

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 27, 2017

Findings Date: October 27, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: E-11377-17

Facility: BMA Lenoir

FID #: 170328

County: Caldwell

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

Project: Relocate the facility which will be certified for only 20 dialysis stations following completion of this project and Project ID #E-11376-17

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 BMA Lenoir (**BMA Lenoir**) proposes to relocate the existing dialysis facility which will be certified for 20 dialysis stations following the relocation. BMA Lenoir is an existing 34 station dialysis facility located in leased space in Caldwell Memorial Hospital in Caldwell County. In Section A.9, page 4, the applicant states the current lease between BMA and Caldwell Memorial Hospital expires in 2019 and the hospital is not proposing to renew the lease.

The applicant also filed a companion application, Project I.D. #E-11376-17, to relocate 14 of the 34 dialysis stations at BMA Lenoir ($34 - 20 = 14$) to develop a new facility, Fresenius Kidney Care Caldwell County (FKC Caldwell), in Caldwell County. Upon completion of this project and Project I.D. # E-11376-17, BMA Lenoir will be certified for a total of 20 dialysis stations and FKC Caldwell will be certified for a total of 14 dialysis stations. The proposed

replacement facility location for BMA Lenoir and the new facility location for FKC Caldwell are both in Caldwell County. BMA Lenoir also provides home hemodialysis and peritoneal dialysis training.

Need Determination

The applicant proposes to relocate existing dialysis stations within Caldwell County; therefore, there are no need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) that are applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 33 of the 2017 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 33 of the 2017 SMFP is applicable to this review, and 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 for 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 16 - 17, the applicant describes the methods that will be implemented to address energy efficiency and water conservation.

In addition, in Section K.1, pages 50 - 52, the applicant describes how new BMA dialysis centers will include energy efficient lighting methods, water optimization protocols to reduce

water usage, the use of interior finishes/materials based on sustainable design and indoor environmental quality, high performance mechanical systems and facility design/exteriors that meet current energy conservation requirements.

The applicant adequately demonstrates conformity with the requirements of *Policy GEN-4*.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS on page 27 of the 2017 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 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 proposes to relocate 20 existing, certified dialysis stations to develop a replacement 20-station dialysis facility in Caldwell County. The applicant does not propose to add dialysis stations to an existing facility or to establish any new dialysis stations in Caldwell County; rather, it proposes to relocate an existing facility to serve the same patient population. There will be no change in the total dialysis station inventory in Caldwell 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 and Policy GEN-3 in the 2017 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 the existing dialysis facility which is currently located in leased space in Caldwell Memorial Hospital. Currently, BMA Lenoir is certified for 34 in-center dialysis stations. The applicant proposes to relocate the facility and 20 of the 34 stations. Upon completion of this project and Project ID #E-11376-17, BMA Lenoir will be certified for 20 dialysis stations, and FKC Caldwell will be certified for 14 dialysis stations. Both facilities will be located in Caldwell County. The applicant proposes to continue to offer both home hemodialysis and peritoneal dialysis at BMA Lenoir.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Caldwell County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 26, the applicant identifies the in-center patient population historically served at BMA Lenoir, as illustrated in the table below:

Current Patient Origin for BMA Lenoir as of June 30, 2017

COUNTY OF RESIDENCE	# IN-CTR PATIENTS	# HOME HEMODIALYSIS PTS	# PERITONEAL DIALYSIS PTS
Caldwell	110	3	10
Alexander	1	0	0
Burke	3	0	0
Catawba	1	0	0
Wilkes	0	0	1
Other States	1	0	0
Total	116	3	11

In Section C.1, page 22, the applicant identifies the in-center patient population it proposes to serve during the first two calendar years (CY) of operation following project completion, as illustrated in the table below:

COUNTY	OY 1 CY 2019			OY 2 CY 2020			COUNTY PATIENTS AS % OF TOTAL	
	IN-CTR. PTS	HOME HEMO PTS	PERITONEAL PTS	IN-CTR. PTS	HOME HEMO PTS	PERITONEAL PTS	OY 1	OY 2
Caldwell	89	3	12	94	3	12	100.0%	100.0%
Total	89	3	12	94	3	12	100.0%	100.0%

The applicant states it bases the patient origin for its proposed relocated facility on current patient origin. The applicant is the only provider of dialysis services in Caldwell County, and proposes to serve in-center patients and provide home dialysis training. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to relocate 20 of the 34 existing dialysis stations from BMA Lenoir to a new location less than one mile from its current location in Caldwell Memorial Hospital. In Section C.1, pages 18 - 22, the applicant discusses the need to relocate BMA Lenoir, and provides assumptions and methodology to support the need. The application is filed pursuant to *Policy ESRD-2, Relocation of Dialysis Stations* and proposes to relocate stations within Caldwell County. The applicant is currently the only provider of dialysis services in Caldwell County.

