

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-11376-17

Facility: Fresenius Kidney Care Caldwell County

FID #: 170327

County: Caldwell

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

Project: Develop a new 14-station dialysis facility by relocating 14 stations from BMA Lenoir

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA), d/b/a Fresenius Kidney Care Caldwell County (**FKC Caldwell**) proposes to develop a new 14 station dialysis facility by relocating 14 existing dialysis stations from BMA Lenoir.

BMA Lenoir is an existing 34 station dialysis facility located in leased space in Caldwell Memorial Hospital in Caldwell County. In Section I.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 where BMA Lenoir is currently operating.

The applicant also filed a companion application, Project I.D. #E-11377-17, to relocate the remaining 20 dialysis stations at BMA Lenoir (34-14 = 20) to a new location in Caldwell County. Upon completion of this project and Project I.D. # E-11377-17, FKC Caldwell will

be certified for a total of 14 dialysis stations and BMA Lenoir will be certified for a total of 20 dialysis stations. The proposed replacement facility location for BMA Lenoir and the new facility location for FKC Caldwell are both in Caldwell County.

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 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 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 develop a new 14-station dialysis facility, Fresenius Kidney Care Caldwell, in Caldwell County, by relocating 14 existing Caldwell County dialysis stations from BMA Lenoir. Because both facilities are or will be located in Caldwell County, 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 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 develop a new 14-station dialysis facility by relocating 14 existing dialysis stations from BMA Lenoir. Upon completion of the project, FKC Caldwell will be certified for 14 dialysis stations, and BMA Lenoir will be certified for 20 dialysis stations. Both facilities will be located in Caldwell County. The applicant does not propose to provide home therapies at this facility.

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.

Fresenius Kidney Care Caldwell will be a new facility and thus has no historical patient origin to report.

In Section C.1, page 18, the applicant identifies the in-center patient population it proposes to serve during the first two years 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	
			OY 1	OY 2
Caldwell	46.3	48.7	100.0%	100.0%
Total*	46	48	100.0%	100.0%

Note: OY 1 = Operating Year one; and OY 2 = Operating Year two

*The applicant states on page 18 that the total number of patients is “rounded down to the nearest whole number”

The applicant is the only provider of dialysis services in Caldwell County. The applicant projects to serve only in-center patients at the proposed FKC Caldwell, and states it will refer those patients in need of home training to BMA Lenoir (See Section C.6, page 24). In Section C.2, page 20, the applicant states it bases projected patient origin for its proposed facility on patients who reside in Caldwell County and who have signed letters indicating that the proposed facility would be close to their residence and thus a convenient choice for dialysis three times per week. In Exhibit C-1, the applicant provides 47 letters signed by current BMA dialysis patients who receive their care at an existing BMA facility. Six letters are from patients who reside in Caldwell County but receive dialysis services at BMA Hickory, in Catawba County, adjacent to Caldwell County. Each of these letters states that the patient would consider transferring his or her care to the proposed FKC Caldwell facility because the proposed facility would be closer to the patient's home. MapQuest® reveals that the distance from Hickory to Lenoir (the current location of BMA Lenoir) is approximately 18 miles, and the distance from Hickory to Hudson (the proposed location of FKC Caldwell) is approximately 12 miles. The remainder of the patient letters are signed by patients who reside in Caldwell County. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to develop a new 14-stations dialysis facility in Caldwell County by relocating 14 existing stations from BMA Lenoir. In Section C.1, pages 18 - 19, the applicant discusses the need to develop FKC Caldwell in southern Caldwell County, and provides the 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 and operates BMA Lenoir, the only dialysis facility in the county.

In Section C.4, page 22, the applicant provides a map to illustrate the location of the existing and proposed Caldwell County dialysis facilities (BMA Lenoir is currently located in leased space in Caldwell Memorial Hospital in Lenoir, Caldwell County). The applicant states on page 22 that it anticipates the majority of patients will travel less than five miles to receive dialysis at the proposed location of FKC Caldwell.

Projected Utilization

On pages 18 - 19, the applicant provides the assumptions used to project utilization, as summarized below:

1. The applicant plotted the residence location of existing patients who dialyze at BMA Lenoir, and determined that there are a significant number of dialysis patients who reside in southeastern Caldwell County, near the town of Hudson. The applicant states that, taken as a whole, the patient population would be better served by a new dialysis facility focused on providing care to dialysis patients in southeastern Caldwell County.

2. The applicant received 47 letters signed by existing dialysis patients who currently dialyze at a BMA facility, each of whom indicated that a facility located in the southeastern area of the county would be a more convenient dialysis location than the facility in which they are currently dialyzing.
3. The applicant projects that of the 47 patients who signed letters, 44 will transfer their care to the proposed facility, including the six patients who dialyze in Catawba County.
4. 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.

