

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 30, 2017

Findings Date: May 30, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: M-11311-17

Facility: Fresenius Medical Care Anderson Creek

FID #: 110803

County: Harnett

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

Project: Relocate three dialysis stations from FMC Lillington to Fresenius Medical Care Anderson Creek for a total of 14 stations at Fresenius Medical Care Anderson Creek upon project completion

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 Medical Care Anderson Creek (“**FMC Anderson Creek**” or “the applicant”) proposes to relocate three existing dialysis stations from FMC Lillington to FMC Anderson Creek, for a total of 14 dialysis stations at FMC Anderson Creek upon project completion. Both facilities are located in Harnett County. The applicant does not propose to add new dialysis stations to an existing facility or to establish any new dialysis stations in Harnett County; rather, the applicant is proposing an in-county relocation of existing dialysis stations.

Need Determination

The applicant proposes to relocate existing dialysis stations within Harnett 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 relocate three existing Harnett County dialysis stations from FMC Lillington to FMC Anderson Creek. Because both facilities are located in Harnett County, there is no change in the total dialysis station inventory in Harnett 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 relocate three existing dialysis stations from FMC Lillington to FMC Anderson Creek, for a total of 14 dialysis stations at FMC Anderson Creek upon project completion. Both facilities are located in Harnett County. The applicant does not propose to add new dialysis stations to an existing facility or to establish any new dialysis stations in Harnett County; rather, the applicant is proposing an in-county relocation of existing dialysis stations. The applicant currently provides and proposes to continue to provide home therapies at the 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 Harnett County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 23, the applicant provides the in-center (IC), home hemo-dialysis (HHD) and peritoneal dialysis (PD) patient population at FMC Anderson Creek as of March 1, 2017, as shown in the following table:

COUNTY OF RESIDENCE	# IC PATIENTS	# HHD PATIENTS	# PPD PATIENTS
Harnett	30	2	1
Cumberland	7	1	0
Lee	1	0	1
Total	38	3	2

In Section C.1, page 17, the applicant identifies the IC, HHD and PD patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 (CY 2018)			OPERATING YEAR 2 (CY 2019)			COUNTY PATIENTS AS % OF TOTAL	
	IC	PD	HHD	IC	PD	HHD	OY 1	OY 2
Harnett	37.50	2.10	1.05	38.50	2.15	1.08	78.7%	79.1%
Cumberland	8.00	1.00	0.00	8.00	1.00	0.00	17.4%	17.1%
Lee	1.00	0.00	1.00	1.00	0.00	1.00	3.9%	3.8%
Total	46.50	3.10	2.10	47.50	3.20	2.10	100.0%	100.0%

Numbers may not foot due to rounding

The applicant states it projects patient origin for the facility based on patients who are currently dialyzing in existing Harnett County dialysis facilities and who have signed letters indicating that the proposed facility would be closer to their residence. See Exhibit C-1 for copies of the patient support documentation. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section C.1, pages 19 – 21, the applicant discusses the need to relocate three existing dialysis stations from FMC Lillington to FMC Anderson Creek, 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 existing stations within Harnett County.

The applicant is currently the only provider of dialysis services in Harnett County and operates four dialysis facilities, as illustrated in the following table:

Utilization of BMA Harnett County Facilities / January 2017 SDR

FACILITY NAME	# STATIONS	# PATIENTS	% UTILIZATION
FMC Anderson Creek	11	29	65.9%
Dunn Kidney Center	31	103	83.1%
FMC Angier	10	30	75.0%
FMC Lillington	17	36	52.9%

Source: January 2017 SDR, Application page 53

In Section C.12(a), page 24, the applicant states the relocation of existing stations from FMC Lillington to FMC Anderson Creek will provide dialysis care and treatment to dialysis patients at a facility that is closer to their homes. The applicant states FMC Anderson Creek is certified for 11 stations, one of which is dedicated to home training and cannot be dual-utilized as an in-center station. This leaves 10 dialysis stations for the in-center patient population at that facility, which the applicant states was 38 patients as of February 15, 2017 (see page 18), and a utilization rate of 3.8 patients per station per week, or 95% of capacity [$38 / 10 = 3.8$; $3.8 / 4 = 0.95$].

