

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 27, 2018

Findings Date: April 27, 2018

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: N-11447-18

Facility: Fresenius Kidney Care East Lumberton

FID #: 180042

County: Robeson

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

Project: Develop a new 20-station dialysis facility by relocating 20 existing dialysis stations from BMA Lumberton, and relocate the home training program from BMA Lumberton to the new facility

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. (BMA) d/b/a Fresenius Kidney Care East Lumberton [**FKC East Lumberton**] proposes to develop a new 20-station dialysis facility by relocating 20 existing dialysis stations from BMA Lumberton. The applicant also proposes to relocate the existing home training (home hemodialysis and peritoneal dialysis) program from BMA Lumberton to the new facility. Upon completion of the proposed project, BMA Lumberton will be certified for 15 dialysis stations.

Need Determination

The county and facility need methodologies in the January 2018 SDR and the 2018 State Medical Facilities Plan (SMFP) are not applicable to this review.

Policies

There are two policies in the 2018 SMFP applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy ESRD-2

Policy ESRD-2 states:

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

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

The applicant, FKC East Lumberton, proposes to develop a new 20-station dialysis facility by relocating 20 existing dialysis stations from BMA Lumberton. Both BMA Lumberton and the proposed facility location are in Robeson County, therefore there is no change in the dialysis station inventory in Robeson County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4

Policy GEN-4 states:

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

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

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

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.5, pages 13-14, the applicant describes the project's plan to improve energy efficiency and conserve water, including energy efficient lighting, water optimization protocols, sustainable design and building materials, high-performance HVAC systems, and high-efficiency equipment and appliances. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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:

- All facilities are located in Robeson County.
- The applicant provides a written statement demonstrating that the project includes a plan for energy efficiency and water conservation.

- (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, FKC East Lumberton, proposes to develop a new 20-station dialysis facility by relocating 20 existing dialysis stations from BMA Lumberton. The applicant also proposes to relocate the existing home training (home hemodialysis and peritoneal dialysis) program from BMA Lumberton to the new facility. Upon completion of the proposed relocation, BMA Lumberton will be certified for 15 dialysis stations.

The following tables, summarized from Section A.9, page 4 of the application, show the proposed FKC East Lumberton facility, and the existing BMA Lumberton facility from which the applicant plans to relocate 20 stations to develop the proposed new facility.

FKC East Lumberton		
Stations	Description	Project ID #
0	Total existing certified stations as of the January 2018 SDR	
+20	Stations to be added as part of this project	N-11447-18
20	Total stations upon completion of above project	
BMA Lumberton		
Stations	Description	Project ID #
35	Total existing certified stations as of the January 2018 SDR	
-20	Stations to be deleted as part of this project	N-11447-18
15	Total stations upon completion of above project	

As shown in the table above, upon project completion, FKC East Lumberton will be certified for 20 dialysis stations, and BMA Lumberton will be certified for 15 dialysis stations.

Patient Origin

On page 365 the 2018 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 consists of Robeson County. Facilities may also serve residents of counties not included in their service area.

In Section C.1, page 15, the applicant provides the projected patient origin for FKC East Lumberton for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

County	Operating Year 1 CY2020			Operating Year 2 CY2021			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Robeson	66.9	8.0	11.4	69.9	8.3	11.9	96.6%	96.8%
Bladen	0	1.0	0	0	1.0	0	1.1%	1.1%
Hoke	0	0	1	0	0	1	1.1%	1.1%
Scotland	0	1	0	0	1	0	1.1%	1.1%
Total*	66	10	12	69	10	12	100.0%	100.0%

*Applicant states totals are “rounded down to whole patient.”

