

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 21, 2016

Findings Date: October 21, 2016

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project ID #: P-11194-16

Facility: New Bern Dialysis

FID #: 955965

County: Craven

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

Project: Relocate four dialysis stations from FMC Craven County to New Bern Dialysis and decertify four additional stations at FMC Craven County for a total of 41 dialysis stations at New Bern Dialysis and 20 dialysis stations at FMC Craven County upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to relocate four existing certified dialysis stations from FMC Craven County to New Bern Dialysis and decertify four additional stations at FMC Craven County. New Bern Dialysis will be certified for a total of 41 stations and FMC Craven County will be certified for a total of 20 stations upon project completion. Both facilities are located in Craven County. The applicant does not propose to establish new dialysis stations or establish a new dialysis facility.

Need Determination

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

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 39 of the 2016 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 39 of the 2016 SMFP is not applicable to this review because the applicant does not propose a capital expenditure greater than \$2 million.

However, POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS on page 33 of the 2016 SMFP is applicable to this review.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS states:

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

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

The applicant proposes to relocate four existing certified dialysis stations from FMC Craven County to New Bern Dialysis. Because both facilities are located in Craven County, there is no change in the total dialysis station inventory in Craven County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

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

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

C

The applicant proposes to relocate four existing certified dialysis stations from FMC Craven County to New Bern Dialysis and decertify four additional stations at FMC Craven County.

The applicant discusses its rationale for the transfer of stations in multiple places throughout the application. On page 15, the applicant states that both FMC Craven County and New Bern Dialysis are located in the same building in adjoining space; thus, patients at either facility travel to functionally the same location regardless of which facility they seek treatment with. On page 24, the applicant states that the patients served by these two facilities have one of the highest percentages of home dialysis in the state within its population. The applicant states that the data collection forms for December 31, 2015 showed a home dialysis patient population of 53 out of 220 patients, or 24.09 percent. This is more than double that of the state as a whole; the January 2016 SDR, with data from June 30, 2015, shows a home dialysis patient population statewide of 1,935 out of 16,318 North Carolina dialysis patients – a total of 11.86 percent. On page 15, the applicant states that New Bern Dialysis is not certified for home dialysis training while FMC Craven County is, and that the reason for the transfer of stations is to create a more “home centric” dialysis facility with more space for each existing station. Regarding the importance of space for a home training station, the applicant states:

“This additional space contributes to the patient learning experience as the patient performs self-care dialysis. As a point of comparison, compare the space of a typical home hemodialysis training room to the space of a typical isolation station:

- a. *BMA notes that many of our home hemodialysis training and support rooms are comprised of approximately 165 square feet. That space allows room for the patient, equipment, patient partner/family member, and the dialysis RN who is providing the training.*
- b. *A typical isolation station within a dialysis facility will involve approximately 120 square feet. That space allows room for the patient, equipment and dialysis RN. However, that space becomes crowded when a third person is introduced into the room.”*

On page 24, the applicant states that after project completion, it will move to decertify an additional four stations at FMC Craven County (and states that it will demonstrate as part of this application that the loss of those four stations will not adversely impact the existing patient population).

On page 11, the applicant states the following with regard to need and projected utilization:

“BMA notes that the 2016 State Medical Facilities Plan (SMFP), Chapter 14, includes Basic Principles which underlie the projection of need for additional dialysis stations. Basic Principle #6 includes the following language:

‘No existing facility may expand unless its utilization is 80 percent or greater. Any facility at 80 percent utilization or greater may apply to expand.’

The table above indicates that New Bern Dialysis had a census of 81 patients as of December 31, 2015. New Bern Dialysis has 37 dialysis stations. Thus, utilization as of December 31, 2015 was only 2.1892 patients per station, or 54.73%.

As BMA began evaluation for this project, we have communicated with the patients of the New Bern Dialysis facility and have in fact had many patients to transfer their care across the hall from FMC Craven County to New Bern Dialysis.