In Exhibit C-1, the applicant provides seven letters signed by current BMA dialysis patients who receive their care at an existing BMA facility. Each of these letters states that the patient would consider transferring his or her care to FMC Anderson Creek because that facility is closer to that patient’s home.

There is also one petition with 26 signatures, each of which represents another existing BMA patient who currently dialyzes at FMC Anderson Creek, offering support for the proposed relocation of stations.

On pages 17 - 19, the applicant provides the assumptions it used to project utilization for IC, HHD and PD patients, as summarized below:

In-Center Dialysis Patients

1. The applicant states the FMC Anderson Creek facility census increased from 33 to 38 patients in six weeks. The applicant states it does not anticipate that growth at this rate will continue, but does expect admissions to continue to increase.
2. The applicant assumes that the Harnett County patient population will increase at a rate that is consistent with the 2.5% Harnett County Five Year Average Annual Growth Rate (AACR) published in Table B of the January 2017 SDR.
3. The applicant provides seven letters signed, six of which are signed by existing Harnett County dialysis patients, and one of which is signed by an existing Cumberland County dialysis patient. Each letter states that the FMC Anderson Creek facility would be a more convenient dialysis location than the facility in which the patient is currently dialyzing.
4. There were 38 in-center patients dialyzing at FMC Anderson Creek as of February 28, 2017; 30 of whom reside in Harnett County. The applicant projects growth of only the Harnett County patient population, and subsequently adds the eight remaining patients.
5. The applicant projects the project to be complete by December 31, 2018.

Operating Year 1 is Calendar Year 2018, January 1 through December 31, 2018.
 Operating Year 2 is Calendar Year 2019, January 1 through December 31, 2019.

In-Center Projected Utilization

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

Begin with Harnett County patient census as of 3/1/17	30
Project forward 10 months to 12/31/17	$[30 \times (.025 \times 12 \times 10) / 30] = 30.6$
Add six Harnett County patients to transfer to facility upon completion	$30.6 + 6 = 36.6$
Add one Cumberland County patient	$36.6 + 1 = 37.6$
Add eight patients from outside Harnett County currently dialyzing at the facility. This is beginning census for OY 1	$37.6 + 8 = 45.6$
Project Harnett County patient population forward one year to 12/31/18	$36.6 \times 1.025 = 37.5$
Add the nine out-of-county patients; this is ending census for OY 1	$37.5 + 9 = 46.5$
Project Harnett County patient population forward one year to 12/31/19	$37.5 \times 1.025 = 38.5$
Add the nine out-of-county patients; this is ending census for OY 2	$38.5 + 8 = 47.5$

The applicant states on page 18 that it rounds down to the nearest whole number. The applicant projects to serve 46 in-center patients on 14 stations, or 3.3 patients per station per week ($46 / 14 = 3.29$) by the end of Operating Year 1, and 47 in-center patients or 3.4 patients per station per week ($47 / 14 = 3.36$) by the end of Operating Year 2 for the 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 FMC Anderson Creek.

Home Hemodialysis Patients

The applicant assumes the home hemo-dialysis patient population dialyzing at FMC Anderson Creek will increase at 2.5%, consistent with the Hamett County Five Year AACR published in the January 2017 SDR. The applicant states that FMC Anderson Creek was providing home training to two HHD patients as of December 31, 2016. Growth projections are provided on page 19.

Home Peritoneal Dialysis Patients

The applicant assumes the home peritoneal dialysis patient population dialyzing at FMC Anderson Creek will also increase at the Hamett County AACR of 2.5%. The applicant states FMC Anderson Creek was providing home training to three PD patients as of December 31, 2016. Growth projections are provided on page 19.

Access

In Section L.1, pages 55 - 56, the applicant states that each of BMA's 108 facilities in 46 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 88.5% of the in-center patients will be Medicare or Medicaid recipients in the second operating year (CY 2019), based on its current Hamett 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 relocate three existing certified dialysis stations from FMC Lillington to FMC Anderson Creek. The applicant does not propose to add dialysis stations to an existing facility or to establish any new dialysis stations in the county.

Upon completion of the project, FMC Anderson Creek will be certified for 14 dialysis stations, and FMC Lillington will also be certified for 14 stations (17 - 3). Both facilities are located in Harnett County.