The applicant provides the assumptions and methodology used to project patient origin on pages 15-17. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.1, page 16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C.1, pages 15-17, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

1. The applicant projects the first two full operating years of the project will be January 1, 2020 – December 31, 2020 (CY2020) and January 1, 2021 – December 31, 2021 (CY2021).
2. The applicant states that 67 in-center dialysis patients who are currently being treated at BMA Lumberton have signed letters indicating they would consider transferring to FKC East Lumberton. Exhibit C-1 contains copies of the 67 letters.
3. FKC East Lumberton assumes that 64 of the 67 patients identified above will transfer their care to the proposed facility. The applicant assumes that the Robeson County patient population will increase by 4.5 percent per year through the first two operating years of the project. On pages 16-17, the applicant states,

“BMA assumes that 64 of the patients signing letters of support and currently dialyzing at BMA Lumberton will complete the transfer based upon the reduction in travel distance. ... As BMA began discussion of this project, BMA did anticipate such tremendous support as was received. Ultimately BMA received 67 patient letters of support for the project. However, the initial discussions centered on a 12-station proposal. With such support as was received, BMA elected to expand the project to 20 stations. ... BMA has not projected to serve patients from other than Robeson County. This is not to say that BMA will limit admissions to the facility, but rather recognizes that the entirety of the patient population supporting this project does reside within Robeson County. ... The applicant assumes that the Robeson County dialysis patients transferring to the new FKC East Lumberton facility are a part of the Robeson County ESRD patient population as a whole, and that this population

will increase at a rate commensurate with the Robeson County Five Year Average Annual Change Rate as published in the January 2018 SDR. That rate is 4.5%.”

Projected Utilization

In Section C.1, pages 15-19, the applicant provides its methodology for projected in-center utilization as illustrated in the following table.

	In-Center
The applicant begins with the 64 Robeson County residents currently dialyzing at BMA Lumberton who expressed their intention to transfer to FKC East Lumberton upon certification of the new facility on December 31, 2019.	64
The census of Robeson County in-center patients is increased by 4.5% to project the census forward one year to December 31, 2020. This is the projected ending census for Operating Year 1.	$[64 \times 0.045] + 64 = 66.9$
The census of Robeson County in-center patients is increased by 4.5% to project the census forward one year to December 31, 2021. This is the projected ending census for Operating Year 2.	$[66.9 \times 0.045] + 66.9 = 69.9$

The applicant projects to serve 66 in-center patients or 3.3 patients per station per week ($66/20 = 3.2$) by the end of Operating Year 1 and 69 in-center patients or 3.5 patients per station per week ($69/20 = 3.5$) by the end of Operating Year 2 for the proposed 20-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). In this application, the applicant assumes a projected annual rate of growth of 4.5 percent for the in-center patient census at FKC East Lumberton, which is equal to the Robeson County Five Year Average Annual Change Rate as published in the January 2018 SDR. Projected in-center utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Home Therapy Programs

On page 18, the applicant provides the following tables showing its projections of home hemodialysis (HHD) and peritoneal dialysis (PD) patients through the first two operating years of the project.

	Peritoneal Dialysis
The applicant begins with 10 Robeson County patients currently on the peritoneal dialysis program at BMA Lumberton as of December 31, 2017.	10 PD patients
The applicant projects growth based on 4.5% annual rate of increase to December 31, 2018.	$10 \times 1.045 = 10.5$
The applicant projects growth based on 4.5% annual rate of increase to December 31, 2019.	$10.5 \times 1.045 = 10.9$
The applicant projects growth based on 4.5% annual rate of increase to December 31, 2020.	$10.9 \times 1.045 = 11.4$
The applicant adds one patient who resides in Hoke County. This is the projected ending census for Operating Year 1.	$11.4 + 1 = 12.4$
The census of Robeson County PD patients is increased by 4.5% to project the census forward one year to December 31, 2020.	$11.4 \times 1.045 = 11.9$
The applicant adds one patient who resides in Hoke County. This is the projected ending census for Operating Year 2.	$11.9 + 1 = 12.9$

