

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 8, 2019

Findings Date: November 8, 2019

Project Analyst: Celia C. Inman

Team Leader: Gloria C. Hale

Project ID #: J-11766-19

Facility: Cary Kidney Center

FID #: 180166

County: Wake

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

Project: Add no more than 2 dialysis stations and relocate entire home training program from BMA of Raleigh Dialysis for a total of no more than 26 stations upon completion of this project and Project ID #J-11470-18 (relocate 24-station facility to a new location)

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. (hereinafter referred to as “the applicant” or BMA) proposes to add two dialysis stations and relocate the entire home training program from BMA of Raleigh Dialysis (BMA of Raleigh) to Cary Kidney Center for a total of 26 dialysis stations upon completion of this project and Project ID #J-11470-18 (relocate entire 24-station facility to a new location).

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 64, in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 15 stations in Wake County; therefore, there is no county need determination for new dialysis stations for Wake County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for Cary Kidney Center in the July 2019 SDR, Table B, is 3.58 patients per station per week, or 89.58%, based on 86 in-center dialysis patients and 24 certified dialysis stations [$86 / 24 = 3.5833$; $3.5833 / 4 = 0.8958$]. Therefore, Cary Kidney Center is eligible to apply for additional stations based on the facility need methodology.

Application of the facility need methodology indicates up to 2 additional stations may be needed at this facility, as illustrated in the following the table:

Cary Kidney Center		
OCTOBER 1 REVIEW-JULY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		89.58%
Certified Stations		24
Pending Stations		0
Total Existing and Pending Stations		24
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		86
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		88
Step	Description	Result
	Difference (SDR2 - SDR1)	-2
(i)	Multiply the difference by 2 for the projected net in-center change	-4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	-0.0455
(ii)	Divide the result of Step (i) by 12	-0.0038
(iii)	Multiply the result of Step (ii) by 12	-0.0455
(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	82.0909
(v)	Divide the result of Step (iv) by 3.2 patients per station	25.6534
	and subtract the number of certified and pending stations to determine the number of stations needed	1.6534

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Cary Kidney Center is two stations, based on rounding allowed in Step (v). 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 two new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2019 SMFP, is applicable to this review because the facility need methodology is applicable to this review. 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 will promote safety and quality in Section B.3 (a and d), pages 12 and 14-15, respectively; Section N.2(b), page 63; Section O, pages 65-68; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.3 (b and d), pages 13 and 14-15, respectively; Section C.7, pages 26-27; Section L, pages 56-60; Section N.2(c), page 63; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.3 (c and d), pages 13-15; Section N.2(a), page 63; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

The applicant proposes to add two dialysis stations and relocate the entire home training program from BMA of Raleigh for a total of 26 dialysis stations upon completion of this project and Project ID #J-11470-18 (relocate entire 24-station facility to a new location).

The following table, summarized from data on page 7 of the application and Table B of the July 2019 SDR, illustrates the current and projected number of dialysis stations at Cary Kidney Center.

Cary Kidney Center

# of Stations	Description	Project ID #
24	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin *	J-11470-18
2	# of stations to be added as part of this project	J-11766-19
	# of stations to be deleted as part of this project	
	# of stations previously approved to be added but not yet certified	
	# of stations previously approved to be deleted but not yet certified	
	# of stations proposed to be added in an application still under review	
	# of stations proposed to be deleted in an application still under review	
26	Total # of stations upon completion of all facility projects	

*Cary Kidney Center was approved on July 13, 2018 for relocation of the 24-station facility within Wake County in Project ID #J-11470-18

As outlined in the table above, in this application, the applicant proposes to add two dialysis stations and relocate the home training program from BMA Raleigh to Cary Kidney Center for a total of 26 stations, upon the completion of this project and the relocation of the entire 24-station facility approved in Project ID #J-11470-18.

Patient Origin

On page 369, the 2019 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 for this facility is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 17, the applicant provides the patient origin for in-center (IC) dialysis patients at Cary Kidney Center as of December 31, 2018, as summarized in the table below. The center does not currently provide home training.