In Section C.4, page 24, the applicant provides a map to illustrate the location of the existing and proposed relocated BMA Lenoir and FKC Caldwell County. The applicant states on page 24 that it anticipates the majority of patients will travel less than ten miles to receive dialysis at the proposed new location of BMA Lenoir. In Section C.5, page 24, the applicant states the proposed new location for BMA Lenoir is less than one mile from its current location in Caldwell Memorial Hospital.

Projected Utilization

In Section C.1, pages 18 – 22, the applicant projects utilization for in-center, home hemodialysis and peritoneal dialysis patients, each of which is discussed below.

In-Center Utilization Assumptions:

On pages 18 - 19, the applicant provides the assumptions used to project in-center utilization, including securing a Letter of Intent to lease the proposed new location of BMA Lenoir, as summarized below:

1. The applicant projects the certification date for the stations at the replacement BMA Lenoir facility to be December 31, 2018, at which time the applicant projects 38 existing in-center patients will transfer their care to FKC Caldwell County (also scheduled for certification on December 31, 2018), proposed in Project ID #E-11376-17.

2. The applicant assumes the Caldwell County dialysis patients who are projected to transfer their care to the relocated BMA Lenoir facility are part of the Caldwell County ESRD patient population as a whole, and will increase by 5.2% annually, consistent with the Five Year Average Annual Change Rate (AACR) published in the July 2017 SDR for Caldwell County.
3. The applicant states the facility was serving five patients from Alexander, Burke and Catawba counties as of June 30, 2017, and assumes these patients will continue to dialyze at the relocated BMA Lenoir facility. The applicant does not project growth in this patient population, but adds the five patients after calculating growth in the Caldwell County patient population for Operating Years One and Two.
4. The applicant states one patient from outside the state of North Carolina was dialyzing at BMA Lenoir and was a transient patient. Thus, the applicant will not carry that one patient forward in projections of future patient populations.
5. The applicant projects the project to be complete by December 31, 2018.

Operating Year 1 is Calendar Year 2019, January 1 through December 31, 2019.
Operating Year 2 is Calendar Year 2020, January 1 through December 31, 2020.

In Section C.1, page 18, the applicant projects the following in-center utilization:

BMA LENOIR	IN-CENTER PATIENTS
Begin with 110 Caldwell County in-center dialysis patients as of June 30, 2017.	110
Project this population forward six months to December 31, 2017, using one-half of the Caldwell County Five Year AACR of 5.2%.	$[110 \times (0.52 / 12 \times 6)] + 110 = 112.9$
Project the Caldwell County patient population forward one year to December 31, 2018, using the Caldwell County Five Year AACR of 5.2%.	$112 \times 1.052 = 118.7$
Subtract 38 patients projected to transfer to FKC Caldwell County.	$118.7 - 38 = 80.7$
Project the Caldwell County patient census forward one year to December 31, 2019, using the Caldwell County Five Year AACR of 5.2%.	$80.7 \times 1.052 = 84.9$
Add five patients from Alexander, Burke and Catawba counties. This is the end of OY 1.	$84.9 + 8 = 89.9$
Project the Caldwell County patient population forward one year to December 31, 2020, using the Caldwell County Five Year AACR of 5.2%.	$84.9 \times 1.052 = 89.3$
Add five patients from Alexander, Burke and Catawba counties. This is the end of OY 2.	$89.3 + 5 = 94.3$

*On page 18, the applicant state the number of patients was rounded down to the nearest whole number

The applicant projects to serve 89 in-center patients or 4.45 patients per station per week ($89 / 20 = 4.45$) by the end of Operating Year 1 and 94 in-center patients or 4.7 patients per station

per week ($94 / 20 = 4.7$) by the end of Operating Year 2 for the relocated 20-station facility. 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 at BMA Lenoir. Recognizing that the utilization projections result in an overcrowded facility, the applicant states on page 20 that the facility qualifies for additional stations pursuant to the Facility Need Methodology in the July 2017 SDR. In fact, the applicant submitted an application in the September 2017 review cycle for seven additional stations at BMA Lenoir (Project ID #E-11401-17).