	Home Hemodialysis
The applicant begins with 10 Robeson County patients currently on the home hemodialysis program at BMA Lumberton as of December 31, 2017.	7 HH patients
The applicant projects growth based on 4.5% annual rate of increase to December 31, 2018.	$7 \times 1.045 = 7.3$
The applicant projects growth based on 4.5% annual rate of increase to December 31, 2019.	$7.3 \times 1.045 = 7.6$
The applicant projects growth based on 4.5% annual rate of increase to December 31, 2020.	$7.6 \times 1.045 = 8.0$
The applicant adds two patients who reside in Bladen and Scotland Counties. This is the projected ending census for Operating Year 1.	$8.0 + 2 = 10.0$
The census of Robeson County HH patients is increased by 4.5% to project the census forward one year to December 31, 2020.	$8.0 \times 1.045 = 8.3$
The applicant adds two patients who reside in Bladen and Scotland Counties. This is the projected ending census for Operating Year 2.	$8.3 + 2 = 10.3$

On page 17, the applicant describes its assumptions as follows:

“BMA has also proposed to relocate the entire home therapies program from BMA Lumberton to the new FKC East Lumberton facility. BMA will begin projections of future patient populations with the facility census as of December 31, 2017. ... BMA assumes the home dialysis patient population residing within Robeson County will increase at a rate commensurate with the Robeson County Five Year Average Annual Change Rate of 4.5%. ... The BMA Lumberton home program was serving three home patients residing in other counties as of December 31, 2017. BMA will not demonstrate any change in this patient population, but does add these three patients at appropriate points in time.”

Projected utilization for the in-center, HHD and PD dialysis programs at FKC East Lumberton is reasonable and adequately supported for the following reasons:

- The applicant projects the starting patient census for the proposed facility based on existing BMA Lumberton patients who have signed letters expressing their intention to transfer their care to the proposed FKC East Lumberton facility.

- The applicant's growth projections are based on an assumption that patient census will increase at an annual rate of 4.5%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Robeson County, as reported in Table D of the January 2018 SDR.

Access

In Section C.3, pages 19-20, the applicant states that each of BMA's 112 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.1, page 64, the applicant projects the following payor mix during the second full fiscal year of operation (CY2021) following completion of the project, as illustrated in the following table.

Payment Source	Total Patients by Percent of Total
Self Pay/Indigent/Charity	2.11%
Medicare	72.63%
Medicaid	7.37%
Commercial Insurance	8.42%
Medicare/Commercial Insurance	4.21%
Miscellaneous (including VA)	5.26%
Total	100.00%

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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

FKC East Lumberton proposes to develop a new 20-station dialysis facility by relocating 20 existing dialysis stations from BMA Lumberton, which is an existing 35-station facility. The applicant also proposes to relocate the existing home training program (home hemodialysis and peritoneal dialysis) from BMA Lumberton to the new facility. Upon completion of the proposed relocation, BMA Lumberton will be certified for 15 dialysis stations.

The following table shows the projected relocation of stations from BMA Lumberton to the proposed FKC East Lumberton facility and identifies the number of patients projected to transfer from the existing facility to the proposed new facility.

Proposed FKC East Lumberton Project		
Facility	Number of Stations to be Relocated	Number of Patients Transferring
BMA Lumberton	20	64
Total Relocated and Transferred	20	64

In Section D.1, pages 27-30, the applicant explains why it believes the needs of the population presently utilizing the dialysis services to be relocated will be adequately met following completion of the project.

According to the January 2018 Semiannual Dialysis Report (SDR), there were 125 patients dialyzing at BMA Lumberton and 35 certified dialysis stations for a utilization rate of 89.29%, or 3.57 patients per station per week ($125/35 = 3.57$) as of June 30, 2017. In Section D.1, page 28, the applicant states that 121 of the 130 in-center patients reside in Robeson County, five patients originate from Bladen County, two patients originate from Cumberland County, one patient originates from Mecklenburg County and one patient from Scotland County.

The applicant assumes that the number of in-center patients at BMA Lumberton who reside in Robeson County will increase at a rate of 4.5% per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Robeson County, as reported in Table D of the January 2018 SDR. The applicant assumes that there will be no increase in the number of patients from the other counties. The applicant projects that 64 BMA Lumberton patients, all of whom will reside in Robeson County, will transfer their care to FKC East Lumberton upon certification of that facility on December 31, 2019.