**Cary Kidney Center
 In-Center Patients
 1/1/2018 -12/31/2018**

COUNTY	# OF PATIENTS	% OF PATIENTS
Wake	82.0	95.35%
Chatham	1.0	1.16%
Durham	1.0	1.16%
Halifax	1.0	1.16%
Orange	1.0	1.16%
Total	104.0 [86.0]	100.00%

Totals may not sum due to rounding

The table as provided on page 17 and above lists the number of patients by county with an error in the total number of patients. The December 2018 ESRD Collection Data form submitted by the applicant to the Agency confirms the patient origin by county as presented above with a total of 86 patients. The percent of patients was calculated using the correct total confirming the typographical error in the table. The total number of patients is also confirmed by the applicant in Section Q, page 77. An error in referencing number of patients can also be found in the application verbiage in Section C.4, page 24 and Section E.2, page 34, indicating that the verbiage was an error, inadvertently including data from a previous application.

The following table summarizes projected patient origin for the second full operating year following project completion, as provided in Section C, page 18 and includes the proposed home hemodialysis (HH) and peritoneal dialysis (PD) services.

**Cary Kidney Center
 Projected Patient Origin
 OY2 CY2022**

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Wake	87.3	97.8%	5.4	84.3%	14.0	100.0%
Chatham	1.0	1.1%	1.0	15.7%	0.0	0.0%
Durham	1.0	1.1%	0.0	0.0%	0.0	0.0%
Total	89.3	100.0%	6.4	100.0%	14.0	100.0%

Totals may not sum due to rounding

In Section C, pages 18-20, the applicant provides the assumptions and methodology it used to project in-center patient origin. The applicant states that the in-center patient origin is based upon the June 30, 2019 facility information submitted to the Agency in August 2019 and provided on page 18 of the application.

The applicant provides the assumptions for the home training program on pages 20-23, stating that six HH and 13 PD patients being served in Wake County are expected to transfer their care to Cary Kidney Center upon the relocation of the home training program from BMA of Raleigh. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In-Center Dialysis

The applicant proposes to add two dialysis stations for a total of 26 dialysis stations upon completion of this project and Project ID #J-11470-18 (relocate entire 24-station facility to a new location).

In Section Q, pages 77-78, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant provides a table on page 77 that shows the facility in-center census as of December 31, 2018 and June 30, 2019, as summarized below.

**Cary Kidney Center
In-Center Patients**

COUNTY	12/31/2018	6/30/2019
Wake	82	79
Chatham	1	1
Durham	1	1
Halifax	1	0
Orange	1	0
Total	86	81

- The applicant states that the Cary Kidney Center patient census as of June 30, 2019 was submitted to the Agency on the ESRD Data Collection form in August 2019.
 - The applicant states that it assumes the patients from Wake County dialyzing at Cary Kidney Center on June 30, 2019 will continue to dialyze there and will increase at a rate equal to the 3.6% Wake County Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR, Table D.
 - The applicant assumes that one Chatham County and one Durham County patient being served in Wake County on June 30, 2019 will continue to dialyze at Cary Kidney Center but does not assume any growth in patients from these counties.
- Project ID #J-11510-18 assumes the transfer of two Wake County residents dialyzing at Cary Kidney Center to the new FKC Holly Springs facility as of December 31, 2020.
 - Services will be offered as of December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1-December 31, 2021 and OY2 is CY2022, January 1-December 31, 2022.

In-Center Projected Utilization

In Section Q, page 78, the applicant provides its projected utilization methodology, based on its stated assumptions. The projected in-center utilization is summarized in the following table.

