

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 4, 2021

Findings Date: January 4, 2021

Project Analyst: Misty L. Piekaar-McWilliams

Team Leader: Gloria C. Hale

Project ID #: J-11984-20

Facility: Cary Kidney Center

FID #: 180166

County: Wake

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

Project: Add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project and Project ID #J-11766-19, which is also a change of scope and a cost overrun for Project ID #J-11766-19

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 no more than three (3) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project and Project ID #J-11766-19, which is also a change of scope and a cost overrun for Project ID #J-11766-19.

On December 10, 2019, the Agency awarded the applicant a certificate of need for Project ID #J-11766-19 to add two (2) dialysis stations pursuant to Condition 2 of the facility need methodology and a home therapies program at Cary Kidney Center (CKC). The applicant proposed in Project ID #J-11766-19 to relocate the entire home training program from BMA of Raleigh Dialysis to Cary Kidney Center. No stations were to be relocated. In August 2020,

CKC started working through lease modifications which would permit CKC to utilize additional space necessary for the home program at CKC. Construction bids came in higher than expected causing this application to be filed as a cost overrun to Project ID #J-11766-19 in addition to a facility need determination application.

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 170, the county need methodology shows there is no county need determination for additional dialysis stations in Wake County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center, as reported in the 2020 SMFP, is at least 75% or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Cary Kidney Center (CKC) in Table 9B on page 163 of the 2020 SMFP, is 89.58% or 3.5833 patients per station per week, based on 86 in-center dialysis patients and 24 certified dialysis stations as of December 31, 2018 [$86 / 24 = 3.5833$; $3.5833 / 4 = 0.8958$]. Therefore, the applicant exceeds the minimum utilization required in Condition 2.a and is eligible to apply for additional stations based on the facility need methodology in Condition 2.b.

As shown in Table 9E, page 173 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at CKC is up to four (4) additional stations; thus, the applicant is eligible to apply to add up to four (4) additional dialysis stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

However, whereas the applicant can apply to add up to four (4) additional dialysis stations, the applicant proposes to add no more than three (3) new dialysis stations to CKC pursuant to facility need, which is consistent with the 2020 SMFP calculated facility need determination; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 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.5, pages 14-15; Section N.2(b), page 58; Section O, pages 60-63; 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.5 (b and d), pages 14-17; Section C.7, pages 28-29; Section L, pages 51-55; Section N.2(c), page 58; 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.5 (c and d), pages 16-17; Section N.2(a), page 58; 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 no more than three (3) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project and Project ID #J-11766-19, which is also a change of scope and a cost overrun for Project ID #J-11766-19.

The following table, summarized from data on page 7 of the application and page 163 of the 2020 SMFP, shows the current projected number of dialysis stations at CKC upon project completion.

Cary Kidney Center		
# of Stations	Description	Project ID #
24	Total # of existing certified stations as reported in Table 9B of the 2020 SMFP	
3	# of stations to be added as part of this project	
	# of stations to be deleted as part of this project	
2	# of stations previously approved to be added but not yet certified	J-11766-19
	# 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	
29	Total # of stations upon completion of all facility projects	

Note: 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 three (3) dialysis stations for a total of 29 stations upon the completion of this project.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.*” The facility referred to in this application is located in Wake County. Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 20 and 21, the applicant provides the historical and projected in-center (IC) patient origin for CKC during the last full operating year, January 1, 2019 –

December 31, 2019 (CY 2019), and the projected patient origin for the second full operating year following project completion, January 1, 2023 - December 31, 2023 (CY 2023), as summarized in the following table:

CKC Historical & Projected Patient Origin				
	Historical (CY 2019)		Projected (CY 2023)	
	# of IC Patients	% of Patients	# of IC Patients	% of Patients
Wake	76	96.2%	85.3	98.8%
Dare	1	1.3%	0	0.0%
Durham	1	1.3%	1	1.2%
Other States	1	1.3%	0	0.0%
Total	79	100.0%	86.3	100.0%

Totals may not sum due to rounding

The applicant states on page 20 that CKC does not currently offer home dialysis therapies at this facility. Consequently, there is no historical data for home hemodialysis (HH) patients and peritoneal dialysis (PD) patients for CKC. The following table provides the projected HH and PD patients for the second full operating year, CY 2023.