In Section D.1, pages 27 - 28, the applicant discusses how the needs of existing dialysis patients at FMC Lillington will continue to be met after the relocation of three stations to FMC Anderson Creek. The applicant states FMC Lillington serves only in-center patients, and as of March 1, 2017 was serving 44 in-center patients.

The applicant projects growth of those patients using the Harnett County Five Year AACR from Table B of the January 2017 SDR. In Exhibit C.1, the applicant provides letters from existing patients who indicate they would consider transferring their care to FMC Anderson Creek once the stations are relocated. One of those letters is signed by a patient who currently dialyzes at FMC Lillington; thus, the applicant subtracts that patient from the growth projections, which follow:

- FMC Lillington was serving 44 in-center patients as of March 1, 2017
- The applicant projects this population forward ten months to December 31, 2017, using the Harnett County Five Year AACR: $[44 \times (.025 / 12 \times 10) + 44 = 44.9$
- Subtract one Harnett County patient who will transfer his care to FMC Anderson Creek when the three stations are relocated: $44.9 - 1 = 43.9$. This is the projected census when the stations are to be relocated.

Therefore, when the stations are relocated, FMC Lillington will have 44 in-center patients dialyzing on 14 in-center stations, for a utilization rate of 79%, or 3.14 patients per station per week.

In Section D.2, page 28, the applicant states that the station relocation “*will not have any negative impact of the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly or any other underserved groups to obtain needed healthcare*” at either their current dialysis facility or a BMA dialysis facility closer to their residence.

Conclusion

The applicant demonstrates that the needs of the population presently served at FMC Lillington will continue to be adequately met following the proposed relocation of three dialysis stations

from FMC Lillington to FMC Anderson Creek, 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.

C

In Section E, page 29, 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 FMC Anderson Creek, and would be better served by relocating the stations to FMC Anderson Creek.
- Relocate stations from another BMA facility, FMC Angier - The applicant states this is not an effective alternative. FMC Angier has ten stations, which is the minimum number of stations required by the State Medical Facilities Plan.
- Relocate stations from another BMA facility, BMA Dunn – The applicant states it rejected this alternative because the BMA Dunn facility is located on the eastern side of Harnett County and serves an entirely different dialysis patient population.

After considering the above alternatives, the applicant states the proposed project represented in the application is the most effective alternative to meet the identified need.

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

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

1. **Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Medical Care Anderson Creek shall materially comply with all representations made in the certificate of need application.**
2. **Bio-Medical Applications of North Carolina, Inc. shall relocate no more than three dialysis stations from FMC Lillington.**
3. **Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Medical Care Anderson Creek shall install plumbing and electrical wiring through the**

walls for three additional dialysis stations for a total of 14 dialysis stations which shall include any home hemodialysis training or isolation stations.

- 4. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify three dialysis stations at FMC Lillington for a total of no more than 14 dialysis stations at FMC Lillington upon project completion.**
 - 5. Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Medical Care Anderson Creek shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate three existing dialysis stations from FMC Lillington to FMC Anderson Creek for a total of 14 stations at FMC Anderson Creek upon project completion.

Capital and Working Capital Costs

In Section F.1, page 31, the applicant projects \$11,250 in capital costs to relocate the stations. In Sections F.10 - F.12, page 34, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project, since FMC Anderson Creek is an existing facility.

Availability of Funds

In Section F.2, page 32, the applicant states it will finance the capital costs with the accumulated reserves / owner's equity of Fresenius Medical Care, Inc.

Exhibit F-1 contains a letter dated March 15, 2017, from the Senior Vice President & Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), as the parent company of BMA, which confirms authorization and commitment of the cash reserves for the full project capital costs "*as may be needed for this project.*" Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$249.3 million in cash and cash equivalents as of December 31, 2015, \$19.3 in total assets and \$10.1 in net assets (total assets less total liabilities).