CARY KIDNEY CENTER IN-CENTER PATIENTS

Begin with facility census of Wake County patients as of June 30, 2019.	79
Project this population forward six months to December 31, 2019, using the Wake County Five Year AACR of 3.6%. (3.6% / 12 x 6 = 1.8%)	$79 \times 1.018 = 80.4$
Project Wake County patients forward one year to December 31, 2020, using the Wake County Five Year AACR of 3.6%.	$80.4 \times 1.036 = 83.3$
Subtract two patients projected to transfer to FKC Holly Springs (Project ID #J-11510-18)	$83.3 - 2 = 81.3$
Add patients from Chatham and Durham counties projected to continue to dialyze at CKC. This is the starting census on January 1, 2021.	$81.3 + 2 = 83.3$
Project Wake County patients forward one year to December 31, 2021, using the Wake County Five Year AACR of 3.6%.	$81.3 \times 1.036 = 84.2$
Add patients from Chatham and Durham counties projected to continue to dialyze at CKC. This is the ending census on December 31, 2021.	$84.2 + 2 = 86.2$
Project Wake County patients forward one year to December 31, 2022, using the Wake County Five Year AACR of 3.6%.	$84.2 \times 1.036 = 87.3$
Add patients from Chatham and Durham counties projected to continue to dialyze at CKC. This is the ending census on December 31, 2022.	$87.3 + 2 = 89.3$

Source: Table in Section Q, page 78

At the end of OY1 (CY2021) Cary Kidney Center is projected to serve 86.2 in-center patients on 26 stations; and at the end of OY2 (CY2022) the facility is projected to serve 89.3 in-center patients on 26 stations.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.32 patients per station per week, or 82.9% utilization [$86.2 / 26 = 3.315$; $3.315 / 4 = 0.8288$].
- OY 2: 3.43 patients per station per week, or 85.9% utilization [$89.3 \text{ patients} / 26 \text{ stations} = 3.434$; $3.434 / 4 = 0.8586$].

The projected utilization of 3.32 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- Cary Kidney Center was operating at 89.58% capacity as of December 31, 2018, as reported in the July 2019 SDR.
- The applicant projects growth in the Wake County patient population using the Wake County Five Year AACR of 3.6%, as published in the July 2019 SDR.
- The applicant appropriately subtracts the patients who intend to transfer their care from Cary Kidney Center pursuant to a previously approved CON project.
- The applicant does not project growth for patients residing outside of Wake County.

- Projected IC utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Home Dialysis Training

The applicant proposes to relocate the entire home training program from BMA of Raleigh Dialysis to Cary Kidney Center. No stations are to be relocated.

In Section C, page 20, the applicant states that Cary Kidney Center does not currently offer home dialysis training services. However, the applicant plans to lease additional space at the proposed facility (Project ID #J-11470-18) for the development of the home therapies space. The applicant further discusses the relocation of the entire home training program from BMA of Raleigh to Cary Kidney Center and the need for those services in western Wake County, providing a map on page 22 that roughly shows the location of Wake County home therapy patients' residences, some of whom could be better served at Cary Kidney Center.

On page 25, the applicant states that BMA is relocating the home program from BMA of Raleigh in an effort to redistribute its existing healthcare resources within Wake County in a cost-efficient manner. At the present time, BMA has the following facilities within Wake County which offer home therapies:

- Wake Dialysis Clinic
- BMA of Raleigh Dialysis
- FMC New Hope
- FMC Northern Wake
- BMA of Fuquay Varina Kidney Center

The applicant states that none of the above facilities are located in western Wake County. However, the home training patient population is dispersed across the county, to include Cary, Morrisville and western areas of Wake County. The applicant states:

“Relocating home therapies to the BMA Cary facility, as it is being relocated, will provide better access to care for the home patients residing in western areas of Wake County, especially those residing in the Cary and Morrisville areas, south of the I-440.”

Home Therapy Projected Utilization

In Section Q, pages 80-81, the applicant makes the following assumptions in the projection of home therapies:

- The applicant projects that 13 PD patients and six HH patients from the stated area on the map on page 80 would be better served at the proposed Cary location and are expected to transfer their care to Cary Kidney Center upon certification of the home therapies program. One of the six HH patients is from Chatham County and the rest of the HH and PD patients are from Wake County.

- The Wake County population will increase commensurate with the Wake County five-year AACR of 3.6% as published in the July 2019 SDR.
- The Chatham County patient population is not expected to increase.
- Services will be offered as of December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1 - December 31, 2021 and OY2 is CY2022, January 1 - December 31, 2022.