Home Hemodialysis and Peritoneal Dialysis Utilization Assumptions:

On pages 21 - 22, the applicant provides the assumptions it used to project home dialysis utilization, including hemodialysis and peritoneal dialysis, as summarized below:

1. The applicant states it was serving three home hemodialysis patients and 11 home peritoneal dialysis patients as of June 30, 2017. The applicant states the home hemodialysis and peritoneal dialysis patients are part of the Caldwell County ESRD patient population as a whole, and will increase by 5.2% annually, consistent with the Five Year Average Annual Change Rate (AACR) published in the July 2017 SDR for Caldwell County.
2. The applicant states it was serving one peritoneal dialysis patient from Wilkes County as of June 30, 2017, and assumes the patient dialyzes at that facility by choice. The applicant does not project growth in this population, but will add that patient to the projected population after calculating growth in the Caldwell County patient population for Operating Years One and Two.

In Section C.1, page 21, the applicant projects the following peritoneal dialysis utilization:

BMA LENOIR	PERITONEAL PATIENTS
Begin with 10 Caldwell County peritoneal dialysis patients as of June 30, 2017.	10
Project this population forward six months to December 31, 2017, using one-half of the Caldwell County Five Year AACR of 5.2%.	$[10 \times (0.52 / 12 \times 6)] + 10 = 10.3$
Project the Caldwell County patient population forward one year to December 31, 2018, using the Cumberland County Five Year AACR of 5.2%.	$10.3 \times 1.052 = 10.8$
Project the Caldwell County patient census forward one year to December 31, 2019, using the Cumberland County Five Year AACR of 5.2%.	$10.8 \times 1.052 = 11.4$
Add one patient from Wilkes County.	$11.4 + 1 = 12.4$
Project the Caldwell County patient population forward one year to December 31, 2020, using the Cumberland County Five Year AACR of 5.2%.	$11.4 \times 1.052 = 11.9$
Add one patient from Wilkes County.	$11.9 + 1 = 12.9$

In Section C.1, page 22, the applicant projects the following home hemodialysis utilization:

BMA LENOIR	HOME HEMODIALYSIS PATIENTS
Begin with 3 Caldwell County home hemodialysis patients as of June 30, 2017.	3
Project this population forward six months to December 31, 2017, using one-half of the Caldwell County Five Year AACR of 5.2%.	$[3 \times (0.52 / 12 \times 6)] + 3 = 3.1$
Project the Caldwell County patient population forward one year to December 31, 2018, using the Cumberland County Five Year AACR of 5.2%.	$3.1 \times 1.052 = 3.2$
Project the Caldwell County patient census forward one year to December 31, 2019, using the Cumberland County Five Year AACR of 5.2%. This is the end of OY 1.	$3.2 \times 1.052 = 3.4$
Project the Caldwell County patient population forward one year to December 31, 2020, using the Cumberland County Five Year AACR of 5.2%. This is the end of OY 2.	$3.4 \times 1.052 = 3.6$

Thus, at the end of Operating Year One, the applicant projects to serve 3 home hemodialysis patients and 12 peritoneal dialysis patients. Projected utilization of home hemodialysis and peritoneal dialysis patients is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1, pages 56 - 57, the applicant states that each of BMA’s 109 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.

The applicant projects that 85.6% of its in-center patient population at BMA Lenoir will be Medicare or Medicaid recipients in CY 2020, based on its current Caldwell County patient data. The applicant projects that 81.07% of the home hemodialysis and peritoneal dialysis patient population will be Medicare recipients in CY 2020. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the services proposed and the extent to which all residents of the area, including underserved groups, are likely to 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 BMA Lenoir by relocating 20 of the 34 existing dialysis stations. The applicant filed a companion application, Project I.D. #E-11377-17, to relocate the remaining 14 dialysis stations at BMA Lenoir ($34 - 20 = 14$) to a new location in Caldwell County, FKC Caldwell. Upon completion of this project and Project I.D. # E-11376-17, BMA Lenoir will be certified for a total of 20 dialysis stations and FKC Caldwell will be certified for a total of 14 dialysis stations. The proposed replacement facility location for BMA Lenoir and the new facility location for FKC Caldwell are both in Caldwell County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations in the county.