The applicant states the ESRD patient population to transfer their care to the proposed facility will be a part of the Caldwell County dialysis patient population as a whole and will increase at a rate commensurate with the Caldwell County 5.2% Five Year Average Annual Change Rate (AACR), as published in the July 2017 SDR.

In Section C.1, page 19, the applicant projects the following utilization for FKC Caldwell for CY 2019 and CY 2020:

FKC CALDWELL	IN-CENTER PATIENTS
Begin with 44 Caldwell County in-center dialysis patients projected to transfer their care to the new facility upon certification on December 31, 2018.	44
Project this population forward one year to December 31, 2019, using the Caldwell County Five Year AACR of 5.2%. This is the end of OY 1.	$44 \times 1.052 = 46.3$
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.	$46.3 \times 1.052 = 48.7$

The applicant projects to serve 46 in-center patients or 3.29 patients per station per week ($46 / 14 = 3.29$) by the end of Operating Year 1 and 48 in-center patients or 3.43 patients per station per week ($48 / 14 = 3.43$) by the end of Operating Year 2 for the proposed 14-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 FKC Caldwell.

Access

In Section L.1, pages 63 - 64, 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 patients will be Medicare or Medicaid recipients in CY 2020, based on its current Caldwell County patient data. 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 develop a new 14-station dialysis facility, FKC Caldwell, by relocating 14 existing certified dialysis stations from BMA Lenoir, which is currently certified for 34 in-center dialysis stations. BMA Lenoir is currently located in leased space in Caldwell Memorial Hospital. The lease term is ending and will not be renewed; therefore, BMA Lenoir filed a companion application, Project ID #E-11377-17, to relocate the remaining 20 dialysis stations at BMA Lenoir to a new replacement facility. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations in the county.

Upon completion of the project, FKC Caldwell will be certified for 14 dialysis stations and BMA Lenoir will be certified for 20 dialysis stations. Both facility locations are in Caldwell County.

In Section D.1, pages 30 - 34, the applicant discusses how the needs of existing dialysis patients at BMA Lenoir will continue to be met after the relocation of stations to the proposed FKC Caldwell dialysis facility. The assumptions are summarized as follows:

- BMA Lenoir is currently certified for 34 dialysis stations as reported in the July 2017 SDR. Fourteen dialysis stations will be relocated to FKC Caldwell, leaving 20 dialysis stations to remain at BMA Lenoir.
- As of June 30, 2017 there were 116 patients dialyzing at BMA Lenoir. Of those patients, 110 were from Caldwell County, one each were from Alexander and Catawba counties, three were from Burke County and one was from a different state. The applicant assumes the one patient from another state was a transient patient and will not transfer care to the proposed replacement BMA Lenoir facility.

- The applicant projects that 38 Caldwell County patients who currently dialyze at BMA Lenoir and who submitted letters of support for this project will transfer their care to FKC Caldwell as of December 31, 2018, when that facility is projected to become operational.
- The applicant projects the Caldwell County patient population will grow at an annual rate of 5.2%, which is the Five Year AACR published in the July 2017 SDR. No growth will be projected for patients living outside Caldwell County.
- The five remaining patients from Alexander, Catawba and Burke counties will be added at the end of the calculations for each year.

Based on the above assumptions, the applicant projects utilization at BMA Lenoir from June 30, 2017 through December 31, 2018 as follows:

BMA LENOIR	
Begin with the Caldwell County ESRD patient population at BMA Lenoir as of June 30, 2017.	110
Project this population forward 6 months to December 31, 2017, applying the Caldwell County Five Year AACR of 5.2%.	$110 \times (0.52 / 12 \times 6) + 110 = 112.9$
Project this population forward 12 months to December 31, 2018, applying the Caldwell County Five Year AACR of 5.2%.	$112.9 \times 1.052 = 118.7$
Subtract 38 Caldwell County patients projected to transfer their care to FKC Caldwell.	$118.7 - 38 = 80.7$
Add five patients from Alexander, Burke and Catawba counties	$80.7 + 5 = 85.7$

The applicant projects that as of the projected certification date for FKC Caldwell (December 31, 2018), BMA Lenoir will have 85 in-center dialysis patients dialyzing on 20 stations for a utilization rate of 4.25 patients per station per week, or 106% of capacity [$85 / 20 = 4.25$; $4.25 / 4 = 1.0625$ or 106.25%]. On page 32, the applicant states utilization above 100% necessitate a third dialysis shift; and in Section D, page 33, the applicant provides a table to illustrate that BMA Lenoir will qualify for additional stations based on the Facility Need Methodology in the 2017 SMFP during the September review cycle. In fact, the applicant submitted an application on September 15, 2017 (Project ID #E-11401-17) to add seven stations to BMA Lenoir pursuant to the Facility Need Methodology.