CARY KIDNEY CENTER HOME THERAPY PATIENTS

	HH	PD
Begin with the Wake County home patients projected to transfer their care as of December 31, 2020.	5	13
Project this population forward one year to December 31, 2021, using the Wake County Five Year AACR of 3.6%.	$5 \times 1.036 = 5.2$	$13 \times 1.036 = 13.5$
Add the one HH patient from Chatham County projected to dialyze at CKC. This is the ending census on December 31, 2021.	$5.2 + 1 = 6.2$	$13.5 + 0 = 13.5$
Project Wake County patients forward one year to December 31, 2022, using the Wake County Five Year AACR of 3.6%.	$5.2 \times 1.036 = 5.4$	$13.5 \times 1.036 = 14.0$
Add the one HH patient from Chatham County projected to continue to dialyze at CKC. This is the ending census on December 31, 2022.	$5.4 + 1 = 6.4$	$14.0 + 0 = 14.0$

Source: Table in Section Q, page 81

At the end of OY1 (CY2021) Cary Kidney Center is projected to serve 6.2 HH patients and 13.5 PD patients; and at the end of OY2 (CY2022) the facility is projected to serve 6.4 HH patients and 14 PD patients.

Projected utilization of the home training program is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the need for home training services in western Wake County.
- The applicant projects the transfer of six HH and 13 PD patients based on patient location and being better served by transferring their care to Cary Kidney Center. Some BMA Raleigh home training patients will choose to go to other Wake County BMA home training programs.
- The applicant projects growth in the Wake County patient population using the Wake County Five Year AACR of 3.6%, as published in the July 2019 SDR.
- The applicant does not project growth for patients residing outside of Wake County.

The total IC, HH, and PD projected utilization is shown in Section Q, page 82 and summarized below to include the Durham County in-center patients.

**Cary Kidney Center
 Projected Patient Utilization**

COUNTY	December 31, 2021			December 31, 2022			County Patients as % of Total	
	# IC PATIENTS	# HH Patients	# PD Patients	# IC PATIENTS	# HH Patients	# PD Patients	OY1	OY2
Wake	84.2	5.2	13.5	87.3	5.4	14.0	97.2%	97.3%
Chatham	1.0	1.0	0.0	1.0	1	0.0	1.9%	1.8%
Durham	1.0	0.0	0.0	1.0	0.0	0.0	0.9%	0.9%
Total	86.2	6.2	13.5	89.3	6.4	14.0	100.0%	100.0%

Totals may not sum due to rounding

Projected utilization of the total proposed IC, HH, and PD program at Cary Kidney Center is reasonable and adequately supported for the reasons stated above.

Access

In Section C.7, page 27, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

...

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.”

In Section L, page 59, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Cary Kidney Center
 Projected Payor Mix CY 2022**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	2.09	2.35%	0.00	0.00%	0.00	0.00%
Commercial Insurance*	5.81	6.51%	1.98	31.85%	4.12	30.56%
Medicare*	52.43	58.73%	4.07	65.53%	7.90	58.62%
Medicaid*	12.04	13.49%	0.00	0.00%	0.25	1.83%
Medicare/Commercial	15.59	17.47%	0.16	2.63%	1.21	8.99%
Miscellaneous (Incl. VA)	1.30	1.46%	0.00	0.00%	0.00	0.00%
Total	89.28	100.00%	6.22	100.00%	13.47	100.00%

Totals may not sum due to rounding
 *Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(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

In Section C, page 25, the applicant states that BMA is relocating the home training program from BMA of Raleigh in an effort to redistribute its existing healthcare resources within Wake County in a cost-efficient manner.

In Section D, page 31, the applicant states:

“No stations are to be relocated. . . . BMA will direct the existing patient population to the home training program nearest their residence location, or other home training program of the patient choice.

Home dialysis patients come to the center on average, once per month. . . . Redirecting the home patient to another home therapies program does not cause the patient to travel to the center more, or less, frequently.

The home peritoneal dialysis patients of BMA of Raleigh Dialysis will be directed to either Wake Dialysis Clinic, FMC Northern Wake, BMA of Fuquay Varina Kidney Center, or to the new home program at BMA Cary.”