In Section D.1, page 30, the applicant states that this Criterion does not apply; however, the applicant proposes to relocate an existing facility and thus the Criterion does apply. In Section A.8(a), the applicant provides the current address of BMA Lenoir, and in Section A.8(b), the applicant provides the proposed location of the relocated facility. According to MapQuest[®], the two address are less than two miles apart. Thus it is reasonable to conclude that the same patient population that was being served by BMA Lenoir while it was located within Caldwell Memorial Hospital will continue to be served following the facility relocation less than two miles away. Thus, the needs of the population presently served will be met adequately by the proposed facility relocation.

Conclusion

The applicant demonstrates that the needs of the population presently served at BMA Lenoir will continue to be adequately met following the proposed relocation of the facility to a new location less than two miles from its present location, 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.

C

In Section E, page 31, the applicant describes the alternatives it 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 the hospital in which BMA Lenoir is currently located will not renew the lease and thus the facility will have no space in which to treat its patients upon lease expiration, in 2019.

- Develop a smaller relocated facility and plan for more stations at FKC Caldwell (companion application Project ID #E-11376-17) - The applicant states this is not an effective alternative. The applicant states it could not substantiate the need for more than 14 in-center dialysis stations at FKC Caldwell County, and thus must plan for the relocation of 20 stations in this application to relocate BMA Lenoir.
- Propose a smaller, third facility in Caldwell County – The applicant states it rejected this alternative because there was not another location within the county that was suitable for development of the patient population served by BMA Lenoir and projected to be served by FKC Caldwell County. Furthermore, the applicant states the additional costs of construction and start-up for a new 10-station dialysis facility would make this alternative not a viable option.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served at the relocated BMA Lenoir and the projected patient population growth, the project represented in the application presents 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 is approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc., d/b/a BMA Lenoir 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 BMA Lenoir, shall relocate 20 dialysis stations to a new replacement facility.**
 - 3. Bio-Medical Applications of North Carolina, Inc., d/b/a BMA Lenoir shall install plumbing and electrical wiring through the walls for no more than 20 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate the existing BMA Lenoir facility, which will be certified for 20 dialysis stations to a new location in Caldwell County.

Capital and Working Capital Costs

In Section F.1, page 33, the applicant projects \$2,624,459 in capital costs to develop the proposed project, including \$1,860,888 for construction, \$225,000 for RO water treatment equipment, \$269,673 for equipment and \$268,898 for fees and contingency costs. In Sections F.10 - F.12, page 36, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since it is an existing operational facility.

Availability of Funds

In Section F.2, page 34 the applicant states it will finance the entire capital cost with accumulated reserves of Fresenius Medical Care Holdings (FMCH), the parent company.

Exhibit F-1 contains a letter dated July 17, 2017, from the Senior Vice President & Treasurer for FMCH, which authorizes and commits cash reserves for the full project capital costs as well as “any additional funds as may be necessary for start-up costs in the new location.” Exhibit F-2 contains the Consolidated Financial Statements for FMCH and subsidiaries which indicates that FMCH had \$357,899,000 in cash and cash equivalents, \$20,135,661,000 in total assets and \$10,533,297,000 in net assets (total assets less total liabilities) as of December 31, 2016. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In Section R of the application, 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		
	OY 1 (CY 2019)	OY 2 (CY 2020)
Total Treatments	12,893	13,634
Total Gross Revenue (Charges)	\$58,137,182	\$62,712,027
Total Net Revenue	\$ 5,667,059	\$ 6,234,874
Average Net Revenue per Treatment	\$439.54	\$457.30
Total Operating Expenses (Charges)	\$ 4,150,969	\$ 4,344,842
Average Operating Cost per Treatment	\$321.95	\$318.67
Net Income	\$ 1,516,090	\$ 1,890,032

Source: Forms B and C, Application Section R

The Project Analyst notes that staffing expenses reported on Form A in Section R are higher than those reported in Section H.1, page 42. Total salary costs are higher in Form A than the salaries reported in Section H.1. Nevertheless, the applicant projects a net profit in OY1 and OY2. 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. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate the existing dialysis facility which is currently located in leased space in Caldwell Memorial Hospital. Currently, BMA Lenoir is certified for 34 in-center dialysis stations. The applicant proposes to relocate the facility and 20 of the 34 stations. A companion application, Project ID#E-11376-17, was also filed during the same review cycle, and proposes to develop a new facility, FKC Caldwell County, in Caldwell County by relocating 14 of the 34 stations that make up BMA Lenoir. Upon completion of this project, BMA Lenoir will be certified for 20 dialysis stations, and FKC Caldwell will be certified for 14 dialysis stations. Both facilities will be located in Caldwell County.