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 14 dialysis stations from BMA Lenoir to the proposed FKC Caldwell facility.

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 14 dialysis stations to FKC Caldwell, and that access for medically underserved groups will not be negatively impacted at either facility.

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 35 - 36, 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 there are a significant number of dialysis patients currently being served by BMA who reside close to the proposed FKC Caldwell location.
- Develop a facility in another area of Caldwell County - The applicant states this is not an effective alternative. The applicant evaluated existing patient populations currently served by Caldwell County BMA and Fresenius related facilities, as well as projected future patient populations in the southeastern area of Caldwell County, near the proposed location of FKC Caldwell. The applicant determined that dialysis patients living in that area of the county might be better served by a facility in that area.
- Propose a larger facility with more in-center stations – The applicant states it rejected this alternative because the proposed 14-station facility will serve an initial patient population of 44 in-center patients, which will grow to 46 patients at the end of the first year. The applicant states this will meet the performance standards at 10A NCAC 14C .2203.
- Provide home training therapies at FKC Caldwell – The applicant states that this is not an effective alternative because BMA Lenoir, which is approximately seven miles away according to MapQuest®, provides home therapies programs. Additionally, electing not to provide home therapies at FKC Caldwell contains development and construction costs for the applicant.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served at FKC Caldwell 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 Fresenius Kidney Care Caldwell County 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. shall develop a new kidney disease treatment center to be known as Fresenius Kidney Care Caldwell County by relocating 14 dialysis stations from BMA Lenoir.**
 3. **Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Kidney Care Caldwell County shall install plumbing and electrical wiring through the walls for no more than 14 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 14 dialysis stations at BMA Lenoir for a total of no more than 20 dialysis stations at BMA Lenoir.**
 5. **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 develop a new 14-station dialysis facility by relocating 14 existing dialysis stations from BMA Lenoir.

Capital and Working Capital Costs

In Section F.1, page 38, the applicant projects \$1,959,630 in capital costs to develop the proposed project, including \$1,371,352 for construction, \$225,000 for RO water treatment equipment, \$165,117 for furniture and \$198,161 for professional fees and contingency. In Sections F.10 - F.12, pages 41 - 42, the applicant states that start-up expenses and initial operating expenses incurred for this project will be \$199,247 and \$1,289,240, respectively, for a total estimated working capital of \$1,488,487.

Availability of Funds

In Section F.2, page 39, and Section F.13, page 43, the applicant states it will finance the capital costs and working capital costs 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 and working 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		
FKC CALDWELL COUNTY	OPERATING YEAR 1 CY 2019	OPERATING YEAR 2 CY 2020
Total Treatments	6,669	6,965
Total Gross Revenues (Charges)	\$25,595,972	\$27,776,420
Total Net Revenue	\$ 2,058,354	\$ 2,149,713
Average Net Revenue per Treatment	\$ 308.65	\$ 308.65
Total Operating Expenses (Costs)	\$ 1,933,861	\$ 1,988,429
Average Operating Cost per Treatment	\$ 289.98	\$ 285.49
Net Income	\$ 124,494	\$ 161,285

The Project Analyst notes that staffing expenses reported on Form A in Section R are higher than those reported in Section H.1, page 48. 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, cost 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 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 develop a new 14-station dialysis facility by relocating 14 existing dialysis stations from BMA Lenoir. 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. BMA Lenoir is currently located in leased space in Caldwell Memorial Hospital. In Section A, page 4, the applicant states the existing lease will expire in 2019, and the hospital does not propose to renew the lease. In Section G.1, page 47, the applicant states:

“This application includes letters of support from 47 in-center patients, each of whom has indicated that a BMA facility in this area would be a more convenient setting for their dialysis care.

...

Approval of this application will not unnecessarily duplicate an existing health service. The patients projected to transfer their care to the facility are existing dialysis patients at BMA facilities. ... Approval of this application will not create additional stations in the county, but does enhance community based delivery of health care. This application will shift some of the high levels of utilization at BMA Lenoir to another... dialysis facility.”

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 14 existing dialysis stations that are the subject of this application, the applicant projects to relocate BMA Lenoir from the hospital to another location in Caldwell County [see Project ID # E-11377-17].

In Section C, pages 18 - 20, 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, FKC Caldwell projects the in-center utilization will be 3.2 in-center patients per station (46 patients / 14 dialysis stations = 3.29), which is 82% of capacity. The applicant does not propose to add another provider of dialysis services or to increase the number of dialysis stations in Caldwell County; rather, it proposes to continue to

serve a patient population it currently serves at a proposed location that is less than ten miles from where existing BMA dialysis patients are currently served. The applicant provides 44 letters signed by existing patients which indicate the proposed location will be easier for those patients to travel to in order to receive necessary dialysis care. The applicant adequately demonstrates the need to develop a new 14-station dialysis center by relocating existing Caldwell County dialysis stations.