After the relocation of the BMA of Raleigh home training program to Cary Kidney Center, based upon residence location and choice, BMA Raleigh home training patients will transfer their care to one of the following home training programs that will continue to operate in Wake County:

- Wake Dialysis Clinic
- FMC New Hope
- FMC Northern Wake
- BMA of Fuquay Varina Kidney Center
- Cary Kidney Center

The applicant further states on page 32:

“No patients will be adversely affected by this relocation of the home training program from BMA of Raleigh Dialysis.”

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
 - The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (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

The applicant proposes to add two dialysis stations and relocate the entire home training program from BMA of Raleigh Dialysis for a total of 26 dialysis stations upon completion of this project and Project ID #J-11470-18 (relocate entire 24-station facility to a new location).

In Section E, pages 34-36, the applicant states it considered the following alternatives to serve the needs of the patients in the area:

1. Maintain the status quo – the applicant states that this alternative fails to recognize the growth of the ESRD patient population residing in the Cary Kidney Center area. The applicant states that failure to add stations will result in higher utilization rates at the facility and fewer opportunities for patient admission.
2. Retain the home program at BMA of Raleigh – the applicant states that failure to place home therapies at Cary Kidney Center would mean that home dialysis patients of the western area of the county would continue to travel across Raleigh to home programs on the east side of the city.
3. Relocate stations from a BMA facility in Wake County – the applicant lists multiple facilities from which stations could be relocated and states that the Fresenius related facilities are well utilized. The applicant states that relocating stations from these facilities would be inappropriate under the existing circumstances listed with each facility, as discussed on pages 34-36.

On page 36, the applicant states that it elected to add two stations and relocate the home training program because this proposal is the most cost-effective approach to providing the necessary services for the patient population projected to be served at Cary Kidney Center.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provided credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than two additional dialysis stations and relocate the home training program from BMA of Raleigh Dialysis to Cary Kidney Center for a total of no more than 26 certified stations upon completion of this project and Project ID #J-11470-18 (relocate the entire facility), which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add two dialysis stations and relocate the entire home training program from BMA of Raleigh Dialysis for a total of 26 dialysis stations upon completion of this project and Project ID #J-11470-18 (relocate entire 24-station facility to a new location).

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 85, the applicant projects the following total capital cost associated with this project.

Construction/Renovation	\$301,404
Architect/Engineering Fees	\$27,126
Furniture	\$46,099
Contingency	\$32,853
Total Capital Cost	\$407,482

In Section Q, page 86, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 38-39, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 37, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans		
Accumulated reserves or OE *	\$407,482	\$407,482
Bonds		
Other (Specify)		
Total Financing	\$407,482	\$407,482

* OE = Owner's Equity

Exhibit F-2 contains a letter dated September 16, 2019 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings (FMCH), the parent company for BMA, for the capital costs of the project. The letter also documents that the 2018 Consolidated Balance Sheet for FMCH reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, page 88, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

Cary Kidney Center Projected Revenue and Operating Expenses

	OY 1 CY2021	OY 2 CY2022
Total Treatments (IC, HH, and PD)	13,953.57	15,851.25
Total Gross Revenue (charges)	\$87,781,930	\$99,720,189
Total Net Revenue	\$4,256,235	\$5,050,849
Average Net Revenue per Treatment	\$305.03	318.64
Total Operating Expenses (costs)	\$3,587,825	\$3,851,122
Average Operating Expense per Treatment	\$257.13	\$242.95
Net Income / Profit	\$668,410	\$1,199,727

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q 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.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates the availability of 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.

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

C

The applicant proposes to add two dialysis stations and relocate the entire home training program from BMA of Raleigh Dialysis for a total of 26 dialysis stations upon completion of this project and Project ID #J-11470-18 (relocate entire 24-station facility to a new location).