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		
FMC ANDERSON CREEK	OPERATING YEAR 1 CY 2018	OPERATING YEAR 2 CY 2019
Total Treatments	7,176	4,332
Total Gross Revenues (Charges)	\$30,007,038	\$30,597,262
Total Net Revenue	\$ 2,378,562	\$ 2,425,023
Total Operating Expenses (Costs)	\$ 2,353,094	\$ 2,402,505
Net Income	\$25,468	\$22,518

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 on reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the project is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate three existing dialysis stations from FMC Lillington to FMC Anderson Creek, for a total of 14 dialysis stations at FMC Anderson Creek upon project completion. All of the involved facilities are located in Harnett County. The applicant does not propose to add new dialysis stations to an existing facility or to establish any new dialysis stations in Harnett County; rather, the applicant is proposing an in-county relocation of existing dialysis stations. The applicant currently provides and proposes to continue to provide home therapies at the facility.

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 Harnett County. Facilities may also serve residents of counties not included in their service area.

The applicant currently operates four dialysis centers in Harnett County, and is the only provider of dialysis services in the county. See the following table:

Utilization BMA Harnett County Facilities / January 2017 SDR

FACILITY NAME	LOCATION	# STATIONS	# PATIENTS	% UTILIZATION
FMC Anderson Creek	Cameron	11	29	65.91%
FMC Lillington	Lillington	17	36	52.94%
FMC Angier	Angier	10	30	75.00%
BMA Dunn	Dunn	31	103	83.06%

Source: January 2017 SDR, Application page 53

This application does not propose to add dialysis stations to the Harnett County inventory; rather, it proposes to relocate existing but underutilized stations from FMC Lillington to FMC Anderson Creek. FMC Lillington is located in Lillington, in central Harnett County. FMC Angier is located in the northeastern part of the county, BMA Dunn is located in the southeastern part of the county, and FMC Anderson Creek is located in the southwestern part of the county. The distance between Lillington and Cameron is approximately 29 miles, according to MapQuest®. The applicant provides letters signed by existing patients who indicate that they live closer to FMC Anderson Creek and would transfer their care to that facility. The applicant states on page 39 that FMC Anderson Creek has limited capacity to dialyze additional patients on the traditional dialysis shift and does not operate a third shift.

In Section C.1, pages 17 - 20, the applicant provides reasonable projections for the patient population it proposes to serve. The growth projections are based on a projected 2.5% average annual growth rate in the number of Harnett County dialysis patients who will dialyze at the proposed facility. At the end of the first operating year following project completion, FMC Anderson Creek projects the in-center utilization will be 3.3 in-center patients per station (46 patients / 14 dialysis stations = 3.285), which is 82% of capacity. The applicant does not propose to increase the number of certified stations in the service area; rather, the applicant proposes to relocate existing dialysis stations from one of its facilities to another. In Exhibit C-1, the applicant provides a patient petition signed by 26 patients and additional patient letters which state that FMC Anderson Creek will be a more convenient location and closer to home for those patients to receive their necessary dialysis care. The applicant adequately demonstrates the need to relocate three existing stations from FMC Lillington to FMC Anderson Creek to serve an existing dialysis patient population.

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.

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In Section H, page 41, the applicant provides the following table to illustrate projected staffing in full time equivalents (FTEs) for FMC Anderson Creek. The applicant states the Medical Director is not directly employed by the facility, and thus is not reflected on the staffing chart.

POSITION	#CURRENT FTEs	#FTEs TO BE ADDED	TOTAL FTEs
Registered Nurse	2.00	0.50	2.50
Technician (PCT))	4.00	1.00	5.00
Clinical Manager	1.00	0.00	1.00
Administrator	0.15	0.00	0.15
Dietician	0.40	0.00	0.40
Social Worker	0.40	0.00	0.40
Home Training Nurse	1.50	0.00	1.50
Chief Tech	0.15	0.00	0.15
Equipment Tech	0.50	0.00	0.50
In-Service	0.15	0.00	0.15
Clerical	1.00	0.00	1.00
Total	11.25	1.50	12.75

As illustrated in the table above, the applicant projects to add 1.5 FTEs to the existing staff, for a total of 12.75 FTEs after the stations are relocated.

In Section H.7, page 43, the applicant provides the projected direct care staff for the proposed facility in OY 2 (CY 2019), 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	2.50	2,080	5,200	3,432	1.52
Technician (PCT)	5.00	2,080	10,400	3,432	3.03
Total	7.50	4,160	15,600	3,432	4.55

In Section H.6, page 43, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday, for a total of 11 hours per day / 66 hours per week.