As of June 1, 2016, (two weeks before this application is filed, and one month prior to the beginning of the review period for this application) the in-center census at New Bern Dialysis was 124 patients. This equates to a utilization of 3.3514 patients per station, or 83.79% utilization.

BMA has discussed this concept of 80% utilization in order to expand with Ms. Frisone, Assistant Chief, CON Section, Healthcare Planning and Certificate of Need. Ms. Frisone has indicated that the applicant must demonstrate the conformity with the 80% requirement. In this case, BMA has demonstrated conformity with the requirement. New Bern Dialysis is operating at or above the 80% minimum as discussed in the SMFP, Chapter 14, Basic Principle #6.”

Population to be Served

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Craven County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 18, the applicant provides the projected patient origin for New Bern Dialysis patients for the first two operating years following completion of the project as shown in the table below.

New Bern Dialysis Patients by County/State – OYs 1 & 2				
County	OY1 – CY 2018	OY2 – CY 2019	Patients as % of Total	
	In-Center	In-Center	OY1	OY2
Craven	110.3	112.5	83.2%	82.5%
Beaufort	4.0	4.0	3.0%	2.9%
Jones	1.0	1.0	0.8%	0.7%
Pamlico	17.3	18.8	13.1%	13.8%
Total	132.6	136.3	100.0%	100.0%

Note: Numbers are rounded down to one decimal point to be consistent with later calculations.

The applicant provides the assumptions and methodology used to project patient origin on pages 18-20. The applicant adequately identifies the population to be served.

Analysis of Need

New Bern Dialysis proposes to transfer four dialysis stations from FMC Craven County for a total of 41 certified dialysis stations upon project completion. In Section C, pages 18-25, the applicant states the need for the proposed project is based on the following factors:

1. There is more than double the percentage of home trained patients at the two facilities than for the average of the state of North Carolina as a whole. By transferring these four stations and later de-certifying an additional four stations, the applicant can still serve all its existing in-center patients at New Bern Dialysis as well as create a more home-focused training environment for patients at FMC Craven County.
2. The first two full OYs of the project are expected to be CY 2018 and CY 2019.
3. On June 1, 2016, New Bern Dialysis was providing dialysis treatment for 124 in-center patients, including 105 patients who reside in Craven County, 14 patients who reside in Pamlico County, four patients who resides in Beaufort County, and one patient who resides in Jones County.
4. The applicant assumes the Craven County ESRD patient population utilizing the facility will increase at the rate of 1.94 percent per year. The applicant explains that it used a growth rate of 25% of the facility census growth rate from June 30, 2014 to December 31, 2015:

The applicant subtracted the patient population on June 30, 2014 from the patient population on December 31, 2015.	96 patients – 86 patients = 10 new patients
The applicant determined the net percent of change for that time period.	10 patients / 86 patients = 0.11627907
The applicant divided the net percent of change by the 18 month time period.	0.11627907 / 18 months = 0.00646
The applicant then annualized the net percent of change by multiplying the monthly change by 12 months.	0.00646 X 12 months = 0.07752
The applicant then calculated 25% of the annual growth rate.	0.07752 X 25% = 0.01938 or 1.94%

5. The applicant assumes the Pamlico County ESRD patient population utilizing the facility will increase at the rate of 8.6 percent per year, the Five Year Average Annual Change Rate (AACR) for Pamlico County as published in the January 2016 SDR.
6. The applicant states that it assumes the patients from Beaufort County and Jones County are dialyzing at New Bern Dialysis by patient choice. No growth was calculated for the patients residing outside of Craven County and Pamlico County.
7. The applicant states that New Bern Dialysis has a need for the four additional stations due to the plan to make FMC Craven County more home training centered, the patient population growth, and because the projected patient population at the end of the first operating year is projected to have a utilization rate of approximately 80.5 percent.

Projected Utilization

The applicant’s methodology is illustrated in the following table, based on information provided by the applicant in Section C.1, page 19.