On page 373, the 2017 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 Caldwell County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates one dialysis center in Caldwell County, and thus is the only provider of dialysis services in the county.

According to the July 2017 SDR, BMA Lenoir was operating at 82.35% utilization, with 112 in-center patients dialyzing on 34 stations [$112 / 34 = 3.29$; $3.29 / 4 = 0.8235$]. Following the proposed relocation of this facility, the applicant projects to relocate the remaining 14 stations to a new facility in Hudson, approximately five miles away [See Project ID # E-11377-17].

The patients currently served by BMA Lenoir will continue to be served by their current dialysis provider in the same area.

In Section C, pages 18 - 22, the applicant provides reasonable projections for the patient population it proposes to serve. The growth projections are based on a projected 5.2% average annual growth rate (found in Table D of the July 2017 SDR) in the number of Caldwell County dialysis patients transferring their care to the proposed facility. At the end of the first operating year following project completion, BMA Lenoir projects the in-center utilization will be 4.45 in-center patients per station (89 patients / 20 dialysis stations = 4.45), which is 111% of capacity. The applicant submitted an application for additional stations at BMA Lenoir pursuant to the Facility Need Methodology on September 15, 2017. The applicant does not propose to add another provider of dialysis services to the county; rather, it proposes to continue to serve a patient population it currently serves at a proposed location that is less than five miles from where existing BMA dialysis patients are currently served. The applicant adequately demonstrates the need to relocate BMA Lenoir.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, the application is conforming to this criterion.

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

C

In Section H, page 42, the applicant provides a table to illustrate projected staffing in full time equivalents (FTEs) for BMA Lenoir. The applicant projects to begin the proposed facility with 25.18 FTEs. In Section H.7, page 45, the applicant provides the projected direct care staff for the proposed facility in OY 2 (CY 2020). On page 42, the applicant states the Medical Director is not directly employed by the facility, and thus is not reflected on the staffing chart.

In Section H.6, page 44, the applicant states dialysis services will be available from 5:00 AM to 5:00 PM, Monday through Saturday, for a total of 12 hours per day / 72 hours per week. The applicant states it has planned for six hour shifts to allow for a graduated patient arrival and discharge time, thus creating a smoother treatment transition for patients.

In Section I.3, page 47, the applicant identifies Dr. Robert Qualheim as the Medical Director of the proposed facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Qualheim supporting the project and confirming his commitment to serve as Medical Director. In Section H.3, page 43, the applicant describes the methods used to recruit and fill the new positions at the proposed relocated facility.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis 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 46, the applicant identifies the necessary ancillary and support services that will be provided at BMA Lenoir following the relocation, and indicates how those services will be made available. The applicant discusses coordination with the existing health care system on pages 47 - 48, including physician support and the commitment from the Medical Director. Exhibits I-1 through I-4, respectively, contain copies of agreements for home training, lab services, acute services and transplantation services. 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.

C

In Exhibit K-5, the applicant provides documentation from D&H Real Estate, LLC (D&H) which indicates that D&H owns a building at the location of the proposed BMA Lenoir facility, and that D&H will lease the building to Fresenius Kidney Care for the development of BMA Lenoir upon approval for a certificate of need. In Section K.2 – K.4, pages 52 - 53, the applicant states it proposes to lease and upfit 5,257 square feet of space in which to develop the proposed relocated facility. In Section K, pages 50 - 55, the applicant describes how the facility will be constructed in compliance with all laws and regulations pertaining to staffing, fire and safety equipment, physical environment and other relevant health safety requirements. In Section B.4, pages 11 - 15, and Section K, pages 50 - 55, the applicant describes its plans for energy-efficiency and water conservation at the relocated facility. Costs and charges are described by the applicant in Section R of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, 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.1, page 57, the applicant provides a table to illustrate the historical payor mix for BMA Lenoir for the last full operating year (CY 2016). See the following table:

Historical Payor Mix, BMA Lenoir (CY 2016)

PAYMENT SOURCE	IN-CTR PTS	HOME HD	PD	TOTAL FACILITY
Self-Pay / Indigent / Charity	0.27%	0.00%	0.00%	0.27%
Medicare	63.93%	81.07%	81.07%	63.93%
Medicaid	5.95%	0.00%	0.00%	5.95%
Commercial Insurance	6.07%	18.93%	18.93%	6.07%
Medicare / Commercial	15.72%	0.00%	0.00%	15.72%
Miscellaneous (Incl. VA)	8.07%	0.00%	0.00%	8.07%
Total	100.00%	100.00%	100.00%	100.00%

Totals may not sum due to rounding

On page 57, the applicant states it does not anticipate any significant change to the payor mix when BMA Lenoir is relocated.