On page 369, the 2019 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 14 dialysis centers in Wake County. Also, BMA has been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry, but the facilities were not yet operational on December 31, 2018. DaVita is the only other provider of dialysis services in Wake County, and currently operates Wake Forest Dialysis, and has been approved to develop Oak City Dialysis. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table B of the July 2019 SDR:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina Kidney Center (BMA)	28	0	84.82%	3.3929
BMA of Raleigh Dialysis (BMA)	50	0	90.50%	3.6200
Cary Kidney Center (BMA)	24	0	89.58%	3.5833
FMC Eastern Wake (BMA)	17	0	64.71%	2.5882
FMC Morrisville (BMA)	10	0	45.00%	1.8000
FMC New Hope Dialysis (BMA)	36	0	86.11%	3.4444
FMC Northern Wake (BMA)	14	0	87.50%	3.5000
Wake Dialysis Clinic (BMA)	50	4	98.50%	3.9400
FKC Holly Springs (BMA)	0	10	NA	NA
FMC Apex (BMA)	20	0	82.50%	3.3000
FMC Central Raleigh (BMA)	19	0	67.11%	2.6842
FMC Millbrook (BMA)	17	0	76.47%	3.0588
FMC Rock Quarry (BMA)	0	10	NA	NA
FMC White Oak (BMA)	12	0	62.50%	2.5000
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake County Dialysis (BMA)	30	-2	95.00%	3.8000
Wake Forest Dialysis Center (DaVita)	22	-4	98.86%	3.9545
Zebulon Kidney Center (BMA)	30	-4	86.67%	3.4667

Source: July 2019 SDR, Table B.

In Section G, pages 42-43, the applicant provides the Wake County BMA facility utilization for the periods ended December 31, 2018 and June 30, 2019. The applicant states that the June 30, 2019 data was submitted to the Agency on the ESRD Data Collection form in August 2019. In Section G, page 44, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states:

“This is an application to add two dialysis stations,[sic] to BMA Cary. The application will also re-distribute existing health services, and place a home training program into a facility which is convenient for the patient population proposed to be served by the facility.

The July 2019 SDR does report a surplus of 15 dialysis stations in Wake County. The SDR also reports that the Wake County ESRD Census for December 31, 2018 was 1,388, and that this census was increasing at a rate of 3.6%. The growth of the Wake County ESRD patient population results in a projection of 49.8 new dialysis patients for 2019. If this growth rate is sustained, (and there is no indication that the growth rate will not be sustained), and assuming the home patient population percentage remains the same, Wake County will need 13 new dialysis stations each year (at 80% utilization; 14 new stations at 75% utilization). The current surplus of stations will be quickly eroded.

Approval of this application [sic] not cause unnecessary duplication of services, but will ensure an adequate inventory of dialysis stations exists for the ESRD patient population of the county.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a facility need determination at Cary Kidney Center, as calculated using the methodology in the July 2019 SDR, for the proposed additional dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved additional dialysis stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Q Form H Staffing, page 96, the applicant provides a table illustrating current and projected OY2 staffing in full time equivalents (FTEs) for Cary Kidney Center, as summarized below.

POSITION	FTE Positions as of 6/30/19	FTE POSITIONS OY1	FTE POSITIONS OY2
FMC Clinic Manager	1.00	1.00	1.00
RN	4.00	4.00	4.00
Home Training RN	0.00	2.00	2.00
Patient Care Technician	10.00	10.00	10.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Equipment Technician	1.00	1.00	1.00
Administration	1.00	1.00	1.00
FMC Director Operations	0.15	0.15	0.15
In-Service	0.15	0.15	0.15
Chief Technician	0.15	0.15	0.15
Total	19.45	21.45	21.45