CKC Projected Patient Origin				
	Projected (CY 2023)		Projected (CY 2023)	
	# of HH Patients	% of Patients	# of PD Patients	% of Patients
Wake	5.4	100.0%	14.0	100.0%
Total	5.4	100.0%	14.0	100.0%

As shown in the table above and shown on page 21 of the application, CKC projects all of its HH and PD patients to reside in Wake County.

Analysis of Need

In Section C.4, pages 26-27, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant discusses the need based on CKC’s and Wake County’s patient growth rate over the last year. The applicant states:

- The patient population requires frequent treatments. Patients typically receive three (3) treatments per week and either dialyze on a Monday/Wednesday/Friday morning or afternoon or Tuesday/Thursday/Saturday morning or afternoon. If patients do not receive sufficient treatments, it will lead to the patients’ demise.
- CKC’s projected patient population for the first full operating year (OY) (01/01/2022 to 12/31/2022) is projected to grow to 83.4 in-center patients with a utilization rate of 72.50%, or 2.9 patients per dialysis station.
- The OY projections for patient population is based upon the 3.6% Wake County Five Year Average Annual Change Rate (AACR) as indicated in Table 9C of the 2020 SMFP.
- The applicant does not project growth for patients who reside outside of Wake County.

The information is reasonable and adequately supported for the following reasons:

- According to the 2020 SMFP, as of December 31, 2018, CKC was operating at a rate of 3.583 patients per station per week, or 89.58 percent of capacity.
- The applicant adequately demonstrates the need to add three (3) dialysis stations pursuant to facility need based on its existing and future patient population.

In-Center Projected Utilization

In Section Q, pages 73-74, 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 Dec. 31, 2019.	76
Project this population forward one year to December 31, 2020, using the Wake County Five Year AACR of 3.6%.	$76 \times 1.036 = 78.7$
Subtract two patients projected to transfer to FKC Holly Springs (Project ID #J-11510-18).	$78.7 - 2 = 76.7$
Project Wake County patients forward one year to December 31, 2021, using the Wake County Five Year AACR of 3.6%.	$76.7 \times 1.036 = 79.5$
Add patient from Durham County projected to continue to dialyze at CKC. This is the projected starting census for this project.	$79.5 + 1 = 80.5$
Project Wake County patients forward one year to December 31, 2022, using the Wake County Five Year AACR of 3.6%.	$79.5 \times 1.036 = 82.4$
Add patient from Durham County projected to continue to dialyze at CKC. This is the projected ending census for operating year 1 (OY1).	$82.4 + 1 = 83.4$
Project Wake County patients forward one year to December 31, 2023, using the Wake County Five Year AACR of 3.6%.	$82.4 \times 1.036 = 85.3$
Add patient from Durham County projected to continue to dialyze at CKC. This is the projected ending census for operating year 2 (OY2).	$85.3 + 1 = 86.3$

Source: Table in Section Q, page 74

At the end of OY1 (CY2022) Cary Kidney Center is projected to serve 83.4 in-center patients on 29 stations; and at the end of OY2 (CY2023) the facility is projected to serve 86.3 in-center patients on 29 stations.

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

- OY1: 2.9 patients per station per week, or 72.5% utilization [83.4 patients / 29 dialysis stations = 2.9; $2.9 / 4 = 0.7250$].
- OY 2: 3.0 patients per station per week, or 75% utilization [86.3 patients / 29 dialysis stations = 3.0; $3.0 / 4 = 0.7500$].

The projected utilization of 2.9 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

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

- CKC was operating at 89.58% capacity as of December 31, 2018, as reported in the 2020 SMFP which exceeds the required minimum utilization of 75%.
- The applicant projects growth in the Wake County patient population using the Wake County Five Year AACR of 3.6% as published in the 2020 SMFP.
- The applicant appropriately subtracts two (2) patients who intend to transfer their care from CKC to FKC Holly Springs pursuant to a previously approved CON project (CON Project ID #J-11510-18).
- 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 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Home Dialysis Training Background

On December 10, 2019, the Certificate of Need Section awarded the applicant a certificate of need for Project ID #J-11766-19 to add a home therapies program at CKC. The applicant proposed in Project ID #J-11766-19 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 23, the applicant states that Cary Kidney Center does not currently offer home dialysis training services. The applicant further states that BMA projected six (6) HH patients and 13 PD patients would transfer their care to CKC upon certification of the home program. Since then, one (1) of the HH patients has changed their modality and is not projected to transfer their care to CKC. 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 24 that shows the approximate location of Wake County home therapy patients' residences, some of whom could be better served at Cary Kidney Center.