New Bern Dialysis		
Methodology	Craven County	Pamlico County
Begin with the facility census of Craven County and Pamlico County patients as of June 1, 2016.	105	14
Project the Craven and Pamlico patient population forward for seven months to December 31, 2016.	$[105 \times (0.0194 / 12 \times 7)] + 105 = 106.2$	$[14 \times (0.086 / 12 \times 7)] + 14 = 14.7$
Project the Craven and Pamlico patient population forward one year to December 31, 2017.	$(106.2 \times 0.0194) + 106.2 = 108.2$	$(14.7 \times 0.086) + 14.7 = 16.0$
Add patients from Beaufort County and Jones County. This is the starting facility census for December 31, 2017.	$108.2 + 16 + 4 + 1 = 129.2$	
Project the Craven and Pamlico patient population forward one year to December 31, 2018.	$(108.2 \times 0.0194) + 108.2 = 110.3$	$(16 \times 0.086) + 16 = 17.3$
Add patients from Beaufort County and Jones County. This is the facility census for OY 1 (ending December 31, 2018).	$110.3 + 17.3 + 4 + 1 = 132.6$	
Project the Craven and Pamlico patient population forward one year to December 31, 2019.	$(110.3 \times 0.0194) + 110.3 = 112.5$	$(17.3 \times 0.086) + 17.3 = 18.8$
Add patients from Beaufort County and Jones County. This is the facility census for OY 2 (ending December 31, 2019).	$112.5 + 18.8 + 4 + 1 = 136.3$	

The applicant projects to serve 132 in-center patients or 3.22 patients per station (132 patients / 41 stations = 3.22) by the end of Operating Year 1 and 136 in-center patients or 3.32 patients per station (136 patients / 41 stations = 3.3) by the end of Operating Year 2 for the proposed 41-station facility following the addition of four transferred stations. This satisfies the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1(a), pages 56-57, the applicant states that each of BMA’s 104 facilities (including affiliations) in 42 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. On page 57, the applicants project the payor mix for the second operating year of the project, and they project that more than 88 percent of projected patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that this population has for the proposed project, and adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate four existing dialysis stations from FMC Craven County to New Bern Dialysis. On page 27, the applicant also states it plans to decertify four stations at FMC Craven County following completion of the project.

In Section D, pages 27-29, the applicant discusses how the needs of dialysis patients at FMC Craven County and New Bern Dialysis will continue to be met after the proposed relocation of stations to the New Bern Dialysis facility.

FMC Craven County

On pages 27-28 of the application, the applicant provides the assumptions used to project FMC Craven County's utilization on December 31, 2017. The assumptions are summarized below:

- The patient census for June 1, 2016 was 36 patients.
- The applicant states that, as of the completion of this project, FMC Craven County will have transferred four stations to New Bern Dialysis, down from 28 stations to 24. Additionally, FMC Craven County will then take steps to decertify four additional stations, which will bring the number of stations down to 20.
- The applicant projects a growth rate of six percent for its remaining patients, and says the following on page 27:

“Moving forward, the FMC Craven County facility is expected to realize growth of the patient population at least equal to the Craven County Five Year Average Annual Change Rate. Based on Dr. Montero’s interest in the home dialysis modality, and the wide service area of the facility, BMA will project the census forward at 6%. This is 500% of the current published Five Year Average Annual Change Rate [for Craven County] of 1.2%. While BMA

isn't expecting sustained growth rates of 6% at the FMC Craven County facility, this will certainly serve to demonstrate the possible effects of the relocation of four stations."