In Section I.3, page 46, the applicant identifies Dr. Michael Monahan as the Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Monahan supporting the project and confirming his commitment to continue to serve as Medical Director. In Section H.3, page 42, the applicant describes the methods used to recruit and fill the new positions.

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.

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In Section I.1, page 44, the applicant provides a table that identifies the necessary ancillary and support services and indicates how they will be made available. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system in Section I.3, page 47. Exhibits I-1 through I-4, respectively, contain copies of agreements for 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.

NA

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

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In Section L.7, page 59, the applicant provides two tables to illustrate historical payor mix for the two facilities that are involved in this review (FMC Lillington and FMC Anderson Creek) for CY 2016. See the following table, which combines the two tables on page 59:

PAYMENT SOURCE	FMC LILLINGTON PERCENT OF TOTAL PATIENTS	FMC ANDERSON CREEK PERCENT OF TOTAL PATIENTS
Self-Pay / Indigent / Charity	3.35%	0.61%
Medicare	77.14%	81.40%
Medicaid	8.68%	6.37%
Commercial Insurance	4.73%	7.04%
Medicare Commercial	0.35%	6.75%
Miscellaneous (Incl. VA)	0.00%	3.09%
Other	5.76%	0.00%
Total	100.00%	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 & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Harnett	11%	51%	37%	21%	10%	19%
Statewide	15%	51%	36%	17%	10%	15%

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

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

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

The IPRO ESRD Network of the South Atlantic Network 6 provides prevalence data on ESRD Network 6 dialysis patients by age, race, and gender on pages 27-28¹. The ESRD Network 6 service area contract, previously managed by Alliant Healthcare Solutions' Southeastern Kidney Council, was awarded to IPRO in April 2016 and is now called the IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6). IPRO SA Network 6 is still comprised of North Carolina, South Carolina and Georgia. The 2015 Annual Report, submitted in November 2016 by IPRO differs somewhat from the reports submitted in the past by The Southeastern Kidney Council.

The statistics on number and percent of dialysis patients by age, gender and race are now shown only in total for Network 6; the statistics are no longer separately shown for North Carolina in the report. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*² percentages for North Carolina and the total Network shows very little variance; therefore the statistics for the total Network 6 are representative of North Carolina's statistics. One would also assume the 2015 percentages for the total Network 6 should also very closely reflect North Carolina percentages by age, gender and race. The following table shows the North Carolina and total Network data for 2014 as provided by the Southeastern Kidney Council, and compared with the IPRO 2015 Network totals.

¹http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

²<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014 and 2015						
	2014 Patients and Percentages*				2015 Patients and Percentages**	
	NC Patients	NC Percentage	Total Network 6 Patients	Total Network 6 Percentage	Total Network 6 Patients	Total Network 6 Percentage
Age						
0-19	52	0.3%	137	0.3%	137	0.3%
20-34	770	4.8%	2,173	4.9%	2,142	4.7%
35-44	1,547	9.7%	4,385	9.9%	4,493	9.8%
45-54	2,853	17.8%	8,070	18.3%	8,422	18.3%
55-64	4,175	26.1%	11,706	26.5%	12,024	26.1%
65+	6,601	41.3%	17,716	40.1%	18,817	40.9%
Gender						
Female	7,064	44.2%	19,923	45.1%	20,805	45.2%
Male	8,934	55.8%	24,264	54.9%	25,230	54.8%
Race						
African-American	9,855	61.6%	29,191	66.1%	30,092	65.4%
White	5,778	36.1%	14,222	32.2%	15,049	32.7%
Other	365	2.3%	774	1.8%	894	1.9%

*2014 Calendar Year data from the Southeastern Kidney Council Network 6 2014 annual Report at <http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

**2015 Calendar Year data from the IPRO ESRD Network of the South Atlantic at http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian comparing with 85% of Network 6 patients being 45 and over and 69% being non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*). In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older and over 67% were non-Caucasian. (IPRO SA Network 6).