The applicant further states that upon completing the relocation of CKC (Project ID #J-11470-18) to its new location, BMA began working through lease modifications which would permit CKC to have additional space for the transferred home program; however, the construction bids for the new space came in higher than expected which is why the applicant is filing this application as a cost overrun to Project ID #J-11766-19 in addition to a facility need determination application.

Home Therapy Projected Utilization

In Section Q, pages 75-77, the applicant makes the following assumptions in the projection of home therapies:

- The applicant projects that five (5) HH patients and 13 PD patients from the stated area on the map on page 76 would be better served at the proposed Cary location and are expected to transfer their care to CKC upon certification of the home therapies program. All 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 2020 SMFP.
- The applicant does not project growth for patients residing outside of Wake County.
- Services will be offered as of December 31, 2021. Therefore, OY1 is CY2022, January 1, 2022 - December 31, 2022 and OY2 is CY2023, January 1, 2023 - December 31, 2023.

CARY KIDNEY CENTER HOME THERAPY PATIENTS

	HH	PD
Begin with the Wake County home patients projected to transfer their care as of December 31, 2021.	5	13
Project this population forward one year to December 31, 2022, using the Wake County Five Year AACR of 3.6%.	$5 \times 1.036 = 5.2$	$13 \times 1.036 = 13.5$
Project Wake County patients forward one year to December 31, 2023, using the Wake County Five Year AACR of 3.6%.	$5.2 \times 1.036 = 5.4$	$13.5 \times 1.036 = 14.0$

Source: Table in Section Q, page 78

At the end of OY1 (CY2022) CKC is projected to serve 5.2 HH patients and 13.5 PD patients; at the end of OY2 (CY2023) the facility is projected to serve 5.4 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 five (5) HH and 13 PD patients based on patient location and being better served by transferring their care to CKC. 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 total IC, HH and PD projected utilization is shown in Section Q and summarized below to include the Durham County in-center patients.

**Cary Kidney Center
 Projected Patient Utilization**

COUNTY	December 31, 2022			December 31, 2023			County Patients as % of Total	
	# IC PATIENTS	# HH Patients	# PD Patients	# IC PATIENTS	# HH Patients	# PD Patients	OY1	OY2
Wake	82.4	5.2	13.5	85.3	5.4	14.0	98.8%	98.8%
Durham	1.0	0.0	0.0	1.0	0.0	0.0	1.2%	1.2%
Total	83.4	5.2	13.5	86.3	5.4	14.0	100.0%	100.0%

Totals may not sum due to rounding

Projected utilization of the total proposed IC, HH and PD programs at CKC is reasonable and adequately supported for the reasons stated above.

Access

In Section C.7, pages 28-29, 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 C.7, pages 28-29, the applicant projects the following estimated percentage of total patients for each group during the second year of operation following completion of the project, as summarized in the following table.

**Cary Kidney Center
Projected Estimated Percentage of Total Patients for Each Group**

	Estimated Percentage of Patients by Group
Low Income Persons	40.5%
Racial and Ethnic Minorities	74.3%
Women	33.8%
Handicapped Persons	36.5%
Elderly	41.9%
Medicare Beneficiaries	71.6%
Medicaid Recipients	31.1%

Note: A single patient can be counted in multiple categories.

Source: Current CKC census as of the date the application was prepared.

The projected estimated percentage of total patients by group is reasonable and adequately supported.

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 and adequately supports its assumptions.

Conclusion

The Agency reviewed the:

- Application,
- Exhibits to the application,
- Information publicly available during the review and used by the Agency, and
- Supplemental information requested by the Agency.

- (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 23, the applicant states in Project ID #J-11470-18, BMA projected six (6) home hemodialysis patients and 13 peritoneal dialysis patents to transfer their care to CKC.

Since closing the home training program at BMA of Raleigh Dialysis, these patients have transferred their care to other BMA dialysis facilities located in Wake County. However, several patients have decided to remain at the dialysis facility they transferred to due to convenience and familiarity. The applicant provides a map on page 24 that shows the approximate location of Wake County home therapy patients' residences, some of whom could be better served at Cary Kidney Center. The applicant states, "*The following map...demonstrates that these home patients would be well served by a home training program at the Cary Kidney Center.*" The applicant states the transferred home training program dialysis patients' needs were met despite the relocation of a service and the relocation of the home training program to CKC will better serve the needs of western Wake County dialysis patients.

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

- (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 no more than three (3) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project and Project ID #J-117766-19, which is also a change of scope and a cost overrun for Project ID #J-11766-19.