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
Caldwell	19%	51%	12%	16%	14%	15%
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

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

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 applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L.3(e), page 58, the applicant states, “*Fresenius related facilities in North Carolina do not have any obligation to provide uncompensated care or community service under any federal regulations.*” In Section L.6, page 59, the applicant states “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*” 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 563, the applicant 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 that would classify a patient as underserved.*” In Section L.1(b), page 57, the applicant projects that 85.60% of all patients in CY 2020 (OY 2) will have all or part of their services paid for by Medicare and or Medicaid, as shown in the table below:

**Projected Payor Mix, FKC Caldwell County
OY 2 (CY 2020)**

PAYMENT SOURCE	FMC WEST FAYETTEVILLE PERCENT OF TOTAL PATIENTS
Self-Pay / Indigent / Charity	0.27%
Medicare	63.93%
Medicaid	5.95%
Commercial Insurance	6.07%
Medicare / Commercial	15.72%
Miscellaneous (Incl. VA)	8.07%
Total	100.00%

The projected payor mix is based on the facility's historical payor mix. The applicant adequately demonstrates that medically underserved populations will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 59, the applicant states *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA Lenoir will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”* The applicant adequately demonstrates that BMA Lenoir will offer a range of means by which a person can access the 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 61, the applicant states, *“the applicant has communicated with the local student nursing programs encouraging those programs to utilize the resources of the BMA Lenoir facility to enhance the educational opportunities for the nursing student.”* In Exhibit M-1, the applicant provides a July 17, 2017 letter to Caldwell Community College and Technical Institute which introduces Fresenius Kidney Care and invites the Department Chair of Health Sciences to include BMA Lenoir in student clinical rotations. The information provided in Section M is reasonable and credible and supports a finding of conformity 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 the existing dialysis facility which is currently located in leased space in Caldwell Memorial Hospital. Currently, BMA Lenoir is certified for 34 in-center dialysis stations. The applicant proposes to relocate the facility and 20 of the 34 stations. Upon completion of this project and Project ID #E-11376-17, BMA Lenoir will be certified for 20 dialysis stations, and FKC Caldwell will be certified for 14 dialysis stations. Both facilities will be located in Caldwell County. The applicant proposes to continue to offer both home hemodialysis and peritoneal dialysis at BMA Lenoir.

On page 373, the 2017 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 Caldwell County. Facilities may serve residents of counties not included in their service area.

According to the July 2017 SDR, BMA Lenoir was operating at 82.35% utilization, with 112 in-center patients dialyzing on 34 stations [$112 / 34 = 3.29$; $3.29 / 4 = 0.8235$]. Following the proposed relocation of this facility, the applicant projects to relocate 14 of the 34 stations at BMA Lenoir to develop FKC Caldwell [*see* Project ID # E-11376-17].

The applicant states in Section N.1, page 62 that, as the only provider of dialysis services in Caldwell County, the applicant projects to serve those patients already being served by Fresenius Kidney Care. In addition, the applicant discusses how the project have a positive impact on the cost-effectiveness, quality and access to the proposed services.

The information provided by the applicant in the sections referenced above 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 proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that BMA Lenoir will provide quality dialysis services. The discussions regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that BMA Lenoir will provide access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (13c) 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 Section B.4, pages 12 - 14, Section O, pages 63 - 67 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality in its dialysis facilities.

In Exhibit A-4, the applicant provides a listing of the Fresenius-related owned and operated ESRD facilities in North Carolina. In Section O.3, pages 73 - 74, and Exhibits O-3 and O-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. The facilities that the applicant lists in Section O of the application do not match the facilities identifies in Exhibit O. However, in clarifying information provided at the Agency's request, the facilities identified in Exhibit O are the two facilities that were out of compliance. The applicant provides documentation in Exhibit O that demonstrates those facilities are now back in compliance. In addition, on page 74, the applicant states that both of these facilities were back in full compliance with all CMS Guidelines upon the submittal of the 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 to all applicable Criteria and Standards for End Stage Renal Disease Services 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- The applicant proposes to relocate 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.

-NA- The applicant proposes to relocate an existing facility.

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

-C- In Section C, pages 18 - 22, 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.