existing BMA facility but rejected that alternative because the other BMA facilities in Wake County are currently well-utilized or, based on recent trends, will be fully utilized in the near future.

After considering those alternatives, the applicant states the alternative 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. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC New Hope Dialysis shall materially comply with all representations made in the certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC New Hope Dialysis shall develop and operate no more than six additional dialysis stations for a total of no more than 36 certified stations upon completion of this project and Project I.D. # J-11271-16 (Relocate six stations from FMC New Hope to FMC Rock Quarry), which shall include any isolation or home hemodialysis stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC New Hope 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

In Section F.1, page 28, the applicant states that it will not incur any capital costs to develop this project. In Sections F.10-F.12, page 32, the applicant states there will be no start-up expenses or initial operating expenses incurred for this 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.

	CY2019 Operating Year 1	CY2020 Operating Year 2
Total Treatments	21,933	23,118
Total Gross Revenues (Charges)	$87,468,804	$92,194,584
Total Net Revenue	$10,476,182	$11,097,021
Total Operating Expenses (Costs)	$6,184,290	$6,432,505
Net Income	$4,291,892	$4,664,516

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 sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, 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

The applicant, FMC New Hope, proposes to add six dialysis stations for a total of 36 certified dialysis stations upon completion of this project and Project I.D. # J-11271-16 (Relocate six stations from FMC New Hope Dialysis to FMC Rock Quarry).

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."* Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates twelve dialysis centers in Wake County. Also, BMA has been approved to develop three additional facilities in Wake County, FMC Morrisville, FMC Rock Quarry, and FMC White Oak, but the facilities were not yet operational on June 30, 2016. 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 June 30, 2016. The existing and approved Wake County dialysis facilities are shown below:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/16	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	23	5	83.70%	3.4
BMA of Raleigh Dialysis	50	0	87.00%	3.5
Cary Kidney Center (BMA)	28	-4	70.54%	2.8
FMC Apex (BMA)	20	0	65.00%	2.6
FMC Central Raleigh (BMA)	19	0	82.89%	3.3
FMC Eastern Wake (BMA)	14	3	92.86%	3.7
FMC Millbrook (BMA)	17	0	82.35%	3.3
FMC Morrisville (BMA)	0	10	NA	NA
FMC New Hope (BMA)	36	0	81.94%	3.3
FMC Northern Wake (BMA)	16	0	35.94%	1.4
FMC Rock Quarry	0	0	NA	NA
FMC White Oak	0	0	NA	NA
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake (BMA)	30	0	98.33%	3.9
Wake Dialysis Clinic (BMA)	50	0	102.00%	4.1
Wake Forest Dialysis (DaVita)	20	-7	91.25%	3.7
Zebulon Kidney Center (BMA)	30	-2	81.67%	3.3

Source: January 2017 SDR, Table A.

As shown in the table above, ten of the thirteen operational Wake County dialysis facilities were operating above 80% utilization (3.2 patients per station) as of June 30, 2016.

FMC New Hope proposes to add six in-center dialysis stations for a total of 36 dialysis stations upon project completion. FMC New Hope was serving 118 patients weekly on 36 stations, which is 3.3 patients per station or 82% of capacity, as of June 30, 2016. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 18-21 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 (Wake County residents only) at the FMC New Hope facility. At the end of Operating Year Two, FMC New Hope projects utilization will be 3.7 in-center patients per station (132 patients / 36 dialysis stations = 3.7), which is 92% of capacity. The applicant adequately demonstrates the need to

develop six additional dialysis stations at the existing 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 in Wake County. 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 40, the applicant provides the current staffing for the facility, which includes 35.6 full-time equivalent (FTE) employees. The applicant states that no additional staffing is projected to be added to the facility following completion of the project. In Section H.3, page 41, the applicant describes its experience and process for recruiting and retaining staff. Exhibit I-5 contains a copy of a letter from Michael Oliverio, M.D., expressing his interest in continuing to serve 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 44, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. 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.