In Section E, page 34, 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 CKC area.
2. Apply for fewer than three (3) dialysis stations – the applicant states this alternative fails to recognize the growth of the ESRD patient population residing in the CKC area.
3. Apply for more than three (3) dialysis stations – the applicant states the facility is not projected to need more than 29 (26+3=29) dialysis stations at this time.
4. Reducing the size of the proposed home therapies program– the applicant states this alternative was determined to be less effective as it would limit the number of patients who could be trained for home dialysis.

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. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
 - 2. Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than three (3) additional dialysis stations for a total of no more than 29 dialysis stations upon completion of this project and Project ID #J-11766-19 (add 2 stations), which shall include any home hemodialysis training or isolation stations.**
 - 3. The certificate holder 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 no more than three (3) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project and Project ID #J-11766-19, which is also a change of scope and a cost overrun for Project ID #J-11766-19.

Capital and Working Capital Costs

In Section Q, Form F.1b, Capital Cost COR, page 82, the applicant projects the following total capital cost associated with this project and Project ID # J-11766-19.

	Project ID # J-11766-19	Project ID # J-11984-20	Difference
Construction/Renovation	\$301,404	\$473,364	\$171,960
Architect/Engineering Fees	\$27,126	\$27,126	\$0
Non Medical Equipment	\$0	\$2,250	\$2,250
Furniture	\$46,099	\$55,099	\$9,000
Contingency	\$32,853	\$32,853	\$0
Total Capital Cost	\$407,482	\$590,692	\$183,210

In Section Q, page 81, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 36-37, 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 35, 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 *	\$183,210	\$183,210
Bonds		
Other (Specify)		
Total Financing	\$183,210	\$183,210

* OE = Owner's Equity

Note: Project ID #J-11766-19 indicated the capital cost financing for that project would also be funded through accumulated reserves or OE.

Exhibit F-2 contains a letter dated October 15, 2020, from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings, Inc. (FMCH), the parent company for BMA, for the capital costs of the project. The letter also documents that the 2019 Consolidated Balance Sheet for FMCH reflects more than \$446 million in cash and total assets exceeding \$25 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 83, 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 CY2022	OY 2 CY2023
Total # of Treatments (IC, HH, and PD)	14,837.51	15,366.34
Total Gross Revenue (charges)	\$93,342,797	\$96,669,619
Total Net Revenue	\$4,850,182	\$5,023,206
Average Net Revenue per Treatment	\$327	\$327
Total Operating Expenses (costs)	\$4,146,062	\$4,261,903
Average Operating Expense per Treatment	\$279.43	\$277.35
Net Income / Profit	\$704,120	\$761,303

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,
- Exhibits to the application, and
- Supplemental information requested 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 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 no more than three (3) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of

this project and Project ID #J-11766-19, which is also a change of scope and a cost overrun for Project ID #J-11766-19.

On page 113, the 2020 SMFP defines the service area dialysis stations as “...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.” The facility referred to in this application is in Wake County. Thus, the service area for this application 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 and Downtown Raleigh Dialysis. See the following table that shows the existing and approved dialysis facilities in Wake County including percentage of utilization and patients per station per week from Table 9B of the 2020 SMFP, pages 163-164 and page 40 of the application:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	# of IC Patients 12/31/18	% Utilization
BMA of Fuquay-Varina Kidney Center (BMA)	28	95	84.82%
BMA of Raleigh Dialysis (BMA)	50	181	90.50%
Cary Kidney Center (BMA)	24	86	89.58%
FMC Eastern Wake (BMA)	17	44	64.71%
FMC Morrisville (BMA)*	10	18	45.00%
FMC New Hope Dialysis (BMA)	36	124	86.11%
FMC Northern Wake (BMA)	14	49	87.50%
FMC Wake Dialysis Clinic (BMA)	50	197	98.50%
FKC Holly Springs (BMA)	0	0	NA
FMC Apex (BMA)	20	66	82.50%
FMC Central Raleigh (BMA)	19	51	67.11%
FMC Millbrook (BMA)	17	52	76.47%
FMC Rock Quarry (BMA)	0	0	NA
FMC White Oak (BMA)	12	30	62.50%
Southwest Wake County Dialysis (BMA)	30	114	95.00%
Zebulon Kidney Center (BMA)	30	104	86.67%
Oak City Dialysis (DaVita)	0	0	NA
Raleigh Downtown Dialysis (DaVita)	0	0	NA
Wake Forest Dialysis Center (DaVita)	22	87	98.86%

Source: 2020 SMFP, Table 9B and page 40 of application

*Application referred to facility as CKC when it should state FMC Morrisville

In Section G, page 41, 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 a proposal to add three dialysis stations to an existing dialysis facility. The stations are needed by the patient population to be served by the facility. The projections of future patient populations to be served begins with the current patient population of the facility and an increase of that population at a rate of 3.6%. The applicant has not projected to serve in-center patients currently served in another facility, or served by another provider. The stations are needed at Cary Kidney Center to support the projected patient census at the facility.”