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 48, the applicant provides the following table to illustrate projected staffing in full time equivalents (FTEs) for FKC Caldwell. The applicant states the Medical Director is not directly employed by the facility, and thus is not reflected on the staffing chart.

POSITION	# FTEs
Registered Nurse	3.00
Technician (PCT))	7.00
Clinical Manager	1.00
Administrator	0.15
Dietician	0.40
Social Worker	0.40
Chief Technician	0.10
Equipment Technician	0.40
In-Service	0.10
Clerical	0.75
Total	13.30

As illustrated in the table above, the applicant projects to begin the proposed facility with 13.30 FTEs.

In Section H.7, page 51, the applicant provides the projected direct care staff for the proposed facility in OY 2 (CY 2020), as shown in the table below:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	3.00	2,080	6,240	3,120	2.00
Technician (PCT)	7.00	2,080	14,560	3,120	4.67
Total	10.00	4,160	20,800	3,120	6.67

In Section H.6, page 58, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday, for a total of 10 hours per day / 60 hours per week. The

applicant states that if, after opening, the patients request a later start time (7:00 AM), the facility will adjust the hours of operation to meet patient desire.

In Section I.3, page 53, 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 49, the applicant describes the methods used to recruit and fill the new positions at the proposed 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 52, the applicant identifies the necessary ancillary and support services that will be provided at FKC Caldwell, and indicates how those services will be made available. The applicant discusses coordination with the existing health care system on pages 62 – 63, 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 a July 11, 2017 letter from D&H Real Estate, LLC (D&H) which indicates that D&H owns a building at the location of the proposed FKC Caldwell facility, and that D&H will lease the building to Fresenius Kidney Care for the development of FKC Caldwell upon approval for a certificate of need. In Section K.2 – K.4, pages 59 - 61, the applicant states it proposes to lease and upfit 2,875 square feet of space in which to develop the proposed facility. In Section K, pages 57 - 62, 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 16 - 17, and Section K, pages 57 - 58, the applicant describes its plans for energy-efficiency and water conservation. 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

The facility is not yet developed and has no historical payor mix to report. However, in Section L.7, page 67, the applicant provides a table to illustrate the historical payor mix for the facility that will donate stations for the development of FKC Caldwell, BMA Lenoir. See the following table:

BMA Lenoir

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%

Totals may not sum due to rounding

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 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 65 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 66, 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 63, 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 64, 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:

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

**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%

On page 67, the applicant states it does not anticipate any significant change to the payor mix when FKC Caldwell is developed, since the same patient population will be served as is currently served at BMA Lenoir.

The projected payor mix is based on the historical payor mix of BMA Lenoir. 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 66, the applicant states *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FKC Caldwell County 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 FKC Caldwell 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 68, the applicant states, *“the applicant has communicated with the local student nursing programs encouraging those programs to utilize the resources of the FKC Caldwell County 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 FKC Caldwell and invites the Department Chair of Health Sciences to include FKC Caldwell 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 develop a new 14-station dialysis facility by relocating 14 existing dialysis stations from BMA Lenoir, currently located in Caldwell Memorial Hospital in Lenoir. Upon completion of the project, FKC Caldwell will be certified for 14 dialysis stations, and BMA Lenoir will be certified for 20 dialysis stations. Both facilities will be located in Caldwell County. The applicant does not propose to provide home therapies at this facility.

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 14 stations that are the subject of this application, the applicant projects to relocate BMA Lenoir from the hospital to another location in Caldwell County [*see* Project ID # E-11377-17].

The applicant states in Section N.1, page 69 that, as the only provider of dialysis services in Caldwell County, it proposes to serve patients at the new facility that are already being served at BMA Lenoir, and this patient population is expected to increase consistent with the Caldwell County Five Year AACR published in the July 2017 SDR. In addition, the applicant states the facility will benefit from the collaborative efforts of very qualified nephrologists and will be compelled to operate efficiently due to fixed reimbursement rates received from Medicare and Medicaid.

See also Sections B, C, F, K, L, N and O where the applicant discusses the impact of the project on 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 FKC Caldwell will provide quality dialysis services. The discussions regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that FKC Caldwell 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 - 15, Section O, pages 70 - 74 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.
- C- In Section C.1 – C.2, pages 18 - 20, the applicant adequately demonstrates that FKC Caldwell projects to serve a total of 46 in-center patients at the end of OY 1 (CY 2019) for a utilization rate of 80.00% or 3.3 patients per station per week (46 patients / 14 stations = 3.285; $3.285 / 4 = 0.821$ or 82.00%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (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- FKC Caldwell is not 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 - 25, 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.