Based on the above assumptions, the applicant projects utilization at FMC Craven County as follows:

FMC Craven County	
Begin with the patient census as of June 1, 2016.	36 patients
Project the FMC Craven County patient population forward for seven months to December 31, 2016.	$[36 \times (0.06 / 12 \times 7)] + 36 = 37.3$
Project the FMC Craven County patient population forward one year to December 31, 2018.	$[37.3 \times (0.06 / 12 \times 7)] + 37.3 = 39.5$

Thus, as of December 31, 2017, following the relocation of stations and decertification of other stations, FMC Craven County is projected to have 39 patients for a utilization percentage of just under 50 percent, or 1.98 patients per station. Thus, the needs of the existing patients at FMC Craven County will still be adequately met.

New Bern Dialysis

On page 28, the applicant states that it demonstrated a utilization rate of approximately 80.5 percent by the end of the first operating year following project completion. The applicant states that in a 41-station facility, 100 percent capacity would allow for up to 164 patients to be treated at New Bern Dialysis. The applicant further states that since it only projects to serve 136 patients at the end of operating year two, there is still room for even more patients to be served at New Bern Dialysis without negatively impacting the existing patient population. Thus, the needs of the existing patients at New Bern Dialysis will still be adequately met.

Conclusion

The applicant adequately demonstrates that the needs of the population presently served will continue to be adequately met following the proposed relocation of four dialysis stations from FMC Craven County to New Bern Dialysis and decertification of an additional four stations at FMC Craven County and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E, pages 30-31, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo – The applicant states that maintaining the status quo is not an effective alternative because it would ignore the growing home patient population in the area, since it would not allow for a redistribution of stations to allow for a more dedicated home training area. Therefore, this alternative was rejected.
- Apply to Relocate Eight Stations from FMC Craven County - The applicant states that the existing physical space in New Bern Dialysis would not allow for more than four additional stations without significantly higher capital costs, which would not be justified. Therefore, this alternative was rejected.
- Surrender Eight Dialysis Stations at FMC Craven County – The applicant states it would have the same net effect for FMC Craven County as the current plans but it would result in the loss of eight stations for Craven County. The applicant states that even though Craven County has a 16 station surplus [as of the January 2015 Semiannual Dialysis Report (SDR)], the population of ESRD patients in Craven County is growing. The applicant further states that it has demonstrated that the relocation of the four stations will result in a utilization rate of just over 80 percent at the end of the first operating year. Therefore, this alternative was rejected.
- Develop a Third ESRD Facility - The applicant states that it could have developed a third facility in Craven County by transferring eight stations from FMC Craven County and two from New Bern Dialysis, but did not want to commit to the expenditure of roughly \$1.5 million that would result from developing a new facility. Therefore, this alternative was rejected.

After considering the above alternatives, the applicant states that given the capacity issues within New Bern Dialysis and the goal of further growing and supporting home dialysis patients, the project represented in the application is the most effective alternative to meet the identified need.

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. shall relocate no more than four dialysis stations from FMC Craven County to New Bern Dialysis.**
 3. **Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than four dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify eight dialysis stations at FMC Craven County for a total of no more than 20 dialysis stations at FMC Craven County upon project completion.**
 5. **Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate four existing certified dialysis stations from FMC Craven County to New Bern Dialysis and decertify an additional four stations at FMC Craven County.

Capital and Working Capital Costs

In Section F.1, page 33, the applicant projects \$30,400 (for water treatment and other equipment) in capital costs to develop the proposed project. In Sections F.10-F.12, pages 36-37, the applicant states that there will be no start-up expenses and initial operating expenses incurred for this project because New Bern Dialysis is an existing facility.

Availability of Funds

In Sections F.6 and F.8, page 35, the applicant states it will finance the capital costs with accumulated reserves of Bio-Medical Applications of North Carolina, Inc. Exhibit F-1 contains a letter dated June 15, 2016, from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc. (FMC) (the parent company of BMA) committing to spend \$30,400 on the proposed project as well as any additional funds needed to develop the project. Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$249 million in cash and cash equivalents, along with total assets of \$19,332,539,000 and net assets of \$10,144,288,000 as of December 31, 2015. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statements (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.