In Section D.1, page 28, the applicant calculates the in-center patient census for BMA Lumberton starting December 31, 2017 through the first two operating years (CY2020 and CY2021), summarized as follows:

BMA Lumberton	In-Center Patients
Begin with the ESRD patient population of Robeson County, as of December 31, 2017.	121
Project the Robeson County population forward one year to December 31, 2018, using the Five Year AACR for Robeson County.	$121 \times 1.045 = 126.4$
Project the Robeson County population forward one year to December 31, 2019, using the Five Year AACR for Robeson County.	$126.4 \times 1.045 = 132.1$
Subtract 64 Robeson County patients projected to transfer their care to FKC East Lumberton.	$132.1 - 64 = 68.1$
Add the Bladen and Cumberland County patients expected to remain at BMA Lumberton	$68.1 + 7 = 75.1$

Thus, on December 31, 2019, BMA Lumberton is projected to have 15 certified dialysis stations with an in-center patient population of 75, which is equivalent to a utilization rate of 5.0 patients per station per week ($75 / 15 = 5.0$) or 125% ($5.0 / 4 = 1.25$).

In Section D.1, page 29, the applicant states that the needs of BMA Lumberton’s patients will continue to be met following the proposed relocation of 20 stations to FKC East Lumberton because BMA Lumberton will be eligible to apply for seven additional dialysis stations based on the utilization of the facility as reported in the January 2018 SDR. On pages 29-30, the applicant states:

“BMA readily acknowledges that utilization rates in excess of four patients per station necessarily result in a third, or evening shift. BMA Lumberton does not currently operate a third, or evening dialysis shift, but will do so when patient census requires. ... As an additional consideration, BMA notes that the January 2018 SDR reports facility census on June 30, 2017 was 125 patients. This represents a utilization level of 3.5714 patients per station, or 89.29% of utilization. Utilization rates at or above 80% will allow the facility to qualify for application of Facility Need Methodology and a CON application for additional stations. In this case, the facility will qualify for up to seven additional stations. ... First, and most importantly, BMA is not going to fail to provide care for the patient population of the facility. BMA will ensure that stations are available for the patients of the area. BMA is committed to applying for additional stations at BMA Lumberton as the facility qualifies for additional stations.”

Assuming the applicant adds seven dialysis stations to BMA Lumberton as it proposes above, on December 31, 2019, BMA Lumberton would be projected to have 22 certified dialysis stations ($15 + 7 = 22$) with an in-center patient population of 76, which is equivalent to a utilization rate of 3.45 patients per station per week ($76 / 22 = 3.45$) or 86.25% ($3.45 / 4 = 0.8625$).

The applicant also states that failure to develop the project will result in an over-capacity situation at BMA Lumberton and potential access problems for patients. On page 30, the applicant states:

“The census of the facility will continue to increase. Based on the growth as discussed herein, the facility could be projected to be operating at 100% capacity within three years. Extending the growth projections for another 12 months results in a projected census for December 31, 2020 of 138.1 Robeson County patients. Add to that the seven patients from Bladen and Cumberland Counties, resulting in a projected census of 145.1 in-center patients as of December 31, 2020. A census of 145 patients dialyzing on 35 stations exceeds four patients per station and/or 100% utilization. ... Moving forward from January 1, 2021 (the first day of Operating Year 2 of this proposal), absent an approval for development of FKC East Lumberton, the facility would have no option but to operate a third or evening dialysis shift. ... Thus, in this case, absent the relocation of stations to the new FKC East Lumberton, the existing facility (BMA Lumberton) doesn’t have room for additional stations (relocation of 20 stations to FKC East Lumberton does create internal expansion space). Failure to develop FKC East Lumberton will necessarily result in limited capacity for the Robeson County dialysis patient population of the area.”

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

- The applicant projects the patient census for BMA Lumberton based on existing BMA Lumberton patients, and those patients who have signed letters expressing their intention to transfer their care to the proposed FKC East Lumberton facility.
- The applicant’s growth projections are based on an assumption that patient census will increase at an annual rate of 4.5%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Robeson County, as reported in Table D of the January 2018 SDR.