Source: Section Q Form H, page 96

The assumptions and methodology used to project existing staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, page 46, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 47, the applicant identifies the current medical director for the facility as Dr. Jason Eckel. In Exhibit H-4, the applicant provides a letter from Jason Eckel, MD indicating his intent to continue to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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, page 49, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	BMA on site at project completion
Home training HH PD Accessible follow-up program	BMA on site at project completion
Psychological counseling	Referral to Carolina Partners in Mental Health or Alliance Behavioral Health
Isolation – hepatitis	BMA on site
Nutritional counseling	BMA on site
Social Work services	BMA on site
Acute dialysis in an acute care setting	Referral to WakeMed Cary or Rex Hospital
Emergency care	BMA staff until ambulance transport to hospital
Blood bank services	Referral to WakeMed Cary
Diagnostic and evaluation services	Referral to WakeMed Cary or Rex Hospital
X-ray services	Referral to WakeMed Cary or Rex Hospital
Laboratory services	BMA on site / Spectra
Pediatric nephrology	Referral to UNC Healthcare
Vascular surgery	Rex Hospital or Raleigh Access Center
Transplantation services	Referral to UNC Healthcare
Vocational rehabilitation & counseling	Referral to Wake County Vocational Rehabilitation
Transportation	Go Cary, or Go Wake transportation services

Source: Table in Section I, page 49

In Section I, page 49, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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 add two dialysis stations and relocate the entire home training program from BMA of Raleigh Dialysis for a total of 26 dialysis stations upon completion of this project and Project ID #J-11470-18 (relocate entire 24-station facility to a new location).

In Section K.2, page 52, the applicant states that the project involves renovating approximately 1,650 square feet of additional leased space.

In Section K.3(a), page 52, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Section Q and Exhibit K.2.

On page 52, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. The applicant states:

“The project is a necessary part of doing business. The patient population of the area is increasing and more dialysis stations are necessary at this location. . . .

This project will not increase costs or charges to the public for the proposed services.”

The applicant provides supporting documentation in Section Q.

On pages 53-54, the applicant addresses applicable energy saving features that will be incorporated into the proposed project.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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, page 57, the applicant provides the historical payor mix for Cary Kidney Center patients during CY2018 for its existing services, as shown in the table below.

**Cary Kidney Center
Historical Payor Mix CY2018
In-Center Dialysis Services**

Payor Source	# of Patients	% of Total
Self-pay	2.02	2.35%
Commercial Insurance*	5.60	6.51%
Medicare*	50.51	58.73%
Medicaid*	11.60	13.49%
Medicare/Commercial	15.02	17.47%
Miscellaneous (Incl. VA)	1.26	1.46%
Total	86.00	100.00%

*Including any managed care plans
Total may not sum due to rounding

The applicant also provides the payor mix for the home training program being relocated from BMA of Raleigh to Cary Kidney Center. As of June 30, 2019, BMA of Raleigh had no HH patients. The table on page 57 shows the total number of PD patients (calculated by percent of treatments) under the column heading of “% of Total” and the percent of patients by payor mix under the column heading of “# of Patients”. The table below provides the information accurately.

**BMA of Raleigh
 Historical Payor Mix CY2018
 Peritoneal Dialysis**

Payor Source	# of Patients	% of Total
Self-pay	0.08	0.16%
Commercial Insurance*	12.32	23.69%
Medicare*	26.55	51.05%
Medicaid*	3.26	6.26%
Medicare/Commercial	9.37	18.02%
Miscellaneous (Incl. VA)	0.43	0.82%
Total	52.00	100.00%

*Including any managed care plans
 Total may not sum due to rounding

The applicant proposes the relocation of the entire home training program; however, only the patients, as identified in the assumptions by location of residence, are expected to transfer their care to Cary Kidney Center.

In Section L.1(a), page 56, the applicant provides comparison of the demographical information on Cary Kidney Center patients and the service area patients during CY2018, as summarized below.

	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population of the Service Area*
Female	37.6%	51.3%
Male	62.4%	48.7%
Unknown		
64 and Younger	55.3%	88.4%
65 and Older	44.7%	11.6%
American Indian	0.0%	0.8%
Asian	5.9%	7.5%
Black or African-American	37.6%	21.0%
Native Hawaiian or Pacific Islander	1.2%	0.1%
White or Caucasian	41.2%	59.8%
Other Race	9.4%	10.8%
Declined / Unavailable	2.4%	

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 58, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons under any federal regulations.