Projected Revenues and Operating Expenses		
New Bern Dialysis	Operating Year 1 CY 2018	Operating Year 2 CY 2019
Gross Patient Revenue	\$77,213,990	\$78,983,858
Deductions from Gross Patient Revenue	(\$72,383,993)	(\$74,042,556)
Net Patient Revenue	\$4,829,997	\$4,941,302
Total Operating Expenses	\$4,556,032	\$4,662,772
Net Income/Profit	\$273,965	\$278,530

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, the financial section of the application, for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate four existing certified dialysis stations from FMC Craven County to New Bern Dialysis and decertify an additional four stations at FMC Craven County.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Craven County. Facilities may serve residents of counties not included in their service area.

The applicant operates the only two dialysis facilities in Craven County:

ESRD Facilities – Craven County			
Facility	Certified Stations 6/30/2015	Utilization %	Patients per Station
FMC Craven County	28	63.39%	2.54
New Bern Dialysis	37	64.86%	2.59

As shown in the table above, based on the most recent SDR, both facilities in Craven County were operating at 63 to 64 percent utilization. However, based on the ESRD data form submitted in July 2016 to the Agency, as of June 30, 2016, New Bern Dialysis had 124 patients dialyzing on 37 certified dialysis stations for a utilization percentage of 83.75 percent or 3.35 patients per station per week. Additionally, FMC Craven County had 38 patients dialyzing on 28 certified dialysis stations for a utilization percentage of 34 percent or 1.36 patients per station per week. At the end of Operating Year One, the applicant projects that New Bern Dialysis will be serving 132 patients weekly on 41 stations, which is 3.22 in-center patients per station per week or 80.5 percent of capacity (132 patients / 41 stations = 3.22; $3.22 / 4 = 0.805$ or 80.5%). This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates the need to relocate four dialysis stations from FMC Craven County to New Bern Dialysis and to decertify four additional stations at FMC Craven County based on the number of in-center patients it currently serves and proposes to serve. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Craven County. Consequently, the application is conforming to this criterion.

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

C

In Section H.1, page 44, the applicant provides the following table to illustrate the projected staffing for New Bern Dialysis at the end of OY2.

New Bern Dialysis – Proposed Facility Staffing	
Position	Projected # of FTEs
Medical Director*	
RN	6.00
Patient Care Techs	15.00
Dietary Consultant	1.10
Social Services	1.10
Clinical Manager	1.00
Director of Operations	0.15
In-Service	0.15
Clerical	1.00
Chief Technician	0.50
Equipment Technician	0.75
Total	26.75

*The Medical Director is a contract position and is not an employee of the facility.

The following table shows the applicant’s projected number of direct care staff FTEs at New Bern Dialysis for OY2, as shown on page 46 of the application.

New Bern Dialysis – Projected Direct Care Staff Hours – OY2					
Direct Care Positions	# FTEs* [a]	Hours / Year / FTE [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Annual Hours of Operation ** [d]	FTE Hours / Hours of Operation [e] = [c] ÷ [d]
RN	6	2,080	12,480	3,120	4.00
Technician (PCT)	15	2,080	31,200	3,120	10.00
Total	21	2,080	43,880	3,120	14.00

* The applicant’s numbers of FTEs on this page did not correspond with the table listed on page 44. The Project Analyst recalculated the table using the information from the table on page 44.

The applicant states that the Medical Director is not directly employed by the facility but provides services on a contractual basis. Exhibit I-6 contains a letter dated June 13, 2016, from Thomas Burkart, MD, identifying himself as the current Medical Director for the facility, and supporting the proposed project.

In Section H.3, pages 44-45, the applicant describes its experience and process for recruiting and retaining staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 47, the applicant includes a list of providers of the necessary ancillary and support services. Exhibits I-3, I-4, and I-5 contain documentation for laboratory, hospital, and transplant services, respectively. Exhibit I-6 contains a letter from the proposed medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 48-49. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

C

In Section L.7, page 59, the applicant provides the historical payor mix during the last calendar year (CY 2015), as shown in the table below.