NA

(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.7, page 59, the applicant reports that 85.2% of the patients who received treatments at FMC New Hope had some or all of their services paid for by Medicare or Medicaid in CY2016. The table below shows the historical (CY2016) payment source for the facility:

Payment Source	Total Patients by Percent of Total
Private Pay	0.28%
Commercial Insurance	11.87%
Medicare/Commercial Insurance	26.30%
Medicare	50.89%
Medicaid	8.05%
Miscellaneous (including VA)	2.62%
Total	**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
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 IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*[1] percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28[2]. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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[1] http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf
[2] http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

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, page 57, the applicant states:

> *"BMA of North Carolina 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 58, the applicant states there have been no civil rights access complaints filed within the last 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 56, the applicant projects that 84% of the patients who will receive treatments at FMC New Hope in the second operating year (CY2020) 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 patients:

Payment Source	**Total Patients by Percent of Total**
Self Pay/Indigent/Charity	0.62%
Medicare	52.17%
Medicaid	6.83%
Commercial Insurance	13.04%
Medicare/Commercial Insurance	24.84%
Miscellaneous (Incl. VA)	2.48%
Total	**100.00%**

In Section L.1, pages 55-56, the applicant provides the assumptions used to project payer mix. The applicant's projected payment sources are consistent with the facility's historical (CY2016) payment sources as reported by the applicant in Section L.7, page 59. The applicant adequately demonstrated that medically underserved groups

will have access to the services offered at FMC New Hope. 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 58, the applicant describes the range of means by which a person will have access to the dialysis services at FMC New Hope, including referrals from nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that 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 60, the applicant states that FMC New Hope has established relationships with local community training programs, and the applicant will continue to 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 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

The applicant, FMC New Hope, proposes to add six dialysis stations for a total of 36 certified dialysis stations upon completion of this project and Project I.D. # J-11271-16 (Relocate six stations from FMC New Hope Dialysis to FMC Rock Quarry).

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."* Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates twelve dialysis centers in Wake County. Also, BMA has been approved to develop three additional facilities in Wake County, FMC Morrisville, FMC Rock Quarry, and FMC White Oak, but the facilities were not yet operational on June 30, 2016. 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 June 30, 2016. The existing and approved Wake County dialysis facilities are shown below:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/16	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	23	5	83.70%	3.4
BMA of Raleigh Dialysis	50	0	87.00%	3.5
Cary Kidney Center (BMA)	28	-4	70.54%	2.8
FMC Apex (BMA)	20	0	65.00%	2.6
FMC Central Raleigh (BMA)	19	0	82.89%	3.3
FMC Eastern Wake (BMA)	14	3	92.86%	3.7
FMC Millbrook (BMA)	17	0	82.35%	3.3
FMC Morrisville (BMA)	0	10	NA	NA
FMC New Hope (BMA)	36	0	81.94%	3.3
FMC Northern Wake (BMA)	16	0	35.94%	1.4
FMC Rock Quarry	0	0	NA	NA
FMC White Oak	0	0	NA	NA
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake (BMA)	30	0	98.33%	3.9
Wake Dialysis Clinic (BMA)	50	0	102.00%	4.1
Wake Forest Dialysis (DaVita)	20	-7	91.25%	3.7
Zebulon Kidney Center (BMA)	30	-2	81.67%	3.3

Source: January 2017 SDR, Table A.

As shown in the table above, ten of the thirteen operational Wake County dialysis facilities were operating above 80% utilization (3.2 patients per station) as of June 30, 2016.

In Section N.1, page 61, 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 84% of the In-center patients will be relying upon government payors (Medicare/Medicaid/VA). The facility must capitalize upon every opportunity for efficiency.*
>
> *BMA 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 B, C, E, F, G, H and L 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 and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) 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 65-67, the applicant identifies two of its 105 Fresenius affiliated North Carolina facilities, BMA East Rocky Mount and RAI West College-Warsaw, 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.*

-NA- FMC New Hope is an existing facility.

.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.*

-C- In Section C.1, page 17, the applicant projects to serve 125 in-center patients by the end of Operating Year 1, which is 3.5 patients per station (125 / 36 = 3.5). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 17-20, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.