Further, in Section D.2, page 30, the applicant states that the proposed relocation of stations will not will not adversely affect 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

- The needs of the population currently using the services to be reduced, eliminated or 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

In Section E, pages 31-32, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative due to the fact that BMA Lumberton is projected to exceed capacity in the next three years.
- Another Location – The applicant states it considered locating the facility elsewhere in Robeson County but rejected that alternative because the proposed facility is intended to meet the needs of the Lumberton Community, and the applicant intends to close the existing BMA Lumberton facility at some point in the future.
- Relocate Stations from Other BMA Facilities – The applicant states that it considered relocating dialysis stations from other existing dialysis facilities but rejected that alternative because those facilities are already experiencing high utilization, or they are projected to have high utilization in the near future.
- Relocate the Entire BMA Lumberton Facility – The applicant states it considered relocating the entire BMA Lumberton facility but rejected that alternative because there is a significant amount of time remaining on the lease at the location.

On page 33, the applicant states that its proposal is the most effective alternative because the proposed facility is proximate to the patients currently served by BMA Lumberton and will be large enough to accommodate the projected need for both in-center and home therapy programs for the community.

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

- Maintaining the status quo is not an effective alternative due to the fact that BMA Lumberton is projected to exceed capacity in the next three years.
- Relocating the facility elsewhere in Robeson County is not an effective alternative because the proposed facility is intended to meet the needs of the Lumberton Community, and the applicant intends to close the existing BMA Lumberton facility at some point in the future.

- Relocating the stations from other BMA facilities is not an effective because those facilities are already experiencing high utilization, or they are projected to have high utilization in the near future.
- Relocating the entire BMA Lumberton facility is not an effective alternative because there is a significant amount of time remaining on the lease at the location.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care East Lumberton shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care East Lumberton shall develop a new kidney disease treatment center to be known as FKC East Lumberton by relocating 20 dialysis stations and the home therapies program from BMA Lumberton.**
 - 3. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 20 dialysis stations at BMA Lumberton for a total of no more than 15 dialysis stations at BMA Lumberton.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care East Lumberton shall install plumbing and electrical wiring through the walls for no more than 20 dialysis stations which shall include any isolation stations.**
 - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a Johnston Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

FKC East Lumberton proposes to develop a new 20-station dialysis facility by relocating 20 existing dialysis stations from BMA Lumberton, which is an existing 35-station facility. The applicant also proposes to relocate the existing home training program (home hemodialysis and peritoneal dialysis) from BMA Lumberton to the new facility.

Capital and Working Capital Costs

In Section F.1, page 35, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	\$1,846,199
Miscellaneous Costs	\$765,642
Total	\$2,611,841

In Section F.1, page 34, the applicant provides the assumptions used to project the capital cost.

In Section F.10, pages 38-39, the applicant projects that start-up costs will be \$226,723 and initial operating expenses will be \$2,205,564 for a total working capital of \$2,432,287. On pages 38-39, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2, page 36, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	FKC East Lumberton	(Name of Applicant 2)	Total
Loans	\$	\$	\$
Accumulated reserves or OE *	\$2,611,841	\$	\$2,611,841
Bonds	\$	\$	\$
Other (Specify)	\$	\$	\$
Total Financing	\$2,611,841	\$	\$2,611,841

* OE = Owner's Equity

In Section F.13, page 40, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$2,432,287
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total	\$2,432,287

Exhibit F-5 contains a letter dated January 16, 2018 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 and working capital costs of the project. Exhibit F-2 contains a copy of the Consolidated Financial Statements for FMCH for the year ending December 31, 2016. The report indicates that as of December 31, 2016, FMCH had \$356 million in cash and cash equivalents, \$20.1 billion in total assets and \$8.7 billion in net assets (total assets less total liabilities).