New Bern Dialysis Historical Payor Mix CY 2015	
Payment Source	% Total Patients
Private Pay	0.0%
Commercial Insurance	1.4%
Medicare	77.5%
Medicaid	3.1%
Miscellaneous (including VA)	10.1%
Other Medicare Commercial	7.7%
Total	100.0%

In Section L.1, page 56, the applicant states that it has a long history of providing dialysis services to the underserved populations of North Carolina. FMC, BMA's parent company, currently operates 104 facilities in 42 North Carolina Counties, including affiliations with RRI facilities. The applicant further states it is policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor which would classify a patient as underserved. On page 56, the applicant states:

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

BMA of North Carolina has 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."

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Craven	17%	49%	34%	16%	13%	17%
Pamlico	26%	49%	26%	18%	11%	20%
Beaufort	22%	52%	34%	19%	14%	20%
Jones	22%	51%	38%	22%	17%	22%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

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

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

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

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

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

The applicant demonstrates that it currently provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3, page 58, the applicant states:

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

In Section L.6, page 59, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facilities within the past five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, page 57, the applicant reports that more than 88 percent of the patients who will receive treatments at New Bern Dialysis will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected (CY 2019) payment source for the facility:

New Bern Dialysis Projected Payor Mix CY 2019	
Payment Source	% Total Patients
Private Pay	0.0%
Commercial Insurance	1.4%
Medicare	77.5%
Medicaid	3.1%
Miscellaneous (including VA)	10.1%
Other Medicare Commercial	7.7%
Total	100.0%

The applicant’s projected OY2 payor mix for the facility is the same as the historical payor mix reported by the applicant in Section L.7, page 59. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at New Bern Dialysis. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, pages 58-59, the applicant describes the range of means by which a person will have access to the dialysis services at New Bern Dialysis, including referrals from nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 60, the applicant states that BMA facilities routinely work with local community training programs and students, and that the proposed facility will also offer the same opportunities to local health professional training programs. Exhibit M-1 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicant to offer the facility as a clinical training site. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to relocate four existing certified dialysis stations from FMC Craven County to New Bern Dialysis and decertify an additional four stations at FMC Craven County.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham*

Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Craven County. Facilities may serve residents of counties not included in their service area.

The applicant operates the only two dialysis facilities in Craven County:

ESRD Facilities – Craven County			
Facility	Certified Stations 6/30/2015	Utilization %	Patients per Station
FMC Craven County	28	63.39%	2.54
New Bern Dialysis	37	64.86%	2.59

As shown in the table above, based on the most recent SDR, both facilities in Craven County were operating at 63 to 64 percent utilization. However, based on the ESRD data form submitted in July 2016 to the Agency, as of June 30, 2016, New Bern Dialysis had 124 patients dialyzing on 37 certified dialysis stations for a utilization percentage of 83.75 percent or 3.35 patients per station per week. Additionally, FMC Craven County had 38 patients dialyzing on 28 certified dialysis stations for a utilization percentage of 34 percent or 1.36 patients per station per week. At the end of Operating Year One, the applicant projects that New Bern Dialysis will be serving 132 patients weekly on 41 stations, which is 3.22 in-center patients per station per week or 80.5 percent of capacity (132 patients / 41 stations = 3.22; $3.22 / 4 = 0.805$ or 80.5%). This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

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

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

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. In Section O.3, pages 66-67, the applicant identifies three of its 104 Fresenius affiliated North Carolina facilities, BMA Lumberton, BMA East Charlotte, and RAI West College-Warsaw, as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that all facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10A 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- New Bern Dialysis 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 C.1, pages 18-20, the applicant documents the need for the project and demonstrates that it will serve a total of 132 patients on 41 stations at the end of the first operating year, which is 3.22 patients per station per week or a utilization rate of 80.5 percent. The discussion regarding analysis of need 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 C.1, pages 18-20, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.