In Section L, page 58, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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, page 59, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Cary Kidney Center
 Projected Payor Mix CY 2022**

Payor Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	2.09	2.35%	0.00	0.00%	0.00	0.00%
Commercial Insurance*	5.81	6.51%	1.98	31.85%	4.12	30.56%
Medicare*	52.43	58.73%	4.07	65.53%	7.90	58.62%
Medicaid*	12.04	13.49%	0.00	0.00%	0.25	1.83%
Medicare/Commercial	15.59	17.47%	0.16	2.63%	1.21	8.99%
Miscellaneous (Incl. VA)	1.30	1.46%	0.00	0.00%	0.00	0.00%
Total	89.28	100.00%	6.22	100.00%	13.47	100.00%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 2.35% of in-center dialysis services will be provided to self-pay patients, 76.20% to Medicare patients (includes Medicare and Medicare/Commercial), and 13.49% to Medicaid patients. Relatively, the same percentages for Medicare payors are projected for the home training program; however, commercial insurance is projected to provide just over 30% of the reimbursement for the home training program, with a lower percent provided by Medicaid, as compared to in-center services.

On page 59, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project. The applicant explains that the IC dialysis data is based on the last full operating year at Cary Kidney Center while the HH and PD data is based on the last full operating year at BMA of Fuquay Varina Kidney Center because it is the closest facility to the Cary area with a home training program and the applicant believes it reflects the patients to be served at Cary Kidney Center. The applicant also explains that Fresenius reports payor source of treatments, not whole patients as requested in the table, which the applicant states provides a clear indication of the source of revenue.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Cary Kidney Center and the historical payor mix of BMA of Fuquay Varina Kidney Center's home training program.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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, page 60, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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, page 61, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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 proposes to add two dialysis stations and relocate the entire home training program from BMA of Raleigh Dialysis for a total of 26 dialysis stations upon completion of this project and Project ID #J-11470-18 (relocate entire 24-station facility to a new location).

On page 369, the 2019 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 14 dialysis centers in Wake County. Also, BMA has been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry but the facilities were not yet operational on December 31, 2018. DaVita is the only other provider of dialysis services in Wake County, and currently operates Wake Forest Dialysis, and has been approved to develop Oak City Dialysis. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table B of the July 2019 SDR:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina Kidney Center (BMA)	28	0	84.82%	3.3929
BMA of Raleigh Dialysis (BMA)	50	0	90.50%	3.6200
Cary Kidney Center (BMA)	24	0	89.58%	3.5833
FMC Eastern Wake (BMA)	17	0	64.71%	2.5882
FMC Morrisville (BMA)	10	0	45.00%	1.8000
FMC New Hope Dialysis (BMA)	36	0	86.11%	3.4444
FMC Northern Wake (BMA)	14	0	87.50%	3.5000
Wake Dialysis Clinic (BMA)	50	4	98.50%	3.9400
FKC Holly Springs (BMA)	0	10	NA	NA
FMC Apex (BMA)	20	0	82.50%	3.3000
FMC Central Raleigh (BMA)	19	0	67.11%	2.6842
FMC Millbrook (BMA)	17	0	76.47%	3.0588
FMC Rock Quarry (BMA)	0	10	NA	NA
FMC White Oak (BMA)	12	0	62.50%	2.5000
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake County Dialysis (BMA)	30	-2	95.00%	3.8000
Wake Forest Dialysis Center (DaVita)	22	-4	98.86%	3.9545
Zebulon Kidney Center (BMA)	30	-4	86.67%	3.4667

Source: July 2019 SDR, Table B.

According to Table D in the July 2019 SDR, there is a surplus of 15 dialysis stations in Wake County. The applicant proposes to add two dialysis stations to the existing facility in Wake County pursuant to the facility need determination methodology.

In Section N, pages 62-64, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Wake County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA Cary facility begins with patients [sic] the current patient population.

...

Fresenius related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.

...

Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.

...

Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.

...

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections B, F, and Q of the application and any exhibits).
- Quality services will be provided (see Sections B and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section Q Form A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies 127 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 68, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding

of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Cary Kidney Center is an existing facility.

(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 Q Form C, page 76, the applicant projects that Cary Kidney Center will serve 86.2 in-center patients on 26 stations, or a rate of 3.32 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 3.2 patients per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

- C- In Section Q, pages 77-82, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.