Financial Feasibility

The applicant provided pro forma financial statements in Section R for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	1st Full Fiscal Year CY2020	2nd Full Fiscal Year CY2021
Total Treatments*	12,744	13,337
Total Gross Revenues (Charges)	\$50,823,072	\$53,187,956
Total Net Revenue	\$4,416,868	\$4,624,039
Average Net Revenue per Treatment	\$346.58	\$346.71
Total Operating Expenses (Costs)	\$3,308,346	\$3,416,378
Average Operating Expense per Treatment	\$259.60	\$256.16
Net Income	\$1,108,522	\$1,207,661

*Includes in-center, home hemodialysis and peritoneal dialysis treatments.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R 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
- 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 demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.

- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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

FKC East Lumberton proposes to develop a new 20-station dialysis facility by relocating 20 existing dialysis stations and the home therapies program (home hemodialysis and peritoneal dialysis) from BMA Lumberton (Robeson County).

On page 365 the 2018 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 consists of Robeson County. Facilities may also serve residents of counties not included in their service area.

The applicant operates five dialysis centers in Robeson County. DaVita is the only other provider of dialysis services in Robeson County, and currently operates one dialysis center. The existing and approved Robeson County dialysis facilities are shown below:

Existing and Approved Robeson County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/17	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Red Springs	19	0	75.00%	3.0
FMC Dialysis of Robeson County (BMA)	23	0	70.65%	2.8
FMC Pembroke (BMA)	15	4	91.67%	3.7
FMC St. Pauls (BMA)	20	0	66.25%	2.7
Lumberton Dialysis (BMA)	35	0	89.29%	3.6
St. Pauls Dialysis Center (DaVita)*	10	0	47.50%	1.9
Maxton Dialysis (DaVita)*	14	0	NA	NA

Source: January 2018 SDR, Table B.

*DaVita has been approved to relocate the 10 dialysis stations at St. Pauls Dialysis Center to a new facility, Maxton Dialysis (Project I.D. # N-10321-14), and to relocate 4 dialysis stations from Dialysis Care of Hoke County to Maxton Dialysis (Project I.D. # N-110771-15), for a total of 14 dialysis stations at Maxton Dialysis.

In Section G.2, pages 44-45, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Robeson County. The applicant states:

“This project does not create new stations. Approval of this project will result in another facility to serve the patient population of Robeson County. However, BMA has already stated that it intends to close the BMA Lumberton facility as that facility lease expires. This is the first step toward that closure.”

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

- The proposal would not result in an increase in the number of dialysis stations in Robeson County.
- The applicant adequately demonstrates that the proposed facility is needed in addition to the existing or approved facilities in Robeson County.
- The relocation of existing stations from other BMA facilities would not address the applicant’s lease issues at BMA Lumberton and the need to relocate stations from that facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

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

C

In Section H.1, page 46, the applicant provides projected staffing for the proposed facility in the second year of operation (CY2021) as shown in the following table.

FKC East Lumberton Projected Staffing CY2021	
Position	Total FTE Positions
Medical Director	NA*
Registered Nurse	3.00
Home Training Nurse	2.00
Technician	8.00
Dietitian	1.00
Social Worker	1.00
Clinical Manager	1.00
Administrator	0.20
In-Service	0.20
Clerical	1.00
Chief Technician	0.15
Equipment Technician	0.30
Total FTEs	17.85

*Medical Director is an independent contractor, not an employee.

The assumptions and methodology used to project staffing are provided in Section H.1, pages 45-46, and Sections H.6 and H.7, pages 48-49. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, page 47, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 51, the applicant identifies the proposed medical director. In Exhibit I-5, the applicant provides a letter from the proposed medical director indicating an interest in serving 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
- Exhibits to the application
- 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.

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

C

In Section I.1, page 50, the applicant provides a table showing the ancillary and support services necessary for the proposed services. On page 50, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.

In Section I, pages 50-52, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

- (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

In Section K.2, page 57, the applicant states that the project involves construction and up-fitting of 5,322 square feet in leased space in a building to be constructed by a developer. Line drawings are provided in Exhibit K-1.