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.1, page 55, the applicant states BMA of North Carolina has historically provided care and dialysis services to all persons in need of those services, regardless of income, racial or ethnic background, or any other basis for being underserved. In Section L.6, page 58, 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 55, 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 56, the applicant projects that 89.57% of all in-center patients at FMC Anderson Creek in CY 2019 (OY 2) will have all or part of their services paid for by Medicare and or Medicaid, as shown in the table below:

PAYMENT SOURCE	PERCENT OF IN-CENTER PATIENTS
Self-Pay / Indigent / Charity	0.00%
Medicare	76.60%
Medicaid	6.68%
Commercial Insurance	6.55%
Medicare Commercial	6.29%
Miscellaneous (Incl. VA)	3.88%
Total	100.00%

The projected payor mix is based on the historical payor mix of FMC Anderson Creek. 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 58, the applicant states *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Anderson Creek 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 FMC Anderson Creek 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 60, the applicant states *“BMA has communicated with the local student nursing programs encouraging those programs to utilize the resources of the FMC Anderson Creek facility in their clinical rotations for nursing students.”* In Exhibit M-1, the applicant provides a copy of a letter to Central Carolina’s Community College inviting the nursing students to include FMC Anderson Creek in their 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 three existing dialysis stations from FMC Lillington to FMC Anderson Creek, for a total of 14 dialysis stations at FMC Anderson Creek upon project completion. All of the involved facilities are located in Harnett County. The applicant does not propose to add new dialysis stations to an existing facility or to establish any new dialysis stations in Harnett County; rather, the applicant is proposing an in-county relocation of existing dialysis stations. The applicant currently provides and proposes to continue to provide home therapies at the facility.

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 Harnett County. Facilities may also serve residents of counties not included in their service area.

The applicant currently operates four dialysis centers in Harnett County, and is the only provider of dialysis services in the county. See the following table:

Utilization BMA Harnett County Facilities / January 2017 SDR

FACILITY NAME	LOCATION	# STATIONS	# PATIENTS	% UTILIZATION
FMC Anderson Creek	Cameron	11	29	65.91%
FMC Lillington	Lillington	17	36	52.94%
FMC Angier	Angier	10	30	75.00%
BMA Dunn	Dunn	31	103	83.06%

Source: January 2017 SDR, Application page 53

According to Table B in the January 2017 SDR, there is a surplus of five dialysis stations in Harnett County. However, the applicant is not increasing the number of dialysis stations in Harnett County; rather, it is relocating three existing Harnett County dialysis stations to a facility that is closer to patients living in the area who indicated they would be better served by FMC Anderson Creek than another facility.

In Section N.1, page 61, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services, stating:

“BMA does not expect this proposal to have effect on the competitive climate in Harnett County. The existing operational dialysis facilities in Harnett County are operated by Fresenius Medical Care, parent to FMC Anderson Creek. The projected patient population for the FMC Anderson Creek facility begins with patients currently served by BMA, plus seven patients who have expressed a desire to transfer their care to the facility upon completion of the project. BMA also projects growth of the Harnett County patient population using a five year average annual change rate of 2.3% for the Harnett County patients.”

In addition, the applicant states that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that greater than 89% of the in-center treatments provided at FMC Anderson Creek will be reimbursed by Medicare or Medicaid. Moreover, the applicant states on page 61 that its proposal will “*enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.*”

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

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis 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 FMC Anderson Creek will provide quality dialysis services. The discussions regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that FMC Anderson Creek will continue to provide adequate access to medically underserved populations. The discussions 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.3, pages 10 - 11, Section O, pages 62 - 66 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality in all of its dialysis facilities, including FMC Anderson Creek.

In Section O.3, pages 65 - 66, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, only the two listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
BMA East Rocky Mount	01/25/2017	Yes	03/01/2017
RAI West College-Warsaw	3/15/2016	Yes	4/13/2016

Source: Information provided in Application Exhibit O-3

Based on a review of this certificate of need application and publicly available information, 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- FMC Anderson Creek is an existing facility.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C.1, pages 17 – 18, the applicant projects to serve 46 in-center patients on 14 stations at the end of the first operating year, which is 3.3 patients per station per week [46 / 14 = 3.285].

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

-C- In Section C.1, pages 17 - 19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.