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:

- CKC is currently operating at or above the ESRD performance standard of 2.8 patients per station per week.
- The applicant adequately demonstrates that CKC will be operating above 2.8 patients per station per week in its projected utilization, which is based on historical patient utilization increased by the Five Year AACR of 3.6% for Wake County.
- The applicant adequately demonstrates that the proposed addition of three (3) stations is needed in addition to the existing and approved dialysis services in Wake 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 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 91, the applicant provides a table illustrating current and projected OY1 and OY2 staffing in full time equivalents (FTEs) for CKC, as summarized below.

POSITION	FTE Positions as of 10/1/2020	FTE POSITIONS OY1	FTE POSITIONS OY2
FMC Clinic Manager	1.00	1.00	1.00
Registered Nurse	4.00	4.00	4.00
Home Training RN	0.00	3.00	3.00
Patient Care Technician	10.00	10.00	10.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	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	22.45	22.45

Source: Section Q, Form H, page 91

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 42, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. 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 based on the following:

- The applicant increases personnel numbers as the facility projects to grow based upon the Wake County Five Year AACR of 3.6%.
- The applicant adequately budgets costs for the health manpower and management positions in Form F.4 Operating Costs.

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 44, 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	Referral to FMC New Hope Dialysis for HH training and BMA Raleigh for PD training. After project is completed, HH training will be on site.
Home training	
HH	
PD	
Accessible follow-up program	
Isolation – Hepatitis B Positive Patients	BMA on site
Nutritional counseling	BMA on site
Social Work services	BMA on site
Laboratory services	BMA on site
Vascular surgery	Rex Hospital or Raleigh Access Center
Pediatric nephrology	Referral to UNC Healthcare
Acute dialysis in an acute care setting	Referral to WakeMed Cary or Rex Hospital
Transplantation services	Referral to UNC Healthcare
Emergency care	BMA staff until ambulance transport to hospital
Blood bank services	Referral to WakeMed Cary
X-ray/diagnostic/evaluation services	Referral to WakeMed Cary or Rex Hospital
Psychological counseling	Referral to Carolina Partners in Mental Health or Alliance Behavioral Health (patient choice)
Vocational rehabilitation & counseling	Referral to Wake County Vocational Rehabilitation
Transportation	Go Cary or Go Wake transportation services

Source: Table in Section I, page 44

In Section I, page 45, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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 no more than three (3) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project and Project ID #J-11766-19, which is also a change of scope and a cost overrun for Project ID #J-11766-19.

In Section K.2, page 47, the applicant states that the project involves renovating approximately 2,000 square feet of additional space.

In Section K.3(a), pages 47-48, 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 48, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant 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. . . 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 48-49, 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 52, the applicant provides the historical payor mix for CKC patients during CY2019 for its existing services, as shown in the table below.

**Cary Kidney Center
Historical Payor Mix CY2019
In-Center Dialysis Services**

Payor Source	# of Patients	% of Total**
Self-pay	0.68	0.87%
Insurance*	6.95	8.79%
Medicare*	49.39	62.52%
Medicaid*	10.31	13.05%
Medicare/Commercial	10.85	13.73%
Miscellaneous (Incl. VA)	0.82	1.04%
Total	79.00	100.00%

*Including any managed care plans

**Percentages based upon treatment volumes

The applicant does not include historical payor mix for HH and PD patients since currently CKC does not provide a home therapies program.

In Section L.1(a), page 51, the applicant provides a comparison of the demographical information on CKC patients and the service area population during CY2019, as summarized below.