On pages 55-56, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 58-59, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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

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

C

In Section L.7, page 67, the applicant reports that 84% of the patients who received treatments at BMA Lumberton had some or all of their services paid for by Medicare or Medicaid in CY2017. The table below shows the historical (CY2017) payment source for BMA Lumberton:

Payment Source	BMA Lumberton Patients as Percent of Total
Self Pay/Indigent/Charity	2.11%
Medicare	72.63%
Medicaid	7.37%
Commercial Insurance	8.42%
Medicare/Commercial Insurance	4.21%
Miscellaneous (VA)	5.26%
Total	100.00%

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Robeson	14%	51%	75%	31%	13%	20%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

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

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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, in Section L.3, page 65, the applicant states:

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

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

In Section L.6, page 66, 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.

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

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

C

In Section L.1, page 64, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payment Source	Patients as Percent of Total
Self Pay/Indigent/Charity	2.11%
Medicare	72.63%
Medicaid	7.37%
Commercial Insurance	8.42%
Medicare/Commercial Insurance	4.21%
Miscellaneous (VA)	5.26%
Total	100.00%

Source: Table on page 64 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.11% of total services will be provided to self-pay patients and charity care patients, 76.84% to Medicare patients and 7.37% to Medicaid patients.

On page 64, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for BMA Lumberton.

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

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

C

In Section L.4, page 66, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

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

C

In Section M.1, page 68, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

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, FKC East Lumberton, proposes to develop a new 20-station dialysis facility by relocating 20 existing dialysis stations from BMA Lumberton. The applicant also proposes to relocate the existing home training (home hemodialysis and peritoneal dialysis) program from BMA Lumberton to the new facility. Upon completion of the proposed relocation, BMA Lumberton will be certified for 15 dialysis stations.

On page 365 the 2018 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 consists of Robeson County. Facilities may also serve residents of counties not included in their service area.

The applicant operates five dialysis centers in Robeson County. DaVita is the only other provider of dialysis services in Robeson County, and currently operates one dialysis center. The existing and approved Robeson County dialysis facilities are shown below:

Existing and Approved Robeson County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/17	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Red Springs	19	0	75.00%	3.0
FMC Dialysis of Robeson County (BMA)	23	0	70.65%	2.8
FMC Pembroke (BMA)	15	4	91.67%	3.7
FMC St. Pauls (BMA)	20	0	66.25%	2.7
Lumberton Dialysis (BMA)	35	0	89.29%	3.6
St. Pauls Dialysis Center (DaVita)*	10	0	47.50%	1.9
Maxton Dialysis (DaVita)*	14	0	NA	NA

Source: January 2018 SDR, Table B.

*DaVita has been approved to relocate the 10 dialysis stations at St. Pauls Dialysis Center to a new facility, Maxton Dialysis (Project I.D. # N-10321-14), and to relocate 4 dialysis stations from Dialysis Care of Hoke County to Maxton Dialysis (Project I.D. # N-110771-15), for a total of 14 dialysis stations at Maxton Dialysis.

In Section N.1, page 69, 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. On page 69, the applicant states:

“The applicant does not expect this proposal to have effect on the competitive climate in Robeson County. This is an application to split the BMA Lumberton facility and continue to serve the patients of the facility in a second, convenient location, which will ultimately house the entirety of the BMA Lumberton facility. The applicant does not propose to serve dialysis patients currently being served by another provider.”

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 F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

- (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 O.3, page 74, the applicant states Fresenius owns more than 100 dialysis facilities located in North Carolina. Exhibit A-4 contains a list of the Fresenius dialysis facilities located in North Carolina.

In Section O.3, page 74, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities, BMA East Rocky Mount. The applicant states that BMA East Rocky

Mount is currently back in full compliance with all CMS requirements. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage for the BMA East Rocky Mount facility in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provided 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- C- In Section C.1, page 15, the applicant projects to serve 66 in-center patients by the end of Operating Year 1, which is 3.3 patients per station per week ($66 / 20 = 3.3$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- NA- The applicant is not proposing to increase the number of dialysis stations in an existing facility or one that was not operational prior to the beginning of the

review period.

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

-C- In Section C.1, pages 15-19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.