	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population of the Service Area*
Female	33.8%	51.4%
Male	66.2%	48.6%
Unknown		
64 and Younger	58.1%	88.0%
65 and Older	41.9%	12.0%
American Indian	0.0%	0.8%
Asian	1.4%	7.7%
Black or African-American	47.3%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	25.7%	59.6%
Other Race	25.7%	10.8%
Declined / Unavailable	0.0%	

* 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, pages 52-53, 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 53, 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 53, 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	0.70	0.87%	0.00	0.00%	0.00	0.00%
Insurance*	7.60	8.79%	1.64	30.56%	4.44	31.85%
Medicare*	54.00	62.52%	3.15	58.62%	9.14	65.53%
Medicaid*	11.30	13.05%	0.10	1.83%	0.00	0.00%
Medicare/Commercial	11.90	13.73%	0.48	8.99%	0.37	2.63%
Miscellaneous (Incl. VA)	0.90	1.04%	0.00	0.00%	0.00	0.00%
Total	86.40**	100.00%	5.37	100.00%**	13.95	100.00%

Totals may not sum due to rounding

*Including any managed care plans

**Totals reflect Project Analyst's corrections.

As shown in the table above, in the second full year of operation, the applicant projects that 0.87% of in-center dialysis services will be provided to self-pay patients, 76.25% to Medicare patients (includes Medicare and Medicare/Commercial), and 13.05% to Medicaid patients. The applicant also projects that 67.61% of home hemodialysis dialysis services and 68.16% of peritoneal dialysis services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 1.83% of home hemodialysis dialysis services will be provided to Medicaid patients.

On pages 53-54, 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 CKC while the HH and PD data is based on the last full operating year at BMA of Fuquay Varina 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 CKC. 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 for the following reasons:

- The projected payor mix for IC is based on the historical payor mix of CKC.
- The historical payor mix for the home therapies program is based on BMA of Fuquay Varina's home training program which is the closest facility to the Cary area with a home training program.

Conclusion

The Agency reviewed the:

- Application,
- Exhibits to the application, and
- Supplemental information requested by the Agency.

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 54, 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 56, 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-2.

The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant encourages the nearby health professional program to engage in a rotation with the dialysis facility which would expose the nursing students to a dialysis facility and its patient population.

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 no more than three (3) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of

this project and Project ID #J-11766-19, which is also a change of scope and a cost overrun for Project ID #J-11766-19.

On page 113, the 2020 SMFP defines the service area dialysis stations as “...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.” The facility referred to in this application is in Wake County. Thus, the service area for this application 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 and Downtown Raleigh Dialysis. See the following table that shows the existing and approved dialysis facilities in Wake County including percentage of utilization and patients per station per week, from Table 9B of the 2020 SMFP, pages 163-164 and page 40 of the application:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	# of IC Patients 12/31/18	% Utilization
BMA of Fuquay-Varina Kidney Center (BMA)	28	95	84.82%
BMA of Raleigh Dialysis (BMA)	50	181	90.50%
Cary Kidney Center (BMA)	24	86	89.58%
FMC Eastern Wake (BMA)	17	44	64.71%
FMC Morrisville (BMA)*	10	18	45.00%
FMC New Hope Dialysis (BMA)	36	124	86.11%
FMC Northern Wake (BMA)	14	49	87.50%
FMC Wake Dialysis Clinic (BMA)	50	197	98.50%
FKC Holly Springs (BMA)	0	0	NA
FMC Apex (BMA)	20	66	82.50%
FMC Central Raleigh (BMA)	19	51	67.11%
FMC Millbrook (BMA)	17	52	76.47%
FMC Rock Quarry (BMA)	0	0	NA
FMC White Oak (BMA)	12	30	62.50%
Southwest Wake County Dialysis (BMA)	30	114	95.00%
Zebulon Kidney Center (BMA)	30	104	86.67%
Oak City Dialysis (DaVita)	0	0	NA
Downtown Raleigh Dialysis (DaVita)	0	0	NA
Wake Forest Dialysis Center (DaVita)	22	87	98.86%

Source: 2020 SMFP, Table 9B and page 40 of application

*Application referred to facility as CKC when it should state FMC Morrisville

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 57, 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 Cary Kidney Center facility begins with the current patient population and projects growth of that population consistent with the Wake County Five Year Average Annual Change Rate published in the 2020 SMFP.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 58, the applicant states:

“Approval of this application will allow the Cary Kidney Center facility to continue serving patents who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

See also Sections B, C, F and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 58, the applicant states:

‘We deliver superior care that improves the quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.’

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 58, the applicant states:

“Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities.”

See also Sections B, L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

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 over 100 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 63, 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 CKC will serve 83.4 in-center patients on 29 stations, or a rate of 2.9 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 2.8 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 72